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I. Glenn Cohen is a professor at Harvard Law School; Faculty Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics; and, Co-Lead of the Law and Ethics Initiative of the Football Players Health Study. His award-winning work at the intersection of law, medicine, and ethics—in particular, medical tourism and assisted reproduction—has been published in leading journals, such as the *Harvard Law Review*, *Stanford Law Review*, *New England Journal of Medicine*, *Journal of the American Medical Association*, *American Journal of Bioethics*, and *American Journal of Public Health*. He was previously a fellow at the Radcliffe Institute for Advanced Study and a faculty scholar in bioethics with the Greenwall Foundation. He is the author, editor, and/or co-editor of several books from Oxford, Columbia, John Hopkins, and MIT University Presses. Prior to joining the Harvard faculty, Cohen served as a clerk to Chief Judge Michael Boudin, United States Court of Appeals for the First Circuit, and as an appellate lawyer in the Civil Division of the Department of Justice. He graduated from the University of Toronto with a BA (with distinction) in Bioethics (Philosophy) and Psychology and earned his JD from Harvard Law School.

Holly Fernandez Lynch is Executive Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics; Faculty at the Harvard Medical School Center for Bioethics; and, Co-Lead of the Law and Ethics Initiative of the Football Players Health Study. Her scholarly work focuses on the regulation and ethics of human subjects research and issues at the heart of the doctor-patient relationship. Her book, Conflicts of Conscience in Health Care: An Institutional Compromise, was published by MIT Press in 2008; she is also co-editor with I. Glenn Cohen of Human Subjects Research Regulation: Perspectives on the Future (MIT Press 2014), FDA in the 21st Century: The Challenges of Regulating Drugs and New Technologies (Columbia University Press 2015), and Nudging Health: Health Law and Behavioral Economics (Johns Hopkins University Press 2016). Lynch practiced pharmaceuticals law at Hogan & Hartson, LLP (now Hogan Lovells), in Washington, DC, and worked as a bioethicist in the Human Subjects Protection Branch at the National Institutes of Health's Division of AIDS. She also served as senior policy and research analyst for President Obama's Commission for the Study of Bioethical Issues. Lynch is currently a member of the Secretary's Advisory Committee on Human Research Protections at the US Department of Health and Human Services. She graduated Order of the Coif from the University of Pennsylvania Law School, where she was a Levy Scholar in Law and Bioethics. She earned her master's degree in bioethics from the University of Pennsylvania's School of Medicine, and her BA with a concentration in bioethics, also from the University of Pennsylvania.





ENSURING INDEPENDENCE & DISCLOSURE OF CONFLICTS

The 2011 Collective Bargaining Agreement between the National Football League Players Association ("NFLPA") and the National Football League ("NFL") set aside funds for medical research. The NFLPA directed a portion of those funds to create the Football Players Health Study at Harvard University, of which this Report is a part. Our analysis has been independent of any controlling interest by the NFLPA, the NFL, or any other party; this independence was contractually protected in Harvard's funding agreement with the NFLPA. Per that contract, the NFLPA was only entitled to prior review of this Report to ensure that no confidential information was disclosed.^a Additional information about how this Report came to be is provided in the Preface.

The present Report is part of the Law and Ethics Initiative of the Football Players Health Study at Harvard University. Additional background information about the Football Players Health Study is provided in the Preface. We provide more specific information about the Law and Ethics Initiative here.

The Statement of Work agreed to between the NFLPA and Harvard included as one of the Law and Ethics Initiative's projects to "Conduct Comparative Sports League Analysis." More specifically, Harvard described the work to be done as follows:

We will analyze governance and stakeholder obligations in other professional sports leagues in order to identify best practices and situate the ethics framework developed for professional football. This project will examine, for example, how medical practices in other leagues may result in the encouragement and tolerance of behavior that is risky to health. The project will examine influences among health behaviors of players and team policies regarding player health.

This project description was intended to be preliminary. The actual scope of this Report developed over time, as expected, as the result of considerable research, internal discussion, and conversations with experts. Beyond agreeing to the Statement of Work, the NFLPA did not direct the scope or content of this Report.

As is typical with sponsored research, we provided periodic updates to the sponsor in several formats: Pursuant to the terms of Harvard-NFLPA agreement, the NFLPA does receive an annual report on the progress of the Football Players Health Study as well as one Quad Chart progress report each year. Additionally, on two occasions (August 22, 2014, and January 23, 2015), we presented a summary of the expected scope and content of the Report to the Football Players Health Study Executive Committee, comprised of both Harvard and NFLPA personnel. Those meetings did not alter our approach in constructing this Report, the conclusions reached, or the recommendations made. Moreover, none of the comments made during those meetings altered the content of the Report.

In the Introduction, Section E(2): Describe, we discuss our research process for this Report. Additional information about our communications with the NFLPA and NFL is also relevant here. During the course of our research, we had multiple telephone and email communications with both NFLPA and NFL representatives to gain factual information. These communications were not about the progress, scope, or structure of our Report.

We also concluded that it was essential to provide the applicable stakeholders the opportunity to substantively review the Report. These stakeholders are the leagues discussed in this Report: the National Football League ("NFL"); Major League Baseball ("MLB"); the National Basketball Association ("NBA"); the National Hockey League ("NHL"); the Canadian Football League ("CFL"); and, Major League Soccer ("MLS"). This was necessary to try to fully account for the realities at hand, avoid factual errors, and fairly

The applicable contract language provides that the NFLPA is permitted to review publications 30 days in advance "for the sole purpose of identifying any unauthorized use of Confidential Information."

consider all sides. Accordingly, we provided each league the opportunity to review the Report before publication. Additional information about the leagues' and their corresponding labor unions' cooperation with and review of this Report or failure to do so is included in the Introduction.

The leagues had the opportunity to identify any errors, provide additional information, comment on what action we expected from them going forward, and raise further suggestions or objections. Sometimes these comments led to valuable changes in the Report. We found other comments unpersuasive and they did not result in any changes. It is critical to recognize that no external party, including the NFLPA and NFL, had the ability to direct or alter our analysis or conclusions.

In addition, we subjected the draft Report to peer review by outside experts. We engaged two independent experts in sports law to review the Report for accuracy, fairness, comprehensibility, and its ability to positively impact the health of NFL players. These experts were Marc Edelman, Zicklin School of Business, Baruch College, City University of New York, and, Michael McCann, University of New Hampshire School of Law.

Finally, the content of this Report is solely the responsibility of the authors and does not represent the official views of the NFLPA or Harvard University.

DISCLOSURES:

- The Law and Ethics Initiative's allocated budget is a total of \$1,257,045 over three years, which funds not only the present Report, but also several other projects.^b
- Deubert's salary is fully supported by the Football Players Health Study at Harvard University. From August 2010 to May 2014, Deubert was an associate at the law firm of Peter R. Ginsberg Law, LLC f/k/a Ginsberg & Burgos, PLLC. During the course of his practice at that firm, Deubert was involved in several legal matters in which the NFL was an opposing party. Of relevance to this Report, Deubert represented players disciplined pursuant to the NFL's Policy and Program on Substances of Abuse and the Policy on Anabolic Steroids and Related Substances (now known as the Policy on Performance-Enhancing Substances). Also, since 2007, Deubert has provided research assistance to the Sports Lawyers Association, whose Board of Directors includes many individuals with interests related to this work.

Lastly, in March 2017, as this Report's content was finalized except for incorporating some changes related to new collective bargaining agreements in MLB and the NBA, and with the Law & Ethics Initiative of the Football Players Health Study ending in May 2017 as the funding period came to a close, Deubert communicated with organizations with interests relevant to this work about potential job opportunities, including law firms that represent sports leagues, unions, and players. Following finalization of the Report, Deubert also communicated with some of the sports unions themselves about potential job opportunities. All changes to the Report, including those that occurred during or after March 2017, were reviewed and approved by Cohen and Lynch.

- 20% of Cohen's salary is supported by the Football Players Health Study at Harvard University. Cohen has no other conflicting interests to report.
- 30% of Lynch's salary is supported by the Football Players Health Study at Harvard University. Lynch has no other conflicting interests to report.

Other Law and Ethics projects include: (1) our Report, Protecting and Promoting the Health of NFL Players: Legal and Ethical Analysis and Recommendations (2016); (2) our Report, NFL Player Health: The Role of Club Doctors, 46 Hastings Center Rep. 2 (2016); (3) our law review article, Evaluating NFL Player Health and Performance: Legal and Ethical Issues, 165 Univ. Penn. L. Rev. 227 (2017); and, (4) a qualitative interview study ("listening tour") with players and their families to better understand their legal and ethical concerns related to health and well-being.

PREFACE

THE FOOTBALL PLAYERS HEALTH STUDY AT HARVARD UNIVERSITY

In response to ongoing concerns about NFL player health, the 2011 Collective Bargaining Agreement ("CBA") between the NFL and the National Football League Players Association ("NFLPA") added a number of new health, safety, and welfare provisions. One of these provisions sets aside \$11 million per year through 2021 to be dedicated to medical research. Thus, in the summer of 2012, the NFLPA issued a request for proposals to conduct original research and scientific exploration to be supported by these funds, focusing on "new and innovative ways to protect, treat, and improve the health of NFL players." The NFLPA's request for proposals specified a number of areas of particular interest, including sports medicine, repetitive brain trauma, wellness, aging, and cardiovascular disease. At the top of the list, however, was not a particular medical problem, but instead "Medical Ethics (e.g., examination of health care contexts to obtain a better understanding of internal morality of these practices, accountability, new interventions that avoid harms currently incurred, appropriate informed consent in the context of professional athletics, and consideration of medical care in the labormanagement context of professional football.)."2

To meet the challenge of protecting and improving player health, it is necessary to move beyond clinical issues to simultaneously address structural and organizational issues as well. This is true for healthcare more generally, where it is essential to invest not only in scientific research and development to create new clinical interventions, but also to invest in systems to efficiently administer those interventions to patients in need, as well as public health approaches that can help minimize the need for intervention in the first place. Likewise, to make headway in protecting and improving the health of NFL players, we must go beyond a single-minded focus on their clinical care and instead implement a more comprehensive strategy capable of addressing the myriad of stakeholders and contextual factors (past, present, League-wide, and individual) that play a role in their health. These include not only players' physical issues and risk factors, but also their relationships with clinicians, professional motivations, financial

pressures, and family responsibilities, as well as the centrality of their health to their careers, the competitive nature of the business, constraints on alternative opportunities for many players, and the like. The relevant stakeholders are similarly varied and extensive.

Thus, when submitting its proposal to the NFLPA, our Harvard team included a variety of critical clinical projects alongside an equally robust set of law and ethics proposals. We agreed from the outset that a focus on diagnosing and treating player health issues—while essential—would be insufficient on its own to comprehensively resolve those issues. Instead, our approach has been to also address precisely those structural and organizational factors that are so important to player health but would be neglected by a purely clinical approach.

The NFLPA ultimately agreed, selecting Harvard to receive the funding after a multi-round competitive process involving several universities. In February 2014, Harvard Medical School entered into an agreement with the NFLPA to create the "Football Players Health Study at Harvard University." Drawing on expertise from across Harvard University, the Football Players Health Study is dedicated to understanding the causes of conditions NFL players face, with the goal of improving their health and wellbeing.

The "Law and Ethics Initiative," led by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, encompasses a variety of distinct projects with the primary goal of understanding the legal and ethical issues that may promote or impede player health, and developing recommendations to promote player health through structural change.^a

The existence of the Law and Ethics component differentiates the Football Players Health Study from other studies concerning NFL player health. While there have been many important studies concerning the medical components of

a Other Law and Ethics projects include: (1) our Report, Protecting and Promoting the Health of NFL Players: Legal and Ethical Analysis and Recommendations (2016); (2) our Report, NFL Player Health: The Role of Club Doctors, 46 Hastings Center Rep. 2 (2016); (3) our law review article, Evaluating NFL Player Health and Performance: Legal and Ethical Issues, 165 Univ. Penn. L. Rev. 227 (2017); and, (4) a qualitative interview study ("listening tour") with players and their families to better understand their legal and ethical concerns related to health and well-being.

player health, we are not aware of any that have conducted a comprehensive analysis of the relevant legal and ethical environment.

Additionally, in the Section: Ensuring Independence and Disclosure of Conflicts, we discuss the ways in which the Law and Ethics Initiative interacted with, but was independent of, both the NFLPA and NFL in creating this Report.

In the Introduction that follows, we will describe the scope of this Report, its goals, process, and limitations. First, however, it is essential to explain the guiding principles of the Football Players Health Study as a whole.

Most importantly, the Football Players Health Study is interested in health issues beyond concussions and neurological trauma. Although we recognize that concussions and their possible long-term sequelae are on the minds of many, and are among the most critical health issues facing players today, we simultaneously recognize that player health is larger than concussions alone. Players also have concerns about cardiac health, arthritis and other joint damage, pain management, and a wide variety of other issues. Moreover, their primary concerns are likely to change over time from their playing days to retirement to old age. Thus, we have adopted the following mantra for our work: "The Whole Player, The Whole Life." Rather than a myopic approach, we are taking a wide and long view in order to make players as healthy as they possibly can be over every conceivable dimension of their entire lives.

We approached this project as scholars and social scientists whose goal is to improve NFL player health. We are independent academic researchers first and foremost, regardless of the source of our funding. We have no "client" in this endeavor, other than players themselves, and we have no agenda other than to improve the lives of former, current, and future players. Indeed, the Football Players Health Study is funded pursuant to money set aside under the 2011 CBA for research designed to help players. Because of the way the clubs and players split revenues from NFL games and other operations, the funds used for the Football Players Health Study can reduce the amount of money available to current players in the form of salary. Thus, the players have chosen to pay for the Football Players Health Study. In addition, although our contractual relationship is with

the NFLPA, that very same contract protects our academic integrity without exception; no external party has any control whatsoever over our conclusions.

One of our primary concerns is that too little is known about player health. Specifically, too little is known from a rigorous scientific perspective about the risks and benefits of playing professional football because available data are insufficient in a variety of respects. For example, "[w]e do not know what factors exacerbate or mitigate an individual's risk, including genetics, nutrition, lifestyle, as well as length of time and position played, and injuries sustained during playing years." Professional football players are an elite and unique group of men who must be studied directly and often in large numbers before we can really understand how football has affected them. Only then can we fully address any health problems they may have. We come to this work with no pre-existing agenda—we have neither any interest in ending professional football nor any interest in looking the other way if confronted with compelling data of its downsides. Again, we are interested only in helping players lead the healthiest and most productive lives they possibly can. We are committed to going where the science takes us.

Finally, we are forward-looking. Our role is not to evaluate fault or assign blame for player health problems, and the Football Players Health Study is uninvolved in any litigation related to these issues. Instead, we are working with a single-minded focus to develop a clear path for addressing and remediating existing player health problems, and for preventing such problems from continuing or occurring in the future—from both clinical and organizational perspectives. Although this process does include assignment of shared responsibility for protecting and promoting players' health to a wide variety of parties, the past is relevant only to the extent that it demonstrates ways to successfully improve going forward.

These are the guiding principles motivating every aspect of the Football Players Health Study at Harvard University.

b The players' share of NFL revenues is referred to as the Player Cost Amount. 2011 CBA, Art. 12, § 6(c)(i). The Football Players Health Study is funded from a pool of money known as the Joint Contribution Amount. See 2011 CBA, Art. 12, § 5. If the NFL generates new revenue streams, the players are entitled to 50% of the net revenues from those new ventures less 47.5% of the Joint Contribution Amount. 2011 CBA, Art. 12, § 6(c)(ii). Thus, if the NFL generates new revenue streams, the amount that is passed on to the players is reduced by 47.5% of the Joint Contribution Amount, which includes the Football Players Health Study.