



Friday, February 3, 2017

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## DON'T MISS THESE GREAT FEBRUARY EVENTS!



### [Looking Forward: The Next Generation of Biosimilars](#)

**February 7, 2017 12:00 PM**

[Wasserstein Hall, Milstein East A \(2036\)](#)  
[1585 Massachusetts Ave., Cambridge, MA](#)

Many of today's important medications are biological products made from living organisms, manufactured through biotechnology, derived from natural sources, or produced synthetically. Biosimilars are a type of biological product approved by FDA on the basis of being highly similar to an already approved biological reference product, like a generic drug. This panel of experts will discuss the current state of biosimilars in the healthcare ecosystem and what comes next from a technical and legal perspective. Topics include how the next generation of biosimilars can improve patient access to standard-of-care therapies, the concept of "biobetters," economic and intellectual property considerations, and policy approaches to support existing and future biosimilars.

#### Panelists:

- [Jennifer DiGiacinto](#), RRD International
- [Robert S. Langer](#), MIT; Consultant, Eagle Biologics
- [Benjamin Roin](#), MIT Sloan School of Management
- Moderator: [Aaron Kesselheim](#), Harvard Medical School

This event is free and open to the public. Lunch will be provided.

Sponsored by the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics](#) at Harvard Law School and [Eagle Biologics](#).



### [REGISTER NOW! Returning Results to Research](#)

[Participants: A Health Policy and Bioethics Consortium](#)

**February 10, 2017 12:30 - 2:00 PM**

[Wasserstein Hall, Milstein East C, Harvard Law School, 1585 Massachusetts Ave., Cambridge, MA](#)

Register now [here!](#)

Clinical investigators, public health advocates, and IRBs have been struggling to develop appropriate policies on how to return results to patients involved in research studies. These results may come in a variety of forms, ranging from aggregated study results to individual results to incidental findings. Experts disagree over the optimal timing, how researchers should consider the burden that these results can place on patients, and whether there are circumstances in which certain findings should be withheld. Is clinical utility the appropriate standard, or does mere curiosity suffice to trigger disclosure obligations? How certain must the results be, and what if there is reason to believe that the results will be difficult for participants to understand - or cause them harm? Two experts in the field of research law and ethics will join us to engage these and other questions, and help conceive a way to move forward in the best interests of patients and the

medical research enterprise.

**Panelists:**

- **Pilar Ossorio**, Professor of Law and Bioethics, University of Wisconsin Law School
- **Barbara Bierer**, Program Director, Regulatory Foundations, Law and Ethics Program, Harvard Catalyst and faculty co-director, Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard
- Moderator: **Holly Fernandez Lynch**, Executive Director, Petrie-Flom Center and Faculty, Center for Bioethics, Harvard Medical School

This event is free and open to the public. Lunch will be provided.

**Seating is limited and registration is required. [Register online!](#)**

*The Health Policy and Bioethics Consortia are hosted and organized by the Harvard Medical School [Center for Bioethics](#) and the [Program On Regulation, Therapeutics, And Law \(PORTAL\)](#) at Brigham and Women's Hospital, in collaboration with the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics](#) at Harvard Law School and the Harvard Program in Therapeutic Science. This monthly series convenes international experts from different fields or vantage points to discuss how biomedical innovation and health care delivery are affected by various ethical norms, laws, and regulations. Support provided by the Oswald DeN. Cammann Fund at Harvard University.*

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**NEW PUBLICATION!**

**Legal issues in evaluating NFL player health and performance**

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**Evaluating NFL Player Health and Performance: Legal and Ethical Issues**

**By Jessica L. Roberts, I. Glenn Cohen (Faculty Director), Christopher R. Deubert (Senior Law & Ethics Associate), and Holly Fernandez Lynch (Executive Director)**  
***University of Pennsylvania Law Review, Vol. 165, No. 2, 2017***

On January 24, 2017, the University of Pennsylvania Law Review published [an article](#) by [Jessica L. Roberts](#) from the University of Houston Law Center and researchers from the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics](#) at Harvard Law School, [I. Glenn Cohen](#), [Christopher R. Deubert](#) and [Holly Fernandez Lynch](#). The article analyzes the legality of various health and performance evaluations used by NFL clubs. These include the familiar-such as athletic drills-and those that are more advanced, such as genetic testing and wearable technologies that monitor a player's speed, strength, sleep, heart rate, body temperature and other biometrics.

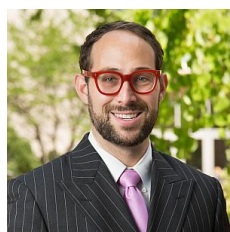
The authors explore whether two federal antidiscrimination employment laws-the Americans with Disabilities Act (ADA) and the Genetic Information Nondiscrimination Act (GINA)-apply to the health evaluations of professional football players, for example, those conducted at the NFL Combine and again after players join an NFL club. Thus, the article raises a number of questions and recommendations for clarification and next steps.

Download the article [here!](#)

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**Scholarship from Petrie-Flom Affiliates**

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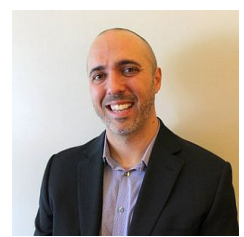


**Traveling for Assisted Suicide**

**by I. Glenn Cohen (Faculty Director)**

***Chapter in Euthanasia and Assisted Suicide: Global Views on Choosing to End Life (Michael J. Cholbi, ed.), Praeger, 2017 (forthcoming)***

**When clinical trials compete: prioritising study recruitment**  
by Luke Gelinas (Clinical Research Ethics Fellow), Holly Fernandez Lynch (Executive Director), Barbara E. Bierer, and I. Glenn Cohen (Faculty Director)  
*Journal of Medical Ethics, January 20, 2017*



**Do ethics demand evaluations of public health laws?: Shifting scientific sand and the case of youth sports-related TBI laws**

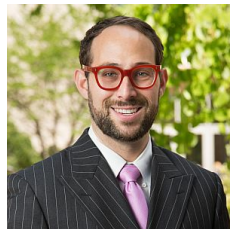
by Kerri McGowan Lowrey, Stephanie R. Morain, and Christine M. Baugh (Student Fellow alumna)  
*Journal of Health Care Law Policy, Vol. 19, Issue 1 (2016)*

### **Bioethics in the law**

by Zachary E. Shapiro (Student Fellow Alumnus)  
*The Hastings Center Report, January/February 2017, Vol. 47, Issue 1*



## **News from Petrie-Flom Affiliates**



**The Trump-era Supreme Court could erode abortion access with a 'death by 1,000 cuts'**

By Rebecca Harrington, quoting I. Glenn Cohen (Faculty Director)  
*Business Insider, February 1, 2017*

### **Vitals**

by David Nather, featuring blog post by Rachel E. Sachs (Academic Fellow Alumna)  
*Axios, January 31, 2017*



### **Morning View 01-31-17**

by Mitchell Stein, featuring blog post by Rachel E. Sachs  
*Institute for Clinical and Economic Review (ICER), January 31, 2017*

### **Trump's travel ban rattles medical residency programs**

by Dan Diamond, featuring blog post by Rachel E. Sachs  
*Politico Pulse, January 31, 2017*



**The \$4,500 injection to stop heroin overdoses**

By Shefali Luthra, quoting W. Nicholson Price II (Academic Fellow Alumnus)  
*Washington Post, January 27, 2017*

## **Recent Blog Posts**



### General health law/policy:

- ["CMS Publishes Final Rule Revising and Expanding Conditions for HHA Participation in Medicare and Medicaid,"](#) by Wendy Salkin
- ["Artificial Intelligence, Medical Malpractice, and the End of Defensive Medicine,"](#) by Shailin Thomas
- ["Housing Equity Week in Review,"](#) by Center for Public Health Law Research
- ["'Safe spaces' in adverse health incident investigation and patient complaints,"](#) by John Tingle
- ["Chimeras with benefits? Transplants from bioengineered human/pig donors,"](#) by Brad Segal

### Bioethics:

- ["Can the Right to Stop Eating and Drinking be Exercised via a Surrogate Acting Pursuant to an Advance Instruction?"](#) by Norman L. Cantor

### Health care reform/finance:

- ["What is the Meaning of Trump's Day 1 Executive Order on the ACA?,"](#) by Erin C. Fuse Brown
- ["Trap for the Unwary Works Again: Federal Healthcare and the Limitations Provision of the Federal Tort Claims Act,"](#) by Alex Stein

### Pharmaceuticals:

- ["National Survey Suggests that Off-Label Status is Material to Informed Consent,"](#) by Christopher Robertson
- ["The 21st Century Cures Act: One of Many Reasons Why Today's Executive Order Is Misguided,"](#) by Rachel Sachs
- ["An Alternative Point of View: The Societal Benefits of the Amgen v. Regeneron Injunction,"](#) by Beau H. Miller

### 'The Week in Health Law' podcasts:

- ["Erin Fuse Brown on 'The Week in Health Law' Podcast,"](#) by Nicolas Terry and Frank Pasquale
- ["Sam Halabi on 'The Week in Health Law' Podcast,"](#) by Nicolas Terry and Frank Pasquale

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## Petrie-Flom Center Events

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Check out our [website](#) for a more complete listing of events as well as full co-sponsorship information about our collaborators. Remember, you can find materials from many of our events, including slide presentations and full event videos, online in our [events archive](#).

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### **Looking Forward: The Next Generation of Biosimilars**

**February 7, 2017 12:00 PM**

[Wasserstein Hall, Milstein East A, Harvard Law School, 1585  
Massachusetts Ave., Cambridge, MA](#)

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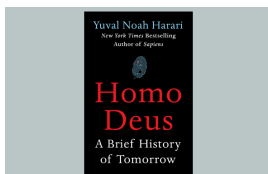


### **REGISTRATION REQUIRED! Returning Results to Research Participants: A Health Policy and Bioethics Consortium**

**Register [here](#)**

**February 10, 2017 12:30 - 2:00 PM**

[Wasserstein Hall, Milstein East C, Harvard Law School, 1585](#)



**Yuval Noah Harari in conversation with Michael Sandel -  
A discussion of Harari's new book Homo Deus: A Brief  
History of Tomorrow**

***Purchase tickets [here!](#)***

**February 22, 2017 6:00 PM**

**[Brattle Theater, 40 Brattle St., Cambridge, MA](#)**



**AGENDA AVAILABLE! 2017 Petrie-Flom Center Annual  
Conference: Transparency in Health and Health Care:  
Legal and Ethical Possibilities and Limits**

**April 28, 2017**

**[Wasserstein Hall, Milstein East ABC \(2036\), Harvard Law School,  
1585 Massachusetts Ave., Cambridge, MA](#)**

## Health Policy and Bioethics Consortia

- **Returning Results to Research Participants**  
**February 10, 2017**
- **Promoting Accurate and Useful Public Reporting on  
Physicians**  
**March 29, 2017**



## Other Harvard Events

**Health Care Conference at HBS**

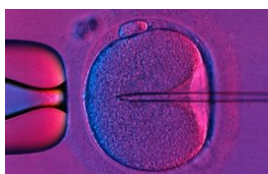
**February 4, 2017**

**[Harvard Business School, Soldiers Field Road, Boston, MA](#)**

**Ayelet Waldman, HLS '91, on her new book, A Really Good Day: How  
Microdosing Made a Mega Difference in My Mood, My Marriage, and My Life.  
Introduced by Jeannie Suk Gersen**

**February 10, 2017**

**[Wasserstein Hall 3019 Classroom, Harvard Law School, 1585 Massachusetts Ave., Cambridge,  
MA](#)**



**Harvard Medical School 2017 Bioethics Conference: The  
Ethics of "Making Babies"**

**April 28, 2017**

**[Harvard Medical School, Boston, MA](#)**

## Health Law Policy & Bioethics Workshops

The 2016-2017 **[Health Law Policy, Biotechnology, and Bioethics Workshops](#)** provide a forum for discussion of new scholarship in these fields from the world's leading experts. Harvard graduate students may register to take the workshop for course credit, but it is also open to the public.

This year, the workshop is led by Professor **[I. Glenn Cohen](#)**, and meets on selected Monday evenings from 5-7 PM on the Harvard Law School **[campus](#)**. The invited presenter generally

speaks for about 30 minutes, after which the floor is opened for Q&A. It is recommended to read the papers in advance. Papers will usually be posted on the [website](#) one week before they are scheduled for presentation, but occasionally are available by request only.

Questions about the workshop should be directed to Jennifer Minnich ([jminnich@law.harvard.edu](mailto:jminnich@law.harvard.edu)).

Upcoming workshops include:

**February 13: Brendan Maher, University of Connecticut School of Law**  
***Download the paper now!***

**March 6: Khiara Bridges, Boston University School of Law**

**March 27: Kathryn Zeiler, Boston University School of Law**

**April 10: Leo Beletsky, Northeastern University School of Law**

**April 17: Judith Daar, Whittier Law School**

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## Harvard Opportunities

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### **Fellowship in Bioethics, 2017-2018**

Harvard Medical School Center for Bioethics

**Application Due: March 6, 2017**

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### **Postdoctoral Research Scholars Program in Bioethics**

Harvard Medical School Center for Bioethics

**Application Due: March 31, 2017**

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## Other Opportunities

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All opportunities are posted once in our newsletter. For the full posting and for other available positions, please visit our [website](#).

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### **Visiting Health Law Position**

Indiana University Robert H. McKinney School of Law

**Application Due: February 24, 2017**

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### **Call for Proposals: Policies for Action: Policy and Law Research to Build a Culture of Health Robert Wood Johnson Foundation**

Robert Wood Johnson Foundation

**Application Due: March 10, 2017**

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### **CDC Fall 2017 Externships in Public Health Law**

CDC's Public Health Law Program

**Application Due: April 30, 2017**

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### **Policy Surveillance Summer Internship**

Temple University's Center for Public Health Law Research at the Beasley School of Law

**Application Due: Open until filled.**

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**Stay Connected!**



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