

**Spring 2024**  
**Biotech Ethics**  
**SCRB 120**

**Meeting Times: Monday and Wednesday 1:30-2:45 PM**

**Location: CGIS S10 Tsai Auditorium**

Section Times: Monday 12pm-1pm; or Thursday 10:30am - 11:30am; or Thursday 12pm - 1pm. You can find your Section assignments under People --> Sections.

Section Location: Sherman Fairchild 261

**Teaching Team**

**Instructor**

Dr. Sergio Imparato

[sergioimparato@fas.harvard.edu](mailto:sergioimparato@fas.harvard.edu)

**Teaching Fellows**

Roshni Chakraborty

[rchakraborty@jd25.law.harvard.edu](mailto:rchakraborty@jd25.law.harvard.edu)

Section times: Thursday 10:30 - 11:30AM, Thursday 12 - 1PM

Erin Liepa Erdinc

[erin\\_liepa\\_erdinc@hks.harvard.edu](mailto:erin_liepa_erdinc@hks.harvard.edu)

Section time: Monday 12 - 1PM

**Course description**

This course explores moral issues related to business practices in the fields of healthcare, medicine, genetics, and biotechnology. The class is divided into four parts. The first part of the course draws on foundational concepts of ethics and applies them to biotech entrepreneurship. In the second and third part, we delve into a series of case studies and analyze the moral quandaries faced by well-known biomedical companies. In the fourth part, students develop ad-hoc ethical frameworks that apply to their own businesses and present them to an ethics panel.

Among the questions asked throughout the semester: Should biomedical enterprises prioritize *cures* over treatment? What are the moral implications for the way pharma companies market and price their drugs? Is there an ethical way to price a drug that can *cure* a disease? Should biomedical companies prioritize their moral obligations towards investors, employees, or society as a whole? Do biomedical companies have a moral obligation to invest in areas of research that are scarcely profitable, yet medically valuable?

In addressing these questions students will learn the core concepts, theories, and methods of ethical

reasoning and how to apply them to the field of biotech entrepreneurship.

## Course Requirements and Grade Distribution

### 1. *Weekly Discussion Forum Posts - 30% of the course grade*

Starting during Week 2, you must post a short reaction to the discussion prompts posted on the Canvas site. You must post discussions for **at least eight** of the eleven prompts, but you are encouraged to post something every week to collect and synthesize your thoughts before class.

The discussion posts are due by **11:59PM each Sunday** before the lecture for that week. Your posts should be 2 or 3 substantial paragraphs and should make explicit reference to the readings assigned for that week's class. You should use the prompts simply as starting points for your post. There is no need to respond directly to the questions asked so long as your post touches on the topics and ideas mentioned in the prompt.

Other students in the course can see your postings. You can respond to each other but are not required to do so. A response to another person's comment will be counted as a post. In your post you should aim to present a clear and persuasive argument on the ethical debate presented in the readings. The posts should not simply be about your personal experience or about current events, nor just a summary of the readings. Instead, they should present a clearly identifiable moral stance. The teaching team will use your posts from the online forum in class discussion.

### 2. *Lecture and Section Participation - 30% of the course grade*

Attendance to and participation to lectures and sections is required and an important aspect of the course grade. You should please come to class prepared to discuss the weekly readings and ready to engage in meaningful ethical deliberation.

Due to the interactive nature of the course, and out of respect for your classmates and instructors, **no laptops, screens, or mobile phones may be used during class or sections**. Students who need accommodations should contact the Accessible Education Office (AEO).

Sections will meet starting from week 2. Sections last one hour and meet once a week. Section times will be determined through a class poll. If you miss a section for a documented health reason (with a note from HUHS or other healthcare provider), you can submit a response paper to make up for section participation.

### 3. *In-class Ethical Dilemma Case Studies - 10% of the course grade*

In the second and third part of the course, we will be conducting two ethical scenarios based on actual business case studies. During these events you will be divided in groups and tasked to come up with a morally sensible solution to the cases presented. You will be evaluated on the basis of your preparation, engagement, and oral presentations during the in-class scenarios.

### 4. *Final Oral Presentations - 30% of the course grade*

The course ends with a set of student presentations on ad-hoc moral frameworks developed for biotech companies. You should get approval on your final topic from the teaching staff no later than April 7th. You can present on a startup idea, an existing business or a company you work/have worked for.

## Important Deadlines

- Discussion Forum Posts - due every Sunday at 11:59PM (starting from week 2)
- Final Oral Presentation topic approval - by March 23 at 11:59PM

## Course Schedule

### Part One: Ethics and the future of Biotechnology

## WEEK 1

*In our introductory week we will touch upon two of the most controversial ethical questions surrounding cutting-edge biotech research and business: human-animal chimeras and artificial wombs. The class serves as a general introduction to the themes and methods of moral deliberation that we will cover throughout the semester.*

Monday (January 22): Introduction, ethics and the future of biotech I

### Readings:

1. [Usha Lee McFarling, \*International team creates first chimeric human-monkey embryos\*. Stat, April 15 2021.](#)
2. [Jason Scott Robert and Francose Baylis, \*Crossing Species Boundaries\*. The American Journal of Bioethics, 3:3, 2003.](#)
3. [Tao Tan et al, \*Chimeric contribution of human extended pluripotent stem cells to monkey embryos ex vivo\*. Cell, 184:8, April 15 2021. \(OPTIONAL\)](#)

Wednesday (January 24): Introduction, ethics and the future of biotech II

### Readings:

1. [David Warmflash, \*Artificial wombs: The coming era of motherless births?\* Genetic Literacy Project, April 22 2022.](#)
2. [Kathryn McKay, \*The 'tyranny of reproduction': could ectogenesis further women's liberation?\* Bioethics: 34 \(4\), 2020.](#)
3. [Bruce Blackshaw and Daniel Rodger, \*Ectogenesis and the case against the right to the death of the foetus\*. Bioethics: 33 \(1\), 2019.](#)

## WEEK 2

*An introduction to the utilitarian ethical framework and how it applies to the life sciences. We will also start our exploration of the foundational principles of bioethics (autonomy, justice, beneficence, and maleficence).*

Monday (January 29): An introduction to Utilitarianism

### Readings:

1. [Jeremy Bentham, \*An Introduction to the Principles of Morals and Legislation\* \(1789\), chapter I.](#)
2. [Jeremy Bentham, \*An Introduction to the Principles of Morals and Legislation\* \(1789\), chapter IV.](#)
3. [John Stuart Mill, \*Utilitarianism\* \(1863\).](#)

Wednesday (January 31): The foundational principles of bioethics: the problem of moral status

### Readings:

1. [Tom Beuchamp and James Childress, \*Principles of Biomedical Ethics\*, Oxford University Press 1979, chapter 3.](#)
2. [Gabriel Andrade, \*Medical Ethics and the Trolley Problem\*, Journal of Medical Ethics and History of](#)

[Medicine, 2019, 12:3.](#)

3. [Agnieszka Jaworska and Julie Tannenbaum, \*The Grounds of Moral Status\*, The Stanford Encyclopedia of Philosophy \(Spring 2021 Edition\), Edward N. Zalta \(ed.\). \(OPTIONAL\)](#)

### WEEK 3

*This week we will continue our exploration of the foundational principle of bioethics by addressing actual case studies in the medical field. We will also consider the principle of procreative beneficence.*

Monday (February 5): The foundational principles of bioethics: autonomy and non-maleficence

#### Readings:

1. [Tom Beuchamp and James Childress, \*Principles of Biomedical Ethics\*, Oxford University Press 1979, chapter 4.](#)
2. [Tom Beuchamp and James Childress, \*Principles of Biomedical Ethics\*, Oxford University Press 1979, chapter 5.](#)
3. [Julian Savulescu, "Procreative Beneficence: Why We Should Select the Best Children," \*Bioethics\*, October 2001, vol. 15, no. 5, pp. 413-426.](#)

Wednesday (February 7): The foundational principles of bioethics and beyond: beneficence, justice, and the limits of 'principlism'

#### Readings:

1. [Tom Beuchamp and James Childress, \*Principles of Biomedical Ethics\*, Oxford University Press 1979, chapter 6.](#)
2. [Norman Daniels et al., \*Is Justice enough?\*, The Hastings Center Report, 1996, 26, 6.](#)
3. [K. Danner Clouser and Bernard Gert, \*A critique of Principlism\*, The Journal of Medicine and Philosophy 15:219-236, 19.](#)
4. [David De Grazia, \*Moving forward in bioethical theory. Theories, cases and specified principlism\*. The journal of Medicine and Philosophy, 1992, 17: 511-539. \(OPTIONAL\)](#)

### **Part Two: Ethical Dilemmas in Biomedical Research and Development**

### WEEK 4

*This week we discuss the ethics of human challenge trials and analyze the case of [Hvivo](#), a company that specializes "in testing infectious and respiratory disease vaccines and antivirals using [human challenge clinical trials](#)" ([hvivo.org](#)).*

Monday (February 12): The ethics of human challenge trials

#### Readings:

1. [Ben Bambery et al, \*Ethical criteria for human challenge studies in infectious diseases\*, Public Health Ethics, 2016, 9:1: 92-103.](#)

2. [Gath Rapeport et al., SARS-CoV-2 Human Challenge Studies – Establishing the Model during an Evolving Pandemic, New England Journal of Medicine, 2021, 385: 961-964.](#)

Wednesday (February 14): Hivivo's Covid and RSV challenge studies

Readings:

1. [Hvivo.com, Human challenge studies, their conduct and safety aspects, August 2022.](#)
2. [SARS-CoV-2 Human Challenge Characterisation Study, NCT04865237](#) [focus on the "eligibility criteria"]
3. [Ben Killingley et al. Safety, tolerability and viral kinetics during SARS-CoV-2 human challenge in young adults, Nature Medicine, 28: 1031-1041.](#)
4. [Robert Steel, Risk dilution or how to run a minimal-risk HIV challenge trial, Journal of Applied philosophy, Vol. 40, No. 1, February 2023, pp.133-149 \(OPTIONAL\)](#)
5. [Edgard Diniba Dabira et. al. Perceptions and acceptability of the controlled human malaria infection \(CHMI\) model in The Gambia: a qualitative study, Nature, Scientific Report 13, 8708 \(2023\). \(OPTIONAL\)](#)

**WEEK 5**

Before we move onto the next case study, we take a closer look at deontological ethics by introducing Kantian moral philosophy.

Monday (February 19): NO CLASS, President's Day

Wednesday (February 21): Deontological ethics: Universal duty vs. utility maximization

Readings:

1. [Immanuel Kant, Groundwork for the metaphysics of morals: Preface and chapter 1.](#)
2. [Immanuel Kant, Groundwork for the metaphysics of morals: chapters 2 and 3.](#)
3. [Immanuel Kant, On a supposed right to lie because of philanthropic concerns.](#)

**WEEK 6**

This week we explore the moral limits of international clinical trials. Pfizer's testing of Trovan, an antibiotic drug.

Monday (February 26): International clinical trials during epidemics

Readings

1. [H.T. Shapiro, Ethical issues in the design and conduct of clinical trials in developing countries, New England Journal of Medicine, 2001, 345 \(2\): 139-142.](#)
2. [Adriana Petryna, Ethical variability: drug development and globalizing clinical trials, American Ethnologist, 32\(2\):183-197.](#)

Wednesday (February 28): Pfizer's testing of Trovan, an antibiotic drug, in Nigeria

## Readings

1. [Joe Stephens, Where profits and lives hang in balance, December 17 2000.](#)
2. [Government of Nigeria, Federal Ministry of Health, Report of the Investigation Committee on the Clinical Trial of Trovafloxacin \(Trovan\) by Pfizer, Kano, 1996.](#)

## **WEEK 7**

*Analysis and discussion of the moral implications of at-home health testing and the moral and legal challenges faced by Theranos.*

Monday (March 4): Theranos, At-Home Health and the Ethical Challenges of Start-up Development

1. [John Carreyrou, Hot Startup Theranos Has Struggled With Its Blood-Test Technology, Wall Street Journal, October 16, 2015.](#)
2. [Norman Paradis, The rise and fall of Theranos, Scientific American, April 22 2016.](#)
3. R.E. McGinn, [Startup Ethics: Ethically Responsible Conduct of Scientists and Engineers at Theranos. Science and Engineering Ethics 28, 39 \(2022\).](#)
4. [Alexander Mebius, Against 'instantaneous' expertise, Philosophy Ethics and Humanities in Medicine 17, 11 \(2022\).](#)

Wednesday (March 6): Legal Ethics and Obligations (Case Study: Theranos)

1. [In re Arizona Theranos Inc Litigation](#)
2. [Jury in Elizabeth Holmes Trial Seized on Two 'Smoking Guns' to Convict Theranos Founder, Juror Says](#)

-- NO CLASS MARCH 11 AND MARCH 13, IN OBSERVANCE OF SPRING BREAK --

## **Part Three: Ethical Dilemmas in Biomedical Entrepreneurship**

## **WEEK 8**

*Analysis and discussion of the moral dilemmas in pricing drugs for rare and common diseases*

Monday (March 18): Gilead and the Pricing of a Cure for Hepatitis C

*Analysis of the moral dilemmas in pricing Sovaldi, a cure for hepatitis C*

## **Readings:**

1. [Sarah Parker-Lue et al. "The Ethics and Economics of Pharmaceutical Pricing", Annual Review of Pharmacology and Toxicology, Vol. 55:191-206.](#)
2. [Editorial Staff, "Sovaldi: Who's to Blame for the \\$1,000 a Day Cure?", Knowledge at Wharton, April 16, 2014.](#)
3. [Ed Silverman, "Hepatitis C drugs remain unaffordable in many countries, says WHO study", Stat News, May 31 2016.](#)

Wednesday (March 20): Turing, Valeant, Novartis, and the Pricing of Treatment for Rare Diseases

*Analysis and discussion of the moral dilemmas in pricing Daraprim, Syprine, and Zolgensma, drugs used to treat respectively: Toxoplasmosis, Wilson Disease, and Spinal Muscular Atrophy.*

*Readings:*

1. [Stephanie Armour and Jonathan Rockoff, "Valeant, Turing Boosted Drug Prices to Fuel Preset Profits", The Wall Street Journal, February 2 2016.](#)
2. [Bethany McClean, "The Valeant meltdown and Wall Street's major drug problem", Vanity Fair, June 5 2016.](#)
3. [Peter B. Bach, "No miracle drug should cost \\$2.1 Million", Bloomberg, May 24 2019.](#)
4. [Robert Pearl, "The \\$2.1 Million Question: What Are The Medical, Ethical Implications Of The World's Priciest Drug?", Forbes, June 10 2019.](#)

## WEEK 9

*Analysis and discussion of the business strategies developed by Purdue Pharma to produce and market OxyContin.*

Monday (March 25) - Case study: Purdue Pharma and the commercialization of OxyContin

*Readings:*

1. [Art Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, American Journal of Public Health, 2009 February; 99\(2\): 221â€“227.](#)
2. [Jason Sanchez, Purdue Pharmaâ€™s Deceptive Research Misconduct: The Importance of the Use of Independent, Transparent, Current Research, Voices in Bioethics, 2021.](#)
3. [PBS Newshour, Interview with Patrick Keefe, author of "Empire of Pain", January 20 2019.](#)
4. [McKinsey & Company, OxyContin Growth Opportunities, August 20 2013.](#)

Wednesday (March 27) - On the ethics of palliative care and chronic pain management

*Readings:*

1. [Shraddha Chakradhar and Casey Ross, The history of OxyContin, told through unsealed Purdue documents, Stat News, December 3 2019.](#)
2. [Guy Schofield et al., Real-world ethics in palliative care: A systematic review of the ethical challenges reported by specialist palliative care practitioners in their clinical practice, Palliative Medicine, 2021; 35\(2\), pp. 315â€“334.](#)
3. [David Casarett and Jason Karlawish, Are Special Ethical Guidelines Needed For Palliative Care Research?, Journal of Pain and Symptom Management, 2000; 20 \(2\), pp. 130-139.](#)
4. [Robert Kugelmann, Review of The Palliative Society: Pain Today: Byung-Chul Han, translated by Daniel Steuer, Polity Press, 2021, Journal for the Psychoanalysis of Culture & Society, 1â€“8. 28 Nov. 2022. \(OPTIONAL\)](#)

## **Part Four: Developing Ethical Approaches to Biomedical Entrepreneurship**

### **WEEK 10**

*Virtue Ethics*

Monday (April 1):

Aristotle's [Nicomachean Ethics](#): Books 2 (ch1-3) and 10 (ch. 1-3)

Wednesday (April 3):

[Jorge Garcia, \*Virtues and Principles in Biomedical Ethics\*, The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine, 2020: 45 \(4-5\), pp. 471-503.](#)

### **WEEK 11**

*Class Exercise: Embryonic Genetic Modification Startup case study*

Monday (April 8)

Readings TBA

Wednesday (April 10)

Readings TBA

### **WEEK 12**

*Class Exercise: Brain-Computer Interface Startup case study*

Monday (April 15)

Readings: TBA

Wednesday (April 17)

Readings: TBA

### **WEEK 13**

Monday (April 22)

Guest Lecture by Professor [Doug Melton](#)

Wednesday (April 24)

Conclusion: Tech, biotech, and the future of human nature



*No readings.*