

Technology, Human Rights, and Equality **Spring 2005**

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Seminar Description

We live in an age of constant technological breakthroughs, designed not only to ease human suffering but also to enhance human powers. At first glance, such progress—particularly in the health care field—appears to be an unqualified gain. However, inequality of access to these advances has worried many thoughtful people. Should individuals' access to technology depend on how much money they have? Or which country they live in?

These concerns are becoming increasingly important as new technologies of medical care and bodily enhancement develop. As we try to understand the moral issues raised by these questions, we will examine how such concerns are translated into laws which set floors and ceilings for access to technology. The moral desirability of such limits on the minimum and maximum amount of technology available (to the poor and rich, respectively) will be the central focus of the course.

We will begin with the idea of the social minimum—the basic level of technology that a just or decent society assures to even its poorest members. We will then explore how the law enacts this idea of a social minimum, both in the United States and (more briefly) internationally. In the U.S., the Emergency Medical Treatment and Active Labor Act of 1986 requires hospital emergency rooms which receive federal funding to screen and stabilize anyone who arrives with a serious condition. Medicaid and state programs assure some level of health care to the indigent. Internationally, some intellectual property laws governing pharmaceuticals also grant poor countries the right to “compulsorily license” lifesaving drugs in times of emergency. We will discuss how these and similar legal protections work, whether they are successful, and their unintended consequences.

We will then move on to consider the idea of a technological “ceiling,” focusing on concerns that certain types of health care or health enhancement should not be available, even if there is a market for them. Many scholars predict that cutting-edge regenerative medicine could greatly extend its “patients’” lifetimes. If such medical care is prohibitively expensive for the vast majority of persons, should it be permitted? Or is there something grotesque about a social order that grants wealthy individuals lifetimes

that are twice as long as those who can't pay for those therapies? After we address these normative questions, we'll look at some legal restrictions that have been placed on current medicine (organ transplants), regenerative medicine (such as stem cell transplants), "prospective" medicine (like genetic engineering), and "enhancements" (such as steroids, cosmetic surgery, and "cosmetic psychopharmacology").

Readings

The primary text for the first half of the class is Hall, Bobinski, and Orentlicher, *The Law of Health Care Finance and Regulation* (Aspen, 2005) [hereinafter HBO]. All required reading for the second half of the course will be distributed via course pack, handouts, and/or a post on the TWEN page.

For this seminar to be successful, it is essential that you do the readings and participate actively in class discussions. I will make every effort to assign a manageable amount of reading each week; in exchange I expect that you will complete all of the readings prior to each class.

Office Hours

I encourage all of you to visit me during office hours to discuss the course, your paper, law school, career paths, or anything else that interests you. If you are not available during my office hours, please contact me via email (pasquafa@shu.edu) or phone (642-8485) to make an appointment.

Seminar Requirements and Grade

JD Students:

All JD students are required to write a seminar paper that meets the law school's advanced writing requirement. The paper requirements are the same for all students in the class regardless of whether the paper is being used to fulfill the advanced writing requirement. The paper must be at least 25 pages (text double spaced; footnotes single spaced) and conform to the latest edition of the Bluebook.

I will expect each student to complete a paper of publishable quality on a topic I have approved in advance. In accordance with the Law School's requirement for certification, your paper must exhibit substantial research and analysis. For many topics in this course, your research will focus on secondary authority and interdisciplinary sources. You may not rely exclusively on internet sources.

You must proofread your paper for grammatical and typographical errors and bluebooking. I will return (without reading) papers that upon first glance clearly do not satisfy these requirements. You will then have 24 hours to return the revised paper to me.

Your paper must be structured around an argument, that is, an original thesis. Although it is important that you demonstrate familiarity with existing law and commentary, papers should not merely summarize the law or views expressed by others.

For more information about writing the seminar paper, please go to the following web site: http://law.shu.edu/administration/registrar_bursar/AWR/index.htm. You should particularly look at the sample papers posted there.

Your paper will count for three-fourths of your overall grade and your in class participation will count for the remaining one-fourth.

The determination of your grade and the certification that the paper meets the advanced writing requirement are separate decisions. Thus, hypothetically, you could receive a passing grade for the seminar but not receive certification of having fulfilled the advanced writing requirement.

M.S./LL.M. Students:

All M.S./LL.M. students are required to write a 48 hours take-home exam that can be picked up at any time during the exam period – as late as May 8 at 5:00. You will not be tested on the materials discussed in the students' presentations, but you are expected to participate during the question and answer sessions of these presentations.

Your exam will count for three-fourths of your overall grade and your in class participation will count for the remaining one-fourth.

Calendar for JD students

The schedule below indicates important dates for the progress and completion of your work.

Thursday, Feb. 3 – **paper topic due**. This should be a one-page description of your paper topic, the areas you have already researched, what additional research you plan to do, and what you think your thesis might be. You should list at least ten sources in this document.

Thursday, Feb. 24 – **paper outline/synopsis due**. The outline/synopsis can be written in either outline or narrative form. It should be at least **4 pages** long, describing, your topic, research findings, arguments and conclusion. You should list at least twenty sources in this document.

Thursday, April 7 – **first draft due**. First drafts should be at minimum **20 pages**. You must treat the first draft as a final product. It must be footnoted and properly bluebooked.

Wednesday, May 11 – **final draft due.**

By 5:00PM on the date due, the assignments must be both emailed to me (with the subject line TEHR: [Paper Title]) and handed in in hard copy either in class or left in my faculty mailbox on the fifth floor.

I will review your work as soon as practically possible so that you may continue working on your papers. I can only do that, however, if you submit your work in a timely manner. These deadlines are, therefore, firm. If you anticipate any problems meeting a deadline, you should speak to me in advance of the deadline so that we can try to work out a way to keep you on track.

Please note that there is no flexibility with the draft and final papers' due dates. If your draft paper is not handed to me by class-time on April 7, your final grade will be dropped by one-third grade. The final grade will be dropped by an additional one-third grade for each week it is late thereafter (with a maximum one full grade reduction for the draft). If your final paper is not placed in my mailbox by 5:00 pm on May 11, your final grade will be dropped by one-third grade. The final grade will be dropped by an additional one-third grade for each week it is late thereafter (with a maximum one full grade reduction for the final paper).

Attendance Policy

In accordance with the Law School's attendance policy, you must attend a minimum of 75% of class sessions or you will be administratively withdrawn from the course. You must sign the attendance sheet during each class to be marked present.

Paper Topics and Resources for Research

I have developed a list of paper topics and further resources for research; it's available below, after the list of readings.

Outline

Here is a bare-bones outline of the course; more complete information appears as the topics are listed week by week below.

I. Floors: The Minimum in Health Care Available to the Poor

A Domestic Approaches to Care

- 1 Tiered Access to Care
- 2 EMTALA

- 3 Public Insurance
- 4 Private Insurance

A Intellectual Property Disputes

- 1 Access to Medicine
- 2 Access to Research

II. Ceilings: Maximum Bodily Alteration or Enhancement

A Domestic Controversies

- 1 Boutique Medicine
- 2 Steroids
- 3 Stem Cell Research
- 4 Germ-line Genetic Engineering

A International Consensus?

- 1 Genetic Engineering
- 2 Organ Commodification

Class Reading

Required reading for each seminar appears below.

Class 1: Introduction and Overview

Pam Belluck, *Doctors' New Practices Offer Deluxe Service for Deluxe Fee*, N.Y. TIMES, Jan. 15, 2002.

Editorial, *Boutique Medicine*, N.Y. TIMES, Jan. 17, 2002.

Sebastian Mallaby, *How Africa Subsidizes U.S. Health Care*, Wash. Post A19, Nov. 29, 2004.

Arthur Caplan and Carl Elliott, *Should We Use Technology to be Better than Well?*, available at <http://www.betterhumans.com/Features/Columns/Guests/column.aspx?articleID=2004-12-30-1>

Class 2: Tiered Access and Medical Spending Decisions

Hall, Bobinski, and Orentlicher (“HBO”) 35-48, 78-90

Class 3: Duties to Treat

HBO 91-108.

Class 4: Introduction to Health Care Financing

HBO 159-184

Class 5: Public Insurance

HBO 185-202

Class 6: The Scope of Coverage

HBO 234-255

Class 7: Determining “Medically Appropriate” Care

HBO 256-273, 284-289

Class 8: Access to Pharmaceuticals: International Debates

Michael R. Reich, The Global Drug Gap, 287 *Science* 1979 (2000), available at <http://www.fordham.edu/law/faculty/patterson/tech&hr/materials/reich.druggap.pdf>

WTO Doha Declaration on TRIPS and Public Health, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

Excerpts from Tracy Kidder, *Mountains Beyond Mountains: The Quest of Paul Farmer, A Man Who Would Cure the World* (2003).

Class 9: Access to Medical Research

Excerpts from *Williams & Wilkins Co. v. U.S.*, 487 F.2d 1345 (1973), avail. at http://fairuse.stanford.edu/primary_materials/cases/c487F2d1345.html

Amanda Schaffer, *Open Access: Should Scientific Articles be available online and free to the public?*, *Slate*, Dec. 16, 2004, available at <http://slate.msn.com/id/2111023>

Rick Weiss, *A Fight for Free Access to Medical Research Online Plan Challenges Publishers' Dominance*, *Wash. Post*, Aug. 5, 2003, at A1, available at <http://www.washingtonpost.com/ac2/wp-dyn/A19104-2003Aug4?Language=printer> (last visited Sept. 22, 2004).

Skim: Samuel E. Trosow, Copyright protection for federally funded research: necessary incentive or double subsidy?, 22 *Cardozo Arts & Ent LJ* 613 (2004)

Class 10: Genetic Engineering: Caste Society or Utopia?

Maxwell J. Mehlman, *The Law of Above Averages: Leveling the New Genetic Enhancement Playing Field*, 85 *Iowa L. Rev.* 517 (2000).

Class 11: “Running as Fast as We Can Just to Stay in Place:” Steroids, Cosmetic Surgery, and the Pressure to Perform

Carl Elliott, *This Is Your Country on Drugs*, N.Y. Times, Dec. 14, 2004.

National Bioethics Advisory Council, *Beyond Therapy: Biotechnology and the Pursuit of Happiness*, Chapter 3: Performance Enhancement

available at <http://www.bioethics.gov/reports/beyondtherapy/chapter3.html>

(Note: You can skip Part III.)

Class 12: Organ Transplants: Commodification vs. Regulation

Mark F. Anderson, The Future of Organ Transplantation: From Where Will New Donors Come, to Whom Will Their Organs Go?, 5 *Health Matrix* 249, 279 (1995).

Press Release, Dep't of Health and Hum. Servs., *Improving Fairness and Effectiveness in Allocating Organs for Transplantation* (March 26, 1998), available at <http://www.hhs.gov/news/press/1998pres/980326b.html> (last visited Nov. 18, 2003).

Class 13: Boutique Medicine: A Role for Antitrust Given Doctors' Control Over their Numbers?

Review newspaper articles from Week 1.

HBO 475-480, 516-528.

Troyen Brennan, *Luxury Primary Care: Market Innovation or Threat to Access?*, 346 *New Eng. J. Med.* 1165 (2002).

Class 14: Moral Responsibility in a World of Growing Inequality

Excerpts from Peter Unger, *Living High and Letting Die: Our Illusion of Innocence* (1996)

OR

Excerpt from Tracy Kidder, *Mountains Beyond Mountains: The Quest of Paul Farmer, A Man Who Would Cure the World* (2003) (Chapter 25).

James R. Otteson, "Limits on Our Obligation to Give," *Public Affairs Quarterly* 14, 3 (July 2000): 183–203, available at <http://www.bama.ua.edu/~jotteson/singer.pdf>

RESOURCES FOR RESEARCH AND PAPER TOPICS

Technology, Human Rights, and Equality Seminar

Since you need to pick a paper topic quickly, I have suggested many below. I suggest more for the second half of the course than the first because *Health Care Financing and Regulation* provides a number of ideas in the "notes" sections that follow the readings.

This document will be posted on the TWEN page and updated throughout the term. If you find a particularly good resource, please email it to me so I can include it below.

I have concentrated on websites in the "resources" area; however, even a cursory search of the library catalog should bring up some good books on the topic not mentioned below. Since many of these issues are "cutting edge," frequent review of the Westlaw and Lexis databases JLR ("Journals and Law Reviews") and "All Cases" may be fruitful.

Resources for Key Topic Areas

Domestic Access to Health Care

Progressive

Kaiser Family Foundation, www.kff.org, <http://www.kff.org/uninsured/index.cfm>
<http://www.kff.org/medicaid/index.cfm>).

Robert Wood Johnson Foundation, www.rwjf.org, <http://www.statecoverage.net/>
Commonwealth Fund, www.cmwf.org

Conservative

Cato Institute, www.cato.org/healthcare/index.html

Heritage Foundation, www.heritage.org/research/healthcare/

Pharmaceuticals Research and Manufacturing Association, <http://www.phrma.org/issues/>

American Medical Association, <http://www.ama-assn.org/>

Neutral

Lexis: News & Business > Market & Industry > By Industry & Topic > Medical & Healthcare

Center for Law and Social Policy (www.clasp.org)

Health Law Center Library; ask me for email of journal titles (including *Health Matrix*, *Journal of Health Care for the Poor and Underserved*, *Health Affairs*, etc.)
American Academy of Family Physicians, <http://www.aafp.org/>
National Health Law Program, www.healthlaw.org

State Issues: New Jersey

Senior Benefits, <http://www.state.nj.us/health/seniorbenefits/paadapp.htm>

New Jersey Family Care, <http://www.njfamilycare.org/>

Charity Care, <http://www.lsnjlaw.org/english/healthcare/charitycare.cfm>

Randy Bovbjerg, State Report for Urban Institute,
<http://www.statecoverage.net/statereports/nj2.pdf>

Commonwealth Fund, <http://www.statecoverage.net/statereports/nj6.pdf>

Rutgers Center for State Health Policy, <http://www.statecoverage.net/statereports/nj8.pdf>.

State Issues: Generally

Health Affairs (July/August 2000) was on State Health Policy

Kaiser Family Foundation, State health policy site, at
<http://www.kff.org/statepolicy/index.cfm>

Access to Medical Research

Creative Commons, <http://creativecommons.org/>

Public Library of Science, <http://www.publiclibraryofscience.org/>

Public Knowledge, <http://www.publicknowledge.org/>

International Access to Health Care

Consumer Project on Technology, www.cptech.org and particularly
<http://www.cptech.org/ip/health/>

Physicians for Human Rights, <http://www.phrusa.org/>

Partners in Health, <http://www.pih.org/library/index.html>

Enhancements

Anti

National Bioethics Advisory Council,
http://www.bioethics.gov/topics/beyond_index.html
National Conference of Catholic Bishops,
<http://www.usccb.org/prolife/issues/bioethic/stemcell/index.htm>
The New Atlantis, available at <http://www.thenewatlantis.com/index.html>

Pro

Transhumanist Network, <http://www.transhumanism.org/index.php/WTA/index/>
Ronald Bailey, <http://reason.com/rb/bailey.shtml>
Dale Carrico, <http://amormundi.blogspot.com/>
Cyborg Democracy, <http://changesurfer.com/blogger.html>
Donna Haraway, <http://www.asahi-net.or.jp/~RF6T-TYFK/haraway.html>
Institute for Ethics and Emerging Technology, <http://ieet.org/index.php>

Neutral

National Institutes of Health, Primer on Stem Cell Research, <http://stemcells.nih.gov/>
Genetics and Public Policy Center, <http://www.dnapolicy.org/>

Organ Transplantation

Jon Elster, *Local Justice: How Institutions Allocate Scarce Goods and Necessary Burdens* (1997).

Richard Epstein, *Mortal Peril: Our Inalienable Right to Health Care?* (1997).

Philosophical Approaches to Inequality

Websites

Entries in Stanford Encyclopedia of Philosophy on “Equality” and the “Social Minimum,” available at
<http://plato.stanford.edu/entries/equality/>
<http://plato.stanford.edu/entries/social-minimum/>

Bibliography on Distributive Justice, available at
<http://www.distributive-justice.com/theory/bibliography-en.htm>

Books and Articles

G.A. Cohen, *If You're An Egalitarian, How Come You're So Rich?* (2000).

Avishai Margalit, *The Decent Society* (1999).

Liam Murphy, *Beneficence, Law, and Liberty: The Case of Required Rescue*, 89 *Geo. L.J.* 605, 653 (2001)

John Rawls, *A Theory of Justice* (1972).

Thomas Scanlon, *The Diversity of Objections to Inequality*, in: *The Lindley Lecture*, Lawrence, KA: The University of Kansas (1996).

Peter Singer, *Famine, Affluence, and Morality*, *Philosophy and Public Affairs* 1, 1972, pp. 229-243.

Peter Unger, *Living High and Letting Die: Our Illusion of Innocence* (1999).

Michael Walzer, *Spheres of Justice: A Defense of Pluralism and Equality* (1977).

Jonathan Wolff, *Fairness, Respect, and the Egalitarian Ethos*, *Philosophy and Public Affairs* 27, 1998, pp. 97-122.

Recommended Reading and Paper Topics, Week by Week

General Ideas for Paper Topics

We will be examining the following questions in this course:

I Floors of Minimum Access to Technology

- A. How much should individuals' access to technology depend on how much money they have? Or which country they live in?
- B. How does law try to assure some “social minimum” of entitlement to important technologies?
- C. Can these legal efforts backfire and hurt the very people they are intended to help?

II Ceilings of Maximum Access to Technology

- A. When technologies of physical enhancement promise to vastly improve the performance or life-chances of one class in society, are there reasons to restrict them until they are more widely available? Is law effective at doing so?
- B. When the wealthiest members of society can spend unlimited amounts on technology and health care, does this divert it from the poorest? Or does this situation ultimately help everyone by assuring investment in new technologies?

These are moral and empirical questions. Once you reach a certain conclusion about them with respect to a particular technology, think about a type of legal change that would promote the conclusion you reach. For example, if you believe that boutique medical care ultimately diverts medical resources from poor and middle class households, and have evidence to back that conclusion, think about the types of legal interventions that can arrest or retard this development. I offer a few ideas below.

Class 1: Introduction and Overview

Paper Topics

- 1 Belluck notes that boutique or “[c]oncierge practices say they adhere to the law by ensuring that their fees pay only for services not covered by insurance or Medicare.” Is there a way to change the law to assure that Medicare is not effectively subsidizing this “tiering” of the healthcare system? Or should Medicare be changed to encourage boutique practices?
- 2 Do any state statutes or regulations prohibit boutique medicine? Discourage it?

- 3 Should the practice of boutique medicine draw antitrust scrutiny from federal or state authorities? The reading from Class 13 focuses on this issue. In ordinary markets, the presence of a class of high-spending consumers will draw more suppliers so that, eventually, supply will equal demand. However, the AMA very strictly controls the number of doctors permitted to graduate each year. Does this market distortion mean that medicine that goes to the rich inevitably is medicine diverted from the poor? Do such diversions merit antitrust scrutiny?
- 4 Should first world employers of immigrant professionals from third world countries be required to pay a tax to subsidize the recruitment and retention of replacements in their home countries? How would such a tax or tariff be structured? You may want to start with some research on SCHIP immigration. Note that Dean Hobbs has proposed that highly ranked law schools which “hire away” professors from other schools should pay some kind of replacement cost to their new hire's previous employer.
- 5 Francis Fukuyama, a member of President Bush's National Bioethics Advisory Board, criticizes the transhumanists for proposing innovations that would create “supermen” whose lifespan and powers would vastly exceed those of fellow citizens. He would presumably outlaw or strictly regulate these innovations. Are there good precedents for such regulation? Arms control? Human subject research? Dangerous or “immoral” devices? For one proposal, see George J. Annas, *The Man on the Moon, Immortality, and Other Millennial Myths: The Prospects and Perils of Human Genetic Engineering*, 49 *Emory L.J.* 753 (2000) (arguing that some proposed genetic engineering should be censured as a “crime against humanity” because of its potential for promoting speciation).

Class 2: Tiered Access and Medical Spending Decisions

Paper Topics

- 1 These readings introduce the idea of a tiered health care system, which provides different levels of care to different health care “consumers,” depending on their ability to pay. Uwe Reinhardt mentions on p. 78 that several European countries have permitted “some degree of tiering” in health care systems that are generally more egalitarian than the American system. Examine the history of tiering in one of these countries, and draw lessons for the American debate over tiering.
- 2 As more expensive therapies develop, federal and state governments are going to face more difficult decisions about what level of care to reimburse. The Oregon experiment with “explicitly rule-based rationing for all of medicine” covered by certain public insurance programs is discussed briefly on p. 81. What lessons can you draw from this experiment in rationing?
- 3 A rough-and-ready, non-monetary method of rationing health care allocates resources to those who are predicted to have the most Quality Adjusted Life Years (QALYs) upon receipt of the resources. For example, if a 25 year old and a 75 year old both need a liver, all things being equal, the liver would go to the 25 year old because he

- can be expected to live longer. Are such allocations a form of age discrimination? If a non-disabled person is favored over a disabled person, is that a form of disability discrimination? See, e.g., Daniel Callahan, *Rationing Health Care: ... Can It be Done Without Age or Disability Discrimination?*, 16 *Law Med. & Health Care* 261 (1988).
- 4 Greely vividly describes the inequality pervasive in the American health care system. However, it's not entirely clear that all the indicia of inequality he mentions mean that poor people are being forced into substandard care. For example, while many people lack health insurance, many of the uninsured may be uninsured by choice. Should uninsured individuals who can afford to pay for insurance be forced to insure themselves? How might the law promote this outcome?

For Further Research

Daniel Callahan, *Rationing Health Care: ... Can It be Done Without Age or Disability Discrimination?*, 16 *Law Med. & Health Care* 261 (1988).

Norman Daniels, et al., *Benchmarks of Fairness for Health Care Reform* (1996).

Larry Palmer, *Law, Medicine, and Social Justice* (1989).

Barbara Starfield, *Is US Health Care Really the Best in the World?*, 284 *JAMA* 483 (2000).

Class 3: Duties to Treat

Paper Topics

- 1 Critics of EMTALA claim that it unfairly burdens institutions that *already* provide care for the poorest with an unfunded mandate to provide further care. Is there evidence that EMTALA has driven any hospitals to close their emergency rooms in order to avoid liability? If so, how can the law be changed in order to avoid this self-defeating result?
- 2 Are there any legal challenges to the Bush Administration's latest change of the EMTALA rules (which reduce the risk of liability)? If so, should they succeed? If not, should there be?
- 3 Have any states developed EMTALA-like rules? Do their stories of success or failure provide any lessons for national debates on EMTALA?

For further research:

HBO 1-7 (another EMTALA case study).

Richard Epstein, *Mortal Peril: Our Inalienable Right to Health Care?* (1997), chapter on EMTALA (free market libertarian approach).

Thomas Greaney, **How Many Libertarians Does it take to Fix the Health Care System?** (review of Epstein).

Troyen A. Brennan, **Moral Imperatives Versus Market Solutions: Is Health Care a Right?**, 65 U. Chi. L. Rev. 345, 355 (1998) (review of Epstein).

Class 4: Introduction to Health Care Financing

Paper Topics

See notes pages, HBO 172 ff.

For Further Reading

John Jacobi, *Mission and Markets in Health Care*, 75 Wash. U.L.Q. 1431 (1997). (Note: Professor Jacobi has written several important articles in this area; consult his homepage for the full list.)

Martin Gaynor and William Vogt, What does economics have to say about health policy anyway? A comment and correction on Evans and Rice, 22 J. Health Pol. Pol'y & L. 475 (1997)

Mark A. Hall, *Making Medical Spending Decisions: The Law, Ethics, and Economics of Rationing Mechanisms* (1997).

Gail B. Agrawal, Review of Mark Hall, *Making Medical Spending Decisions: The Law, Ethics, and Economics of Rationing Mechanisms*, 96 Mich. L. Rev. 1793(1998).

Max Mehlman, *Rationing Expensive Lifesaving Medical Treatments*, 1985 Wis. L. Rev. 239.

Class 5: Public Insurance

Paper Topics

See notes pages, HBO 194 ff.

Class 6: The Scope of Coverage

Paper Topics

See notes pages, HBO 247 ff.

For Further Research

Daniel Callahan, *The Troubled Dream of Life: In Search of a Peaceful Death* (1993).

Class 7: Determining “Medically Appropriate” Care

Paper Topics

See notes pages, HBO 271 ff.

For Further Research

Daniel W. Brock, *Commentary: Implications of New Physician Payment Methods for Access to Health Care and Physician Fidelity to Patients' Interests*, 36 Case W. Res. 760 (1986).

Sara Rosenbaum, *Who Should Determine When Health Care is Medically Necessary?*, 340 New England Journal of Medicine 229 (1999).

Class 8: Access to Pharmaceuticals: International Debates

Paper Topics

- 1 Could the well-developed U.S. regime of compulsory licensing for copyright content be applied to international efforts to compulsorily license essential medicines? Could methods of intellectual property valuation used here provide some stability and regularity to global efforts to assure universal access to medicine? (Feel free to ask me for a fuller explanation of this topic.)
- 2 Pharmaceutical companies that oppose compulsory licensing often claim that it will eventually result in arbitrage—the sale of low-priced drugs (sold in poor countries) that eventually substitute for high-priced drugs (sold in rich countries). Is this a real problem? If so, how can trade and criminal laws be adapted to address it?

For Further Research

Commission on Intellectual Property Rights, Integrating Development and Intellectual Property Rights, available at

http://www.iprcommission.org/papers/text/final_report/reporthtmfinal.htm

Emory International Law Journal Symposium on International Patent and Trade Agreements Related to the Global Fight Against HIV/AIDS, available at

<http://www.law.emory.edu/students/eilr/symposium/index.htm>

Bruce Kuhlik, Testimony of PhRMA before Congress, *on file with instructor*.

Victor Sidel, *What is Social Medicine?*, available at

<http://www.monthlyreview.org/0105anderson.htm>

F. M. Scherer, *The pharmaceutical industry and world intellectual property standards*, 53 Vand. L. Rev. 2245 (2000).

Fordham Law School Technology and Human Rights Seminar, Webpage on International Access to Pharmaceuticals, available at <http://www.fordham.edu/law/faculty/patterson/tech&hr/> (Week 2)

Class 9: Access to Medical Research

Paper Topics

- 1 Research current legislative proposals to make publicly financed research open-access, along with publishing industry criticisms and public interest group commentary. What are the best arguments on each side? Does the publishing industry add enough value to the final product to justify its current copyright revenues? If so, how may the proposal be amended to assure fair compensation? If not, how might this proposal be expanded?
- 2 Would a compulsory license solution, based on micropayments and ability to pay, be appropriate here? Does the experience of the music industry (which is in the process of making all content available on line, for a price) provide any lessons here? Note that while the average price of songs on line is about one dollar, some music industry critics (including John Perry Barlow) claim that a dime or less would be appropriate.

For further research

Mike Sosteric, *At the Speed of Thought: Pursuing Non-Commercial Alternatives to Scholarly Communication*, ARL Newsl, Oct. 1998, at <http://www.arl.org/newsltr/200/sosteric.html> (last visited Sept. 22, 2004).

Samuel E. Trosow, Copyright protection for federally funded research: necessary incentive or double subsidy?, 22 *Cardozo Arts & Ent LJ* 613 (2004).

Thomas J. Walker, *Free Internet Access to Traditional Journals: Can Scientists Find Ways to Share Published Research without High Cost?*, Am. Scientist, available at <http://www.americanscientist.org/template/AssetDetail/assetid/15595?fulltext=true> (last visited Sept. 22, 2004).

Class 10: Genetic Engineering: Caste Society or Utopia?

Paper Topics

- 1 George Annas has argued that genetic engineering and cloning can constitute a “crime against humanity.” Have any nations, or international organizations, taken this stand?

- 2 During the recent debate on cloning, Representative Weldon of Florida proposed that anyone caught cloning an embryo be subject to a fine of up to five million dollars or a five year prison term. Should such measures be applied to genetic engineering in general? To particular types of genetic manipulation?

For Further Research

Allen Buchanan, Dan Brock, Norman Daniels and Daniel Wikler, *From Chance to Choice: Genetics and Justice* (2002).

Leon Kass, *For an International Ban on Human Cloning*, available at <http://www.mindfully.org/GE/Human-Cloning-Ban-KassNBAC14mar97.htm>

Leon R. Kass, *Preventing a Brave New World: Why We Should Ban Human Cloning Now*, *The New Republic*, May 21, 2001, at 22.

Chris Mooney, Irrationalist-in-Chief, *Am. Prospect*, Sept. 24, 2001, available at <http://www.prospect.org/print/V12/17/mooney-c.html> (arguing that Kass criticizes beneficial technologies because of unjustified speculation that they will eventually become harmful).

Maxwell J. Mehlman, *The Law of Above Averages: Leveling the New Genetic Enhancement Playing Field*, 85 *Iowa L. Rev.* 517 (2000).

William Saletan, *Monster Farming: The Creepy Solution to the Stem Cell Debate*, available at <http://slate.com/id/2110670>.

Michael H. Shapiro, *Does technological enhancement of human traits threaten human equality and democracy*, 39 *San Diego L. Rev.* 769 (2002). (Note that this entire issue is devoted to discussing “Genes and the Just Society”).

“Food for Thought:” *Gattaca*, *Twilight of the Gods* (films)

Class 11: “Running as Fast as We Can Just to Stay in Place:” Steroids, Cosmetic Surgery, Cosmetic Psychopharmacology, and the Upward Pressure to Perform

Paper Topics

- 1 Although anabolic steroid use for weight training is illegal, scientists have proven very proficient at evading the law by developing chemicals that have similar effects but are not mentioned specifically in the relevant statutes and regulations. (Mark McGuire appeared to have used such a substance.) How are the relevant federal regulatory authorities (and state law enforcement authorities) responding to this problem? Is there a particularly effective approach?

- 2 Among American sports leagues, baseball appears to be the most ineffective at stopping steroid use among its players. Can legal authorities accelerate action here?
- 3 Members of the NBAC worry that enhancements threaten equality by permitting the exceptional to invest in “self-improvement” that increases the gap between them and the “average person.” Another egalitarian dimension of the problem emerges once we think about the below-average person who wants some help to become average. Are there ways to tweak the legal reforms proposed by the anti-enhancement crowd in order to distinguish between these two cases? For example, if we increase malpractice liability in the case of cosmetic surgery, can we reduce it in case of reconstructive surgery?
- 4 The NBAC has so far proposed few specific legal reforms. This may be because they are primarily promoting a *cultural* change, a society less obsessed with superficial attributes (like beauty) and winning at all costs. As Tocqueville observed long ago, it's hard to develop laws that change individuals' hearts. On the other hand, one could imagine, say, a tax on enhancements themselves, or shows that promote them (like *The Swan* or *Extreme Makeover*). Illinois legislators, for instance, have proposed funding of medical research via taxes on Botox injections. Would a similar tax on enhancement-promoting television shows (or expanded tort liability for them) be feasible? Or would it face First Amendment obstacles?

For further research:

[Peter H. Schwartz](#), *Genetic Breakthroughs and the Limits of Medicine: Short Stature, Growth Hormone, and the Idea of Dysfunction*, 13 St. Thomas L. Rev. 965 (2001).

President's Council on Bioethics, *Beyond therapy: Biotechnology and the pursuit of happiness* (2003).

Bill McKibben, *Enough: Staying human in an engineered age* (2003).

Dan Callahan, *What price better health? Hazards of the research imperative* (2003).

Carl Elliott, *Better than well: American medicine meets the American dream* (2003).

Francis Fukuyama, *Our posthuman future: Consequences of the biotechnology revolution* (2002).

D. and S. Rothman, *The pursuit of perfection: The promise and perils of medical enhancement* (2003).

Leon Kass, *Life, liberty, and the defense of dignity: The challenge for bioethics* (2002).

W. Kristol and E. Cohen, eds., *The future is now: America confronts the new genetics* (2002).

Michael Sandel, The case against perfection, *Atlantic Monthly* 51-62 (April 2004).

Robert Frank, *Are Positional Externalities Different?*, available at http://gemini.econ.umd.edu/cgi-bin/conference/download.cgi?db_name=ACE2004&paper_id=244

Kahneman, Daniel, Ed Diener, and Norbert Schwartz, eds., *Understanding Well-Being: Scientific Perspectives on Enjoyment and Suffering*, New York, Russell Sage, 1998.

Peter Kramer, *Listening to Prozac* (1994).

Charles T. Rubin, *Man or Machine*, available at <http://www.thenewatlantis.com/archive/4/rubin.htm>. (Note that this magazine, closely affiliated with the NBAC, has an entire issue on enhancements available at <http://www.thenewatlantis.com/archive/> (Winter 2004)).

Paul C. Weiler, *Leveling the Playing Field: how the law can make sports better for the fans* (2000).

Class 12: Organ Transplants: Commodification vs. Regulation

Paper Topics

- 1 Would a system that permitted the wealthy to “jump the line” be legitimate if it ensured the provision of more organs in the future, or the development of “plastic organs” that would eventually be made available to all? Have any countries endorsed this type of commodification of organs? What types of incremental legal steps could be taken to establish it?

For further research:

Note: Many health law textbooks cover this issue.

Guido Calabresi, An Introduction to Legal Thought: Four Approaches to Law and to the Allocation of Body Parts, *55 Stanford L. Rev.* 2113, 2114 (2003).

Lloyd R. Cohen, *Increasing the Supply of Transplant Organs: The Virtues of a Futures Market*, *58 GEO. WASH. L. REV.* 1 (1989).

Jon Elster, *Local Justice*.

Richard Epstein, *Mortal Peril*.

David L. Weigert, *Tragic Choices: State Discretion over Organ Transplant Funding for Medicaid Recipients*, 89 *Nw. U.L. Rev.* 268 (1994)

Class 13: Boutique Medicine: A Role for Antitrust Given Doctors' Control Over their Numbers?

Paper Topics

See first week topics.

For further research

Troyen Brennan, *Luxury Primary Care: Market Innovation or Threat to Access?*, 346 *New Eng. J. Med.* 1165 (2002).

For food for thought on the boutique medicine/antitrust issue, looking at a potentially parallel situation in the legal field, see Marina Lao, Discrediting Accreditation?: Antitrust and Legal Education, 79 *Wash. U.L.Q.* 1035 (2001) and *The Rule of Reason and Horizontal Restraints Involving Professionals*, 68 *Antitrust L.J.* 499 (2000).

Class 14: Moral Responsibility in a World of Growing Inequality

Paper Topics

- 1 Tax policy can significantly influence individual giving patterns. The current charitable giving deduction encourages donations to a wide variety of non-profits. Given the urgent needs of the poor, should donations designed to relieve their suffering get preferential treatment? Could the IRS make this change, or would it need statutory authorization? Have any other countries made this type of change in their tax law?

For Further Research

The bibliography of assigned Otteston reading has several good sources.

G.A. Cohen, *If You're An Egalitarian, How Come You're So Rich?* (2000).

Liam Murphy, *Beneficence, Law, and Liberty: The Case of Required Rescue*, 89 *Geo. L.J.* 605, 653 (2001).

Frank Pasquale, *The Cost of Conscience: Quantifying Our Charitable Burden in an Era of Globalization.*

Thomas Scanlon, Preference, Choice, and Urgency, in *Utilitarianism and its Critics*.

Peter Singer, Famine, Affluence, and Morality, *Philosophy and Public Affairs* 1, 1972, pp. 229-243.

Peter Unger, *Living High and Letting Die: Our Illusion of Innocence* (1999).

Entry in Stanford Encyclopedia of Philosophy on The Social Minimum, available at <http://plato.stanford.edu/entries/social-minimum/>