PUBPOL 759: GENETICS AND BIOTECHNOLOGY POLICY
Mondays and Wednesdays, 10-11:30AM, Winter 2011
5240 Weill Hall; 3 credit course

Instructor:
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In one of the hottest areas of scientific and technological development today, genetics and biotechnology are raising a variety of difficult and controversial policy questions. Should the Americans with Disabilities Act be extended to include individuals with genetic conditions? Do the President and Congress have the power to decide whether or not stem cell research, an area of investigation that angers those who believe that life begins at conception, should be conducted? Should genes and stem cells be treated like any other type of intellectual property under the law? Do the World Trade Organization and other international governing bodies need to change their trade policies to accommodate the environmental, economic, health, and social concerns of countries with regard to genetically modified organisms? Who should make decisions about how this new science and technology should be built? How should these decisions be made? Not only do laws and regulatory frameworks need to be devised to promote this area of innovation and regulate the technologies that are developed, but the new powers that this science and technology allow—to peer into human genomes and predict future disease and behavior and manipulate the genomes of humans, plants, and animals, among others things—will require action from policymakers far beyond those who monitor the activities of the laboratory and the clinic.

The central question we will discuss in this course is: **how should we govern emerging science and technology?** Genetics and biotechnology provide an excellent area to explore this question, as they raise new political and policy issues as they challenge our understandings of our bodies, our health, our pasts, our futures, and even the organization of our political and social orders. We will answer the central question of the course by exploring the following:

- The major issues of controversy in genetics and biotechnology in the US and elsewhere;
- The major stakeholders in the politics of genetics and biotechnology in the US and elsewhere;
- The laws and regulatory frameworks in the US and elsewhere, that have been developed to deal with the new science and technology;
- The mechanisms for public participation in science and technology that have been devised in the US and elsewhere to deal with these issues; and
- Available tools to assess new scientific and technological developments and articulate policy positions to influence directions of research and innovation.

This course is designed for graduate students from public policy, public health, and the social, biological, and physical sciences (*there are no prerequisites*.) Topics include: regulation of genetic testing; commodification of genes, seeds, and living organisms through patents; international development and genetically modified organisms; the politics of race and pharmacogenetics; public hype and excitement over genetics and biotechnology; the creation of national DNA databanks; and genetics and biotechnology policy in comparative and international perspective. Students will be asked to actively participate in classroom discussions

and debates and prepare a final policy report (with multiple components) on a topic of their choice. This course is an elective in the STPP Program (For more information on the STPP Program, please see: http://stpp.fordschool.umich.edu).

Course policies:

1) **Course Requirements**:
   a) Regular class ***participation*** **(20%)**—i.e., doing the readings and being ready to talk about them. Because this is a discussion-intensive seminar, students are expected to keep up with weekly readings and come to class each week prepared with questions and topics for discussion. **Both attendance and participation are mandatory and will be important parts of your final grade.**

      i) Each of you will be asked to prepare at least three questions (based on the readings) to stimulate discussion for at least two classes. At least 2 students will be expected to prepare questions for each class session. In developing these questions, keep in mind the broader themes of the course; rather than focusing on details, the questions should focus on broad concepts that we'll be dealing with throughout the semester (e.g., values, governance, politics, democracy, technology assessment.) These questions should be posted on CTools (under *Forums*) by 7pm on the day before class.

      If you are unaccustomed to reading literature from the humanities and social sciences, I strongly encourage you to read *How to Read Books*, by Paul Edwards. (On CTools, under Resources.) It's short but very helpful.

   You should also make an effort to pay attention to current news in genetics and biotechnology. In order to do this, you can read popular journals such as Scientific American (www.scientificamerican.com). Check out The New York Times (http://www.nytimes.com) Science Times section, which runs every Tuesday. We'll spend the first few minutes of each class discussing relevant news.

   b) TERM PROJECT: POLICY REPORT. All assignments should be submitted on CTools, under the correct Assignment, by the deadline (papers will lose one grade—e.g., from A to A—for each day late.) Choose a court case or policy (either established or pending) that is (or is likely to become) controversial. You can choose a policy/court case from anywhere in the world, so long as it is related to genetics or biotechnology. Avoid cases we've discussed in class. Feel free to consider issues that we have not covered in the course, e.g., biological weapons, synthetic biology, human cloning, stem cell research.

      i) Policy Choice: Before January 20th (5pm), you should submit to me a proposal for your policy report. It should include a 1st and a 2nd choice. In this proposal, you should describe each choice and explain briefly what makes it controversial and interesting to you. You should also provide me with copies of the actual policies. You must also set up an appointment with me to discuss your proposal by January 28th (preferably before!)

      ii) Backgrounder (15%), Due February 3rd, 5pm: Each choice should be described in no more than three pages (single-spaced.) For each choice, you should address the following questions. *However, the paper should be structured as a backgrounder with a single coherent argument, not simply as responses to these questions.*

(1) Describe the pending policy and what makes it controversial. What institutions does it involve, and in what capacity? what are the issues of debate and controversy, who are the interest groups involved, and who might be a stakeholder but hasn't yet gotten involved?
(2) Who are the decisionmakers regarding this policy (and changes to it)? In other words, if it is pending, where is it under debate? If it is already enacted, then who might be interested in reevaluating it? In sum, who might be interested in receiving your assessment (this will help you tailor the next parts of the report).
(3) Provide some background on the policy. What is its history? Are there precursors to it?
(4) What is the need for this policy what is the problem it is designed to address? Why is it being considered?
(5) How is this policy designed to fulfill the public interest?
(6) Please submit a copy of the policy with your paper.

iii) Provisional policy assessment (15%), Due February 24th, 5pm: Provide the decisionmaker with an assessment (addressed to her/him/it) of the issues at stake in the policy debate. It should be no more than three page (single-spaced). *However, the paper should be structured as an assessment with a single coherent argument, not simply as responses to these questions.* This assessment should analyze:
(1) the evidence in play: What kind of evidence has been generated vis-à-vis this policy? Does it support or challenge this pending policy? What questions remain unanswered? Does the evidence cluster in a particular field (i.e., are there broad questions that are not being investigated, but that should be?)
(2) what values are being invoked in this particular policy, and how are they being balanced? Which values are being privileged?
(3) Are you satisfied by the way that evidence is used and values balanced to create this policy? In what ways is it adequate or inadequate to fulfill the public interest? What other kinds of evidence should be used, or values considered and balanced?
(4) In addition, you must provide an annotated bibliography at least 10 relevant sources that have been subject to some sort of peer review (e.g., articles, books, and policy reports—blog posts and media articles, for example, are not "reviewed" sources). This annotation should include a brief discussion of the relevance of each source to this part of your analysis. (This annotated bibliography does not count toward your page limit.)

iv) Governance assessment (15%), Due March 24th, 5pm: Provide the decisionmaker with another assessment (addressed to her/him/it) of the governance structures created by this policy. *However, the paper should be structured as an assessment with a single coherent argument, not simply as responses to these questions.* This governance assessment should be no more than three pages (single-spaced). Your analysis should answer the following questions:

(1) What kind of policy is this (e.g., regulatory, innovation-focused)?

(2) What kinds of governance structures and/or regulatory frameworks does it create?

(3) What makes these structures "democratic"?

(4) What are the opportunities for outside/public/stakeholder engagement?

(5) In what ways are these structures and opportunities adequate or inadequate to achieve the public interest?

(6) In addition, you must provide an annotated bibliography for at least 5 relevant sources (e.g., articles, books, policy reports). *Do not use the sources that you used for the policy assessment*. This annotation should include a brief discussion of the relevance of each source to this part of your analysis. (This annotated bibliography does not count toward your page limit.)

v) Policy report, including recommendation (25%), Due April 14th, 5pm: The final policy report should be addressed to the main decisionmaker. I encourage (and will be happy to work with) you to submit the report to the decisionmakers. It should include the following:

(1) **NEW:** An executive summary (no more than one page single-spaced) which briefly describes your backgrounder, assessments, and recommendations;

(2) A ***revised*** version of your backgrounder (no more than two pages, single-spaced), incorporating comments I have provided and additional insights you have gained through the project and the course;

(3) A ***revised*** version of the policy assessment (no more than three pages, single-spaced), incorporating comments I have provided and additional insights you have gained through the project and the course;

(4) A ***revised*** version of the governance assessment (no more than three pages, single-spaced), incorporating comments I have provided and additional insights you have gained through the project and the course;

(5) **NEW:** Policy conclusions/recommendations including justification and next steps (no more than three pages single-spaced). When you develop the recommendations, they should be justified in terms of their basis in evidence, values, AND their political feasibility.

c) Presentation of your policy recommendation (10%). Date TBD. At the end of the course, you will be expected to present your policy assessment and recommendation to the class in the form of a 10-minute presentation. The presentation should be targeted toward the main decisionmaker for your pending policy.

d) Op-ed (10%): Date TBD (72 hours after presentations). This should be a short opinion piece (no more than 500 words) summarizing the argument and recommendations from your policy report. Note that the op-ed will differ in important ways from the executive summary for your policy report; unlike an executive summary, an op-ed is usually written for a broad audience, and is linked explicitly to issues that are currently in the news and are controversial. They usually begin with some kind of "hook", to draw in the reader's attention. Overall, it should follow the customary style of op-eds, which we will discuss in class. I will encourage (and will be happy to work with) you to submit the op-ed for publication.

2) **Citing Sources and Plagiarism**: Plagiarism will be harshly penalized. For more information on what constitutes sourcing, see UM's plagiarism handout: http://www.lib.umich.edu/handouts/plagiar.pdf. For *all* papers, I expect proper sourcing and citation. I do not care which method (e.g., APA, MLA, etc.) you use, so long as you are consistent through the paper. In addition, *do not use Wikipedia as a direct source*. It is anonymously produced, with un-vetted contributors from all over the world, so the information you find there should *never* be automatically trusted as legitimate. That said, I understand that Wikipedia can be extremely useful to introduce you to a particular topic. My suggestion is that you use it to learn the basics about a particular subject, and then follow the links provided there (or the insights you gain) to find a more credible source.

3) **Laptops**: I will permit the use of laptops in the classroom, on an honor system. You can *only* use the laptop during class for PubPol 759-related activities. If I discover *anyone* doing non-759-related activities on the laptop during classtime, then that person will get a zero for class participation for the semester (i.e., a zero for 15% of your grade.) In addition, I will *ban all* laptops in the classroom for the remainder of the course.

4) **Syllabus:** While the syllabus is fairly stable (especially for the first few weeks), I reserve the right to make slight changes to it. For example, I may distribute a slightly altered syllabus shortly after the Drop/Add date for the course. I do not expect, however, the themes, assignments, or even the readings to change significantly. If I do make even a slight alteration, I will tell you at least a week in advance.

Course Readings:

Please do all the required readings before you come to class. There is a fair amount of reading, but the rest of the course workload isn't heavy, so the readings should be manageable. Class discussions won't work if you don't read. I have also spent considerable time ensuring that the readings are both informative and interesting, so hopefully you won't mind the work! The readings include books and articles as well as primary documents from participants in the politics of genetics and biotechnology.

CTools:
All of the readings including relevant excerpts from all books used in the course are posted on CTools.

January 5th: Genetics and Biotechnology Policy: Introduction to the Science and Politics
If you are unaccustomed to reading humanities and social science literature, I strongly encourage you to look at Paul Edwards' "How to Read Books" before the next class. For those new to genetic and biotechnological science, check out the NCBI's Science Primer: http://www.ncbi.nlm.nih.gov/About/primer/index.html. Both are on our CTools site, under Resources.

January 10th: Our Eugenic Past [redacted]
Stern, Alexandra (2005). *Eugenic Nation: Faults and Frontiers of Better Breeding in Modern America*. Berkeley, CA: University of California Press. Introduction and Chapter 3.
Buck v. Bell decision.

January 12th: Our Biotechnological Future? [redacted]

Fukuyama, Francis (2002). *Our Posthuman Future: Consequences of the Biotechnology Revolution*. New York: Picador. Chapters 10-12.

January 19th: The birth of biotechnology and the birth of an industry [redacted]

Schurman, Rachel and William A. Munro (2010). *Fighting for the Future of Food: Activists versus Agribusiness in the Struggle over Biotechnology.* Minneapolis, MN: University of Minnesota Press. Chapter 2.

Hughes, Sally Smith (2001). "Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980." *Isis*. 92(3): 541-575.

JANUARY 21ST: POLICY CHOICE DUE.

January 24th: Asilomar: classifying the Biotechnology Policy Problem and Considering Self-Regulation [redacted]

Schurman, Rachel and William A. Munro (2010). *Fighting for the Future of Food: Activists versus Agribusiness in the Struggle over Biotechnology.* Minneapolis, MN: University of Minnesota Press. Chapter 3.

Weiner, Charles (1999). "Is Self-Regulation Enough Today: Evaluating the Recombinant DNA Controversy." *Health Matrix*. 9: 289-302.

January 26th: Patenting Biotechnological Products in the US: The Debate Begins [redacted]

Diamond v. Chakrabarty decision.

People's Business Commission. 1980. Brief on Behalf of the People's Business Commission, Amicus Curiae,' In the Supreme Court of the United States, Sidney A. Diamond vs. Ananda M. Chakrabarty. No. 79-136.

American Patent Law Association. 1980. Brief on Behalf of the American Patent Law Association, Inc., Amicus Curiae,' In the Supreme Court of the United States, Sidney A. Diamond vs. Ananda M. Chakrabarty. No. 79-136.

January 31st: Patenting Biotechnological Products in Europe: Are there alternative frameworks? [redacted]

Parthasarathy, Shobita (forthcoming). "Whose Knowledge? What Values? The Comparative Politics of Patenting Life Forms in the United States and Europe." *Policy Sciences.*

Emmott, Steve (2001). "No Patents on Life: The Incredible Ten-Year Campaign against the European Patent Directive." In *Redesigning Life? The Worldwide Challenge to Genetic Engineering*. Edited by Brian Tokar. New York: Zed Books.

FOR REFERENCE: Article 53 of the European Biotech Patent Directive

February 2nd: Where does ethics fit in governance of science and technology? [redacted]

Wolfe, Audra. 2000. "Federal Policymaking for Biotechnology, Executive Branch, ELSI." eds. Thomas H. Murray and Maxwell J. Mehlman. *Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology*. pp. 234-240.

Adam Briggle. 2010. *A Rich Bioethics: Public Policy, Biotechnology, and the Kass Council*. Chapter 1.

FEBRUARY 3RD: BACKGROUNDER DUE.

February 7th: Is "bioethics" enough? [redacted]

Adam Briggle. 2010. *A Rich Bioethics: Public Policy, Biotechnology, and the Kass Council*. Chapters 5-7.

Steven Yearley. 2009. "The ethical landscape: identifying the right way to think about the ethical and societal aspects of synthetic biology research and products." *Journal of the Royal Society—Interface.* 6: S559-S564.

February 9th: Genetic testing—the BRCA case [redacted]

Parthasarathy, Shobita (2007). *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care*. Chapters 1 and 2.

February 14th: Should genes be patentable? [redacted]

AMP et al. vs. USPTO and Myriad Genetics. 2010. Appeal on behalf of Myriad Genetics. Read pages 1-62.

Then read either:

AMP et al. vs. USPTO and Myriad Genetics. 2010. Public Patent Foundation & ACLU Brief. Read pages 1-64.

AMP et al. vs. USPTO and Myriad Genetics. 2010. Obama Administration Brief. Read pages 1-37.

February 16th: Whole Genome Testing in the United States: regulating industry [redacted]

United States General Accountability Office. 2010. *Direct-To-Consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices*. Pages 1-33.

Secretary's Advisory Committee on Genetics, Health, and Society. 2010. *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services.* Executive Summary.

Investigate the websites of Navigenics and 23andMe. How do they differ? In particular, how does the experience of the user/customer compare with the two companies?

February 21st: Whole Genome Testing in Europe: industry regulation among public health care systems [redacted]

House of Lords Science and Technology Committee. 2009. *Genomic Medicine*. *Volume I: Report*.

European Society of Human Genetics. 2010. "Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes." *European Journal of Human Genetics*. 1-3.

RECOMMENDED:

PHG Foundation. 2010. *Genomic Medicine: An Independent Response to the House of Lords Science and Technology Committee Report*. Cambridge, UK.

German scientific associations. 2010. *Summary and Recommendations: Predictive Genetic Diagnostics as an Instrument of Disease Prevention.*

February 23rd: Gender and genetic technologies (1) [redacted]

King, D.S. 1999. "Preimplantation Genetic Diagnosis and the 'new' eugenics." *Journal of Medical Ethics*. 25: 176-182.

Nelson, Erin. 2006. "Comparative Perspectives: Regulating Preimplantation Genetic Diagnosis in Canada and the United Kingdom." *Fertility and Sterility*. 85(6): 1646-1652.

Sleeboom-Faulkner, Margaret Elizabeth. 2010. "Genetic testing, governance, and the family in the People's Republic of China." *Social Science & Medicine*. 1-8.

FEBRUARY 24TH: POLICY ASSESSMENT DUE.

March 7th: Where do gender concerns fit in discussions about governing genetics and biotechnology? [redacted]

Almeling, Rene. 2009. "Gender and the Value of Bodily Goods: Commodification in Egg and Sperm Donation." *Law and Contemporary Problems.* 72 (37-58).

Roberts, Dorothy. 2009. "Race, Gender, and Genetic Technologies: A New Reproductive Dystopia?" *Signs: Journal of Women in Culture and Society*. 34(4): 783-804.

Thompson, Charis (2007). "Why we should, in fact, pay for egg donation." *Regenerative Medicine*. 203-209.

SPRING BREAK!!!

March 9th: The politics of biobanks in the United States (1): creating frameworks to emphasize trust and transparency [redacted]

Corrigan, O and R Tutton. 2009. "Biobanks and the Challenges of Governance, Legitimacy and Benefit' in P. Atkinson, P Glasner and M Lock (eds), *Handbook of Genetics and Society: Mapping the New Genomic Era*, Routledge: London.

Eric Meslin. 2010. "The Value of Using Top-Down and Bottom-Up Approaches for Building Trust and Transparency in Biobanking." *Public Health Genomics*. 13: 207-214.

Tutton, Richard. 2007. "Banking Expectations: The Promises and Problems of Biobanks." *Personalized Medicine*. 4(4): 463-470.

Kuras, Amy. 2010. "Michigan Biotrust for Health Spots Opportunities in Blood Research." *Michigan's URC.*

March 14th: Pharmacogenomics: The Promise and the Pitfalls [redacted]

PriceWaterhouseCoopers (2005). *Personalized Medicine: The Emerging Pharmacogenomics Revolution.*

Kahn, Jonathan (2008). "Exploiting Race in Drug Development: BiDil's Interim Model of Pharmacogenomics." *Social Studies of Science*. 38(5): 737-758.

Ozdemir, Vural (2010). "Pharmacogenomics: Reflecting on the Old and New Social, Ethical and Policy Issues in Postgenomics Medicine." In M Schwab, WP Kaschka, and E Spina, eds. *Pharmacogenomics in Psychiatry.* Basel: Karger. pp. 12-29.

March 16th: Pharmacogenomics: Dealing with race in regulation [redacted]

Kahn, Jonathan (2005). "From Disparity to Difference: How Race-Specific Medicines May Undermine Policies to Address Inequalities in Health Care." *Southern California Interdisciplinary Law Journal.* Vol. 15: 105-129.

Winickoff, David E. and Osagie K. Obasogie. 2008. "Race-specific drugs: regulatory trends and public policy." *Trends in Pharmacological Sciences.* 29(6): 277-279.

March 21st: Forensic DNA Databanks (1): What policies are we developing? [redacted]

Krimsky, Sheldon and Tania Simoncelli (2010). *Genetic Justice: DNA Data Banks, Criminal Investigations, and Civil Liberties*. New York: Columbia University Press. Chapters 1 and 2, one additional chapter to be determined.

March 23rd: Forensic DNA Databanks (2): Are these policies appropriate? Are there alternatives? [redacted]

Krimsky, Sheldon and Tania Simoncelli (2010). *Genetic Justice: DNA Data Banks, Criminal Investigations, and Civil Liberties*. New York: Columbia University Press. Chapters 9 and 12, one additional chapter to be determined.

MARCH 24TH: GOVERNANCE ASSESSMENT DUE.

March 28th: Understanding the US approach to regulating biotechnology [redacted]

Pew Initiative on Food and Biotechnology (2001). "Guide to US Regulation of Genetically Modified Food and Agricultural Biotechnology Products."

Pew Initiative on Food and Biotechnology (2007). Lessons Learned: Food for Thought and Discussion.

Steinbrecher, Ricarda (2001). "Ecological Consequences of Genetic Engineering." In *Redesigning Life? The Worldwide Challenge to Genetic Engineering*. Edited by Brian Tokar. New York: Zed Books.

Back and forth with USDA on GM alfalfa etc.

March 30th: Understanding the European approach to regulating biotechnology [redacted]

Jasanoff, Sheila. 1997. "Product, process, or programme: three cultures and the regulation of biotechnology." In Martin Bauer, ed. *Resistance to New Technology: Nuclear Power, Information Technology, and Biotechnology.* New York: Cambridge University Press.

Jasanoff, Sheila. 2000. "Commentary: Between risk and precaution—reassessing the future of GM crops." *Journal of Risk Research*. 3(3): 277-282.

Abels, Gabriele (2005). "The Long and Winding Road from Asilomar to Brussels: Science, Politics, and the Public in Biotechnology Regulation." *Science as Culture*. 14(4): 339-353.

April 4th: How do international IP regimes shape biotechnology? [redacted]

Aoki, Keith (2008). *Seed Wars: Controversies and Cases on Plant Genetic Resources and Intellectual Property.* Durham, NC: Carolina Academic Press. Chapter 4.

Center for Food Safety (2005). "Monsanto vs. US Farmers."

Center for Food Safety (2007). "Monsanto vs. US Farmers: UPDATE."

April 6th: Transatlantic Wars over GMOs: Does the WTO matter? [redacted]

Winickoff, David, S. Jasanoff, L. Busch, R. Grove-White, B. Wynne (2005). "Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law," *Yale Journal of International Law* (forthcoming, Winter 2005).

Winickoff, David E. and Douglas M. Bushey. 2010. "Science and Power in Global Food Regulation: The Rise of the Codex Alimentarius." *Science, Technology, and Human Values*. 35(3): 356-381.

April 11th: Regulating Animal Cloning in the US and Europe [redacted]

Center for Food Safety. 2007. "Cloned Food: Coming to a Supermarket Near You?" *Food Safety Fact Sheet*.

Food and Drug Administration. 2008. Animal Cloning Risk Assessment. Executive Summary.

European Food Safety Authority. 2008. Scientific Opinion of the Scientific Committee. 767: 1-49.

April 13th: GMOs in the developing world: scourge or savior? [redacted]

Shiva, Vandana (2001). "Genetically Engineered 'Vitamin A Rice': A Blind Approach to Blindness Prevention. In *Redesigning Life? The Worldwide Challenge to Genetic Engineering*. Edited by Brian Tokar. New York: Zed Books.

USAID. "Agricultural Biotechnology for Development."

Glover, Dominic (2009). *Undying Promise: Agricultural Biotechnology's Pro-poor Narrative, Ten Years on*, STEPS Working Paper 15, Brighton: STEPS Centre.

APRIL 15TH: POLICY REPORT DUE.

April 18th: GMOs in the developing world: creating legitimate governance [redacted]

(2010) "FORUM: Bt brinjal in India: The nays outnumber the ayes." *International Journal for Rural Development*. 44(3): 34-36.

Carman, Judy (2010). "The inadequacy of GM Brinjal food safety studies." Letter.

Greenpeace India (2009). "You have the right to say no."

(2010). "Government proposes five-member biotech regulator." *Zeenews.com.* December 4.

SELECTED PAGES: Choudhary, Bhagirath and Kadambini Gaur (2009). *The Development and Regulation of Bt Brinjal in India*. pp. i-iii, x-xii, 50-58.

Jasanoff, Sheila (2002). "New Modernities: Reimagining Science, Technology and Development." *Environmental Values.* 11(3): 253-276.

FINAL PRESENTATIONS: DATE TBA

OP-ED DUE: 72 HOURS AFTER FINAL PRESENTATIONS