

SYLLABUS

**“Getting Medicine to Poor People”
Policy Workshop/591h**

**Woodrow Wilson School
Princeton University**

Fall 2003

Visiting Lecturers

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Monday 7 - 10 pm

Summary

We propose to divide the semester into the following segments:

- Weeks 1-2-3: Overview, case studies and foundational material; initial consideration of the seven key elements of response strategies of success.
- Weeks 4-5-6: Complete foundational material, and prepare for country visits by workshop participants; completion of seven elements of success strategies.
- Week 7 (mid-semester travel week): Country visits by workshop participants.
- Weeks 8-9-10: Intensive preparation, consideration of country-study chapters (drafts to be submitted at Week 10).
- Weeks 11-12: Integration of country-study conclusions into cross-cutting chapters on key elements of response strategies. Drafts returned at Week 12. Edited, refined during December-January. Drafts of cross-cutting analysis and conclusions submitted in Week 12.

Week 1: September 15

Topics

1. Overview of course:

- Review of syllabus and issues to be covered, proposed scope of subject matter, written work, class presentations, guest lecturers.
- Basic operational issues for workshop: selection of country case-studies; selection of “client” decision about whether to prepare papers and monograph.
- Course introduction.
 - Identify target countries, analyze health problem(s), solutions attempted.
 - Identify dimensions of problem; analyze and compile dimensions of response/solution:
 - Management, distribution and infrastructure
 - Medicine and technology
 - Law
 - Politics
 - Economics
 - Cultural and societal issues
 - Ethical issues
 - Prepare country reports and integrate into cross-cutting analysis of dimensions.

[60 mins]

2. Consideration of case studies 1 & 2.

[120 mins.]

Required reading:

Overview articles:

- Kremer, Michael. “Pharmaceuticals and the Developing World.” Journal of Economic Perspectives, Fall 2002, pp. 67-90.
- Trouiller, P., et. al. “Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure.” Lancet, Vol. 359, Iss 9324, (2002), pp. 2188-2194.
- Pecoul, B., et. al. “Access to Essential Drugs in Poor Countries – A Lost Battle?” JAMA- Journal of the American Medical Association, Vol. 281, Iss. 4 (1999), pp. 361-367.

Case studies 1 & 2:

- Guerin, P.J., et.al. “Visceral Leishmaniasis: Current Status of Control, Diagnosis, and Treatment, and a Proposed Research and Development Agenda.” Lancet, (August

2002), pp. 494-501. (Note: this article uses medical terminology that may be new to workshop participants. We found the following website helpful in understanding the medical terminology used: www.pharma-lexicon.com.)

- [Achar, S., et. al. "The Brazilian AIDS Model: A Study of Brazilian Efforts to Cope With AIDS." Georgetown University School of Business, April 2001.](#)

Week 2: September 22

Topics

1. Consideration of Case Studies 3-5.

[120 mins]

2. Foundational materials:

- Patents and Access to Medicines (law and economics components)
 - Theory behind patent protection
 - Experience in developed countries with drug patents
 - Experience in developing countries with drug patents

[60 mins]

Required reading:

Case studies:

- Smith, Mogha Kamal, "Has the World Learnt from HIV/AIDS? Another Silent Killer: Hepatitis C – Focus on Egypt." unpublished OxFam paper.
- Ahorlu, CK., et. al. "Malaria-related beliefs and behaviour in southern Ghana: Implications for Treatment, Prevention and Control." Tropical Medicine & International Health. Vol 2, Iss. 5 (1997) pp. 488-498.
- "Cost of School-based Drug Treatment in Tanzania: The Partnership for Child Development." Health Policy Plan (Dec. 1998) pp. 384-96.
- Rangan, S., et. al. "The Mumbai Experience in Building Field Level Partnerships for DOTS Implementation." Tuberculosis, Vol. 83, 1-3 (2003), pp. 165-172.

Foundational Materials:

- Miller & Davis, Intellectual Property: Patents, Trademarks and Copyright, Chapter 1 – The Foundations of Patent Protection (2000), pp. 4-20.
- Adelman, Rader, Thomas and Wegner, Patent Law, Cases and Materials, Chapter 1 – Introduction, pp. 1-8, 33-46.
- Grabowski, Henry, "Patents and New Product Development in the Pharmaceutical and Biotechnology Industries." Georgetown Public Policy Review, 8:2 (Spring 2003).

Additional reading:

Experience of developing countries and TRIPS Agreement patent provisions:

- Attaran, Amir. "The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law." Fordham Intellectual Property, Media, and Entertainment Law Journal, Spring 2002.

- Mashelkar, R.A. "Intellectual Property Rights and the Third World." [Current Science](#), Vol. 81, No. 8, October 25, 2001.
- Weissman, Robert. "A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries." [University of Pennsylvania Journal of International Economic Law](#), Winter 1996.

WTO provisions and health policy in developing countries:

- Bloche, M. Gregg. "WTO Deference to National Health Policy: Toward an Interpretive Principle." [Journal of International Economic Law](#), 2002.

Week 3: September 29

Topics

- Foundational Materials:
 - TRIPS and Patents - Overview (2 classes)
 - The basic obligations
 - TRIPS flexibilities
 - Doha Declaration
 - Debate over paragraph 6

[120 mins]

- Discussion of field study options.

[60 mins]

Required reading:

- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, Arts 1-8, 27-33, 65-66.
- "TRIPS and Pharmaceutical Patents," WTO Fact Sheet, April 2001.
- WTO-related key documents:
 - Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation, WTO Secretariat (July 11, 2002).
 - Declaration on the TRIPS Agreement and Public Health (Doha Declaration), para.6 (Nov. 14, 2001).
 - Draft Legal Language for General Council Decision (Nov. 9, 2002).
 - Possible Elements of a Paragraph 6 Mechanism, Note from the Chairman (Nov. 10, 2002).
 - Chairman's Note on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Dec. 16, 2002).
 - Letter to USTR Zoellick from Reps. Rangel, Levin, Matsui, McDermott and Payne (Dec. 20, 2002).
 - Letter to WTO Trade Ministers from USTR Zoellick (Dec. 27, 2002).
 - Letter to WTO Trade Ministers from EU Trade Commissioner Lamy (Jan 7, 2003).
 - Letter to USTR Zoellick from Reps. Rangel, Levin, Moran (Feb. 14, 2003).
- Sykes, Alan O. "TRIPS, Pharmaceuticals, Developing Countries, and the Doha 'Solution'." Chicago Journal of International Law, Spring 2002.

- t'Hoen, Ellen. "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha." [Chicago Journal of International Law](#), Spring 2002.

Written assignment:

- Workshop participants to prepare travel proposal.

Week 4: October 6

Topic

- Foundational materials.
 - Proposals on Patents and Access to Medicines (1 class)
 - Two tiered pricing
 - Lanjouw proposal (patents enforceable only in certain markets)
 - Make flexibilities in TRIPS more explicit
 - Drug giveaways

[180 mins]

Required reading:

- Lanjouw, Jean O. "Intellectual Property and the Availability of Pharmaceuticals in Poor Countries." Center for Global Development: WORKING PAPER NUMBER 5, April 2002.
- Scherer, F. M. and Watal, Jayashree. "Post-TRIPS Options for Access to Patented Medicines in Developing Nations." Journal of International Economic Law, 2002.
- Laing, RO., et. al. "Ten Recommendations to Improve Use of Medicines in Developing Countries." Health Policy and Planning, Vol. 16, Iss. 1 (2001), pp. 13-20.

Additional reading:

- Bibliography of country-specific reading for site visit, field trip.

Brazil

- Rosenberg, Tina. "Patent laws are malleable. Patients are educable. Drug companies are vincible. The world's AIDS crisis is solvable. Look at Brazil." The New York Times Magazine, January 28, 2001.

India

- Lanjouw, Jean O. "The Introduction of Pharmaceutical Product patents in India: 'Heartless Exploitation of the Poor and Suffering?'" NBER WORKING PAPER NO. 6366, Yale University and the NBER (~1998?: says title was in a report compiled by Indian Drug Manufacturers' Association (1996)).
- Tomar, David K. "A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India." Wisconsin International Law Journal, Fall 1999.

General Materials

- "Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries," [Campaign for Access to Essential Medicines](#). April 24, 2003, no author listed.

Week 5: October 13

Topic

- Complete consideration of foundational materials.

[180 mins]

Required reading:

- Additional foundational materials to be assigned.
- Country-specific reading for site visit, field trip.

Additional reading:

Week 6: October 20

Topics

- Discussion of site visit/field work plans of action.

Required reading:

- Country-specific reading for site visit, field trip.

Additional reading:

Week 7: October 27

Workshop participants travel to Case Study countries.

Week 8: November 3

Topics

- Evaluation of dimensions of response to public health problems. [Guest lecture likely.]

[180 mins]

Required reading:

- None anticipated.

Written work:

- Workshop participants focus on drafting country reports.

Additional reading:

NOTE: INSTRUCTORS PROPOSE THAT WORKSHOP PARTICIPANTS MAKE 1-2 DAY VISIT TO WASHINGTON DC BETWEEN BEGINNING OF NOVEMBER AND END OF SEMESTER FOR ADDITIONAL MEETINGS WITH, INTERVIEWS WITH (1) GOVERNMENT OFFICIALS (ADMINISTRATION, CONGRESS, AGENCIES), (2) PRIVATE SECTOR INDIVIDUALS, (3) LOBBYISTS AND ACTIVISTS, (4) FOREIGN EMBASSY OFFICIALS.

Week 9: November 10

Topic

- Evaluation of dimensions of response to public health problems. [Guest lecture likely.]

[180 mins]

Required reading:

- To be assigned as necessary.

Written work:

- Workshop participants focus on completing country reports.

Additional reading:

Week 10: November 17

Topic

1. Team reports and discussion of country reports.

[180 mins]

Written work:

- Workshop participants focus on completing country reports.

Required reading:

- To be assigned as necessary.

Additional reading:

Week 11: November 24

1. Team reports and discussion of country reports.

[180 mins]

Written work:

- Workshop participants focus on completing country reports.

Required reading:

- To be assigned as necessary.

Additional reading:

Week 12: December 1

Topic

Open

Required reading:

Additional reading:

Final Meeting: January --, 2004

Topic

Presentation and evaluation of report.

Required reading:

Additional reading: