The Pharmaceutical Policy Simulation

The Pharmaceutical Policy Simulation will be held on April 22. The simulation is intended to give you a chance to make use of many of the things we have discussed in class in an actual policy setting. For this exercise, students will be assigned to groups representing various players in the debate over patenting pharmaceuticals in developing countries. The policy simulation will include four such groups: representatives from the governments of the United States, South Africa, and India, as well as representatives from pharmaceutical companies. The back of this handout includes a brief summary of each group’s interests. Further information, including background on recent policy disputes in South Africa and Brazil, is available in the articles contained in the reading packet. You may also consult outside resources, such as the Internet, for other information that you may need.

The policy simulation takes the form of an international negotiation. Patent protection for medicines, as mandated by the World Trade Organization’s Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement of 1994, has created tensions between developing and developed countries. Developing countries are concerned about the high costs of medication, while developed countries are concerned with protecting the intellectual property rights of their firms. The moderator is convening this session with the hope that a dialogue among the affected parties will help to reach a compromise that all groups can be happy with.

Each group will be responsible for preparing a 2-3 page policy brief that outlines your goals. This policy brief is due at the beginning of class on April 17, so that each group will have a chance to review the briefs. You should prepare copies for each of the other groups, as well as one for the moderator of the simulation (that would be me). At the beginning of the simulation, each group will have five minutes in which to present their goals to the group. You may use this five minutes to raise particular concerns and to propose potential areas for negotiation. The remainder of the class will be left for negotiations among the groups.

When preparing for the simulation, please note that there will be no formal class meeting on April 15. You should make use of this time to meet as a group and prepare your presentations. Attendance at the simulation is important, as the simulation makes up 10% of your grade for the course. If you will be unable to attend, please let me know in advance. Unexcused absences will receive a zero for that portion of your grade.
Background Information on Participants of the 2003 Pharmaceutical Policy Simulation

**United States**: The U.S. government representative is concerned about protecting the interests of pharmaceutical companies, although political concerns make the issue more complicated. Protecting the intellectual property rights of American firms is an important policy goal. The US government is not only concerned about protecting the intellectual property rights of pharmaceutical companies, but also of setting precedents that could harm other innovative U.S. firms. For example, waiving intellectual property rights for pharmaceuticals in developing countries could open the door to other waivers in the future. However, political realities necessitate that the government also be sensitive to the concerns of American citizens that drug prices in the United States are often several times higher than prices abroad.

**South Africa**: The South African representative is concerned about providing South African citizens access to affordable medicine. In 1997, South Africa passed the Medicines and Related Substances Control Act, which gave the state more flexibility obtaining medicine. The act eliminated price markups and encouraged the use of generics. 39 pharmaceutical companies sued in 1998, claiming that it violates the constitutional right to patent protection. They dropped their suit in April of 2001. In addition to the above Act, South Africa has also considered the use of parallel imports (importing cheaper drugs from countries with weaker patent laws than South Africa) and compulsory licensing to help make medicine more affordable.

**India**: India does not currently recognize patents on medication, although it will soon need to do so in response to TRIPs. Generic manufacturers from India have successfully produced inexpensive generic drugs. For example, Bristol-Myers Squibb (BMS), an American firm, sells stavudine treatments for $3,400/year in the U.S., and for $55/year in Africa. Cipla, an Indian firm, can sell the same drug for $40/year. In addition, competition from generics forces American companies to sell drugs at lower prices in India. In the U.S., Pfizer sells the antibiotic Zithromax for $2.70/250 mg capsule. In India, Pfizer sells the same drug for $0.84. This is in part due to competition from Indian generics, which are available at prices ranging from $0.39 to $0.54 per pill. Patent protection for medicine will make it difficult for companies such as Cipla to continue their work producing generic drugs.

**The Pharmaceutical Research and Manufacturers of America (PhRMA)**: PhRMA is the industry trade group for the American pharmaceutical industry. Not surprisingly, their main interest is to protect their intellectual property rights. PhRMA maintains that drug companies spend billions on R&D. They claim that the average cost of bringing a new drug to market is $500 million. One problem is that not all projects are successful. PhRMA representatives say that for every 5,000 medicines tested, only 5 are tested in FDA clinical trials, and only one of these five is approved for use. They argue that pharmaceutical pricing must cover the cost of unsuccessful research. More information about this organization can be found at: