



Day of Dialogue

>>

on Public-Sector
Pricing of
Pharmaceutical
Products



Report of a meeting

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 Population Council



One Dag Hammarskjold Plaza
New York, New York 10017
www.popcouncil.org

The Population Council is an international, nonprofit, nongovernmental organization that seeks to improve the well-being and reproductive health of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources. The Council conducts biomedical, social science, and public health research and helps build research capacities in developing countries. Established in 1952, the Council is governed by an international board of trustees. Its New York headquarters supports a global network of regional and country offices.

Background and Introduction

For decades, patients, doctors, ethicists, and other interested parties have debated the economics of the pharmaceutical industry. What is the best way to get medications and related products to the people who need them, regardless of their ability to pay for these drugs? Can prices be lowered without jeopardizing basic research for new drugs? Are pharmaceutical company pricing practices monopolistic? What are the legal and ethical obligations related to drugs developed—partially or fully—with public funds?

The Population Council convened a daylong meeting of an eminent group of academics, scientists, representatives from the nonprofit sector, the pharmaceutical industry, foundations, and government donor agencies, and practicing lawyers and doctors—all of whom have some connection with pharmaceutical

products. The purpose of the Day of Dialogue was to explore ways of getting medicinal products—especially those invented and developed partially or fully using public funding—into the hands of the poor people of the world, wherever they live.

Economics of Pharmaceutical R&D and Pricing

The day opened with a presentation by F.M. Scherer, Emeritus Harvard University John F. Kennedy School of Government professor and current lecturer at Princeton's Woodrow Wilson School, on the economics of pharmaceutical research and development and product pricing.

Scherer's analysis of profits from pharmaceutical sales and investments in research and development (R&D) showed that when profits increase, so does R&D. This suggests that pharmaceutical companies engage in what economists call "virtuous rent-seeking." However, said Scherer, there is still cause for concern. Most R&D is for diseases prevalent in industrialized countries, not those in developing countries. And, while profits themselves drive R&D, the threat that a company will lose profits (via patent expiration, for example) also drives R&D. The percentage of prescriptions filled with generic versions of drugs whose patents have lapsed rose from 18 percent in 1980 to 48 percent in 2000. Another problem is a tendency to develop "me too" drugs—modified mimics of existing medications that are designed to

extend patent protection—rather than to develop drugs to treat diseases that have few or no treatments available.

Pharmaceutical R&D is a risky business, with 7 out of 10 new drug entities failing to recover their R&D costs. To fill otherwise depleted new product pipelines, the drug industry is relying to an increasing extent on publicly financed researchers at universities and nonprofit institutions, along with scientists at biotech firms, to conduct much of the preclinical research. Thus, drug companies' preclinical outlays, as a percentage of total discounted R&D outlays for new drugs, have declined, from 61 percent in the 1970s to 42 percent in the 1990s.

Scherer argued—and many participants agreed—that two types of entities are badly needed if drug prices are to

be held in check and if a greater variety of medicines are to be made available: first, companies that can manage clinical trials (which are costly and complicated) for universities, nonprofit organizations, and biotech firms; second, institutions—like Walter Reed Army Medical Center or the National Institutes of Health (NIH)—that can conduct drug screening, which is currently a bottleneck.

Participants stressed that a vital, undeveloped resource is the chemical libraries owned by large pharmaceutical companies; some of these molecules have been screened already. These libraries serve as the companies' "life savings." However, many companies may be interested in licensing these drugs for developing-country uses as a way of improving the image of an industry that has been embroiled in difficulties. Negotiation with individual companies would be required to gain access to these libraries. Public-private partnerships (PPPs), which team for-profit pharmaceutical companies with nonprofit entities, may be an appropriate construct to bridge this gap.

However, one big stumbling block in developing products to address developing-world diseases is the cost of clinical trials. Continuous, reliable funding is needed. The NIH previously provided this money, but is now doing so less often. Large drug companies have shown some willingness to pay for trials, but will not offer much until the PPP model is proven.

One participant noted that in some countries there is a "use it or lose it" patent policy. A change of this sort, or a variation thereof, in U.S. patent law might be helpful in bringing promising but shelved compounds into testing. Another participant pointed out that one of the costliest and most time-consuming aspects of bringing new drugs to market is the new drug application (NDA) process. She asked whether drug companies should pursue Food and Drug Administration (FDA) or European Medicines Agency (EMA) regulatory approval, or is approval outside the United States and the European Union acceptable?

Ethical Considerations in Public-Sector Pricing of Pharmaceutical Products

Arthur Caplan, chair of the University of Pennsylvania's department of Medical Ethics, explored the question, "Can ethics save pharma?" Caplan acknowledged that NIH funding is limited and will remain so for a while. He stated that those who seek innovation in drug availability and pricing will need to look to the pharmaceutical companies.

Big pharma may very well be interested in pairing with nonprofits to bring medicines to the developing world, but there are ethical issues that concern the industry. For example, the University of Pennsylvania has just launched a project on ethics and vaccines. People on the industry side have said that they think there may be too much risk in these ventures that is not handled by proper informed consent. Similarly, Caplan was asked by a pharmaceutical company about producing anti-malarial drugs. The company was concerned not with pricing, but with being accused of exploitatively experimenting in the developing world.

Potential partners of pharmaceutical companies—nonprofits that would like to bring low-cost medications to the developing world—must recognize and manage these and other ethical problems of the industry. The reputation of big pharma is bad in the U.S., worse in Europe, and worst in the developing world.

The poor image of the industry is the result of several factors. Recent books by Marcia Angell, Jerome P. Kassirer, Jerry Avorn, and others have demonized the industry. Drug prices are skyrocketing. And as some consumers have purchased cheaper Canadian drugs, the industry has launched a campaign, which Caplan termed

“ludicrous,” questioning the safety of Canadian drugs. He said the issue is the reliability of middlemen, not the safety of what is sold in Canadian drug stores.

Revelations in 2004 and 2005 about a link between antidepressants and suicide in children, harmful side effects caused by Vioxx and other cox-2 inhibitor drugs, and other disclosures have further damaged the reputation of the industry. A recent Harris Poll found that only 13 percent of Americans believe that the pharmaceutical industry is “generally honest and trustworthy.” Its reputation has plunged faster than those of the tobacco, oil, and managed care industries.

“Pharma is a very tricky partner to partner with,” said Caplan. “These ethics problems are going to get in the way, no matter how easy it is to get the products on the shelf.” He suggested several means of starting to dispell the demons that haunt the industry. Big pharma could undertake a public relations campaign and redouble its lobbying efforts. The most effective action, however, would be dramatic changes in pharmaceutical industry culture.

Drug companies could rededicate themselves to the scientific foundations of the industry. They could register all clinical trials. When testing a new drug to treat a condition for which there are already existing medications, they could conduct clinical trials that compare the new drug to the best available treatment rather than to a placebo.

The pharmaceutical industry could recommit itself to receiving ethical guidance—from data safety monitoring boards (DSMBs) and institutional review boards (IRBs), among others—on how it does research, marketing, and sales. (Drug companies should ensure that the composition of these groups reflects the public interest and public good.)

The industry could stop its most criticized marketing practices: direct-to-consumer (DTC) marketing and free samples to physicians and patients. Some large drug companies are already taking a step in this direction. On 13 June 2005, for instance, Bristol-Myers Squibb announced that it will refrain from direct-to-consumer advertising for a minimum of 12 months following the launch of any

new drug. It will also limit television advertising to “appropriate audiences at appropriate times.”

(One participant defended DTC marketing in some cases. The ParaGard® T 380A IUD is a great product, he stated, but IUDs have a bad reputation in the U.S. because of the Dalkon Shield tragedy. “How do we get the word out to the public that this is a good product?” asked the participant. DTC marketing is a promising approach.)

Finally, some kind of assessment and accountability should be built into the system. Johnson & Johnson, for example, has set up its management structure so that each drug in its portfolio has an “ethics manager.” This policy sprang from concerns surrounding opioid medicines, but it is a good way for any pharmaceutical company to ensure that greater attention is paid to ethical obligations surrounding all drug developments.

A participant inquired about the ethical obligations that pharmaceutical companies have to their shareholders. How can a company defend its decision to share its drug library, participate in a PPP, or contribute to other ventures that do not increase profits but may help poor people? Caplan replied that suits are possible but that helping the poor sometimes is essential to doing business in healthcare. He said companies in the healthcare sector have particular duties to advance the public good that do not encumber other industries. There is also a public relations value to these activities; they help to de-demonize the company and the industry. Finally, said Caplan, pharmaceutical companies that conduct research in developing countries are obligated to leave something behind, though not necessarily the drug. Companies, for example, can take steps to improve the local infrastructure. Local partners and citizens should be enlisted in determining company obligations, and these promises should be kept whether or not the product being tested is found to be effective.

There are different moral dynamics surrounding the testing of treatments for illnesses and the testing of products for healthy people that are meant to keep them healthy, such as microbicides, contraceptives, and vaccines.

For these types of products, there may be serious repercussions if a clinical trial causes a single death. This may come into play with tests of a rotavirus vaccine, for example, which may begin in Africa and Asia by the end of 2006. Bioethics has not done a good job in addressing this issue, contended Caplan.

Another participant pointed out that in addition to ethical issues related to the development of molecules and research in the field, drug companies need to invest more in product introduction and post-marketing surveillance. She asked whether there is a role for public-sector organizations to do that. Caplan agreed that bad post-marketing surveillance is an important ethical and policy problem. Registering trials should be a condition of working with journals, academic medical centers, universities, and governments. There should be consensus on ethical trial design, and all outcomes of all trials—not just those for drugs that are eventually approved or marketed—should be electronically searchable and accessible. Participants agreed that negative results from trials

have to be made available, whether published in a journal, announced in a news release, or publicized in other ways. Companies and public health both suffer in the long run if adverse findings are or seem to be hidden.

Another participant raised the issue of differential pricing. When research is based on public funds, he said, there should be a different pricing structure, even when the product is licensed to a for-profit pharmaceutical company. Others concurred that there are serious ethical issues related to the pricing of drugs. For example, human papillomavirus (HPV) vaccines—which prevent infection with the virus and, thus, also prevent cervical cancer—are likely to be blockbusters in developed countries. They are also desperately needed in the developing world, but may not be widely available there unless pricing barriers can be overcome. There is a tug of war going on in drug pricing, stated one participant. The pharmaceutical industry and its investors want the highest price possible and the public sector does not want to pay anything.

The Bayh-Dole Act and Its Effect on the Availability of Products Developed with U.S. Public Funding

Howard Bremer, J.D., a consultant in patent, licensing, and technology transfers, is a widely acknowledged expert on the Bayh-Dole Act, which governs the disposition of intellectual property resulting from research funded fully or partially by the U.S. government. He presented information about the Act and its effect on availability of products developed with U.S. public funding.

Bayh-Dole is codified in 35 U.S.C. § 200-212 and is implemented by 37 C.F.R. 401. Prior to the enactment of the legislation in 1980, the United States government retained intellectual property rights to any invention created as a result of government-funded research, regardless of the amount of government funding. This circumstance contributed to the loss of a technological advantage that the United States had previously held in the world. Because organizations did not own the rights to their inventions, they had no incentive to pursue them to commercializa-

tion. Government agencies that funded the research often did not pursue the commercialization of the products either. Accordingly, the number of patents issued each year on technology that was the direct result of federally supported research declined steadily for several years prior to the enactment of the law. As a result, products based on government-funded research never reached the public.

Bayh-Dole was designed specifically to address this roadblock. It allows universities, businesses, and nonprofits to retain rights to inventions they make or

develop with federal funding. In exchange, these organizations are required, among other things, to promote and attempt to commercialize such inventions. At the time the legislation was first proposed, there was some criticism of it. Some senators opposed it on the basis that “if the taxpayer funds the research, the taxpayer should own the ideas produced.” However, in practice this approach had led to a situation in which “the taxpayers were getting no benefit whatsoever,” according to Senator Birch Bayh, co-sponsor of the Act.

As a safeguard against noncompliance with the requirements of the Act, the government reserved “march-in rights.” Under very specific circumstances—for example, if the inventing organization does not actively promote and attempt to commercialize its invention or if action is needed to protect the health and safety of consumers—these march-in rights require the inventor to grant licenses for the invention to responsible applicants, on terms that are reasonable under the circumstances. If the inventor refuses such a request, the government is allowed to grant such licenses itself.

Some observers have argued that the Bayh-Dole Act states that inventions produced by government funding must be made available to the public at a “reasonable price.” However, this contention has been publicly refuted by Senators Bayh and Robert Dole, the co-sponsors of the legislation, and by experts in patent law, including Bremer. In 2004, the National Institutes of Health was petitioned to exercise march-in rights on the basis of the cost of a drug (Norvir, a protease inhibitor used to treat HIV infection). However, to date, no federal agency has exercised these rights.

One participant asked about the mechanism for ethical oversight now that universities and other research organizations stand to profit from their research. Bremer answered that most universities have established conflict-of-interest groups to alleviate perceived and real conflicts of interest. The Bayh-Dole Act is supposed to ensure that the public benefits from federally funded research. The law, says Bremer, is as viable today as it was when it

was enacted. The essence of the law is being emulated around the world: in Germany, Japan, and elsewhere.

Regarding the march-in rights, one participant puzzled over the government’s interpretation of the wording in Bayh-Dole. The law states that the government can march in when “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.” The participant asked rhetorically whether health needs are being reasonably satisfied when the price of a drug is raised by a factor of five (as happened with Norvir).

The government must be very careful, though, not to exercise march-in rights hastily, noted another participant. Innovation would be discouraged if organizations thought that patents would be taken away if they accepted government funds.

The exercise of march-in rights is not likely to be undertaken to correct drug prices, argued another participant. All administrations are pro-business and there is no benefit for businesses in controlling private-sector prices. We would like companies to do good and do well. Companies should make some money—though little—in the public sector. They should not have to give their products away. If there is no profit, what is a reasonable return for selling it in the public sector only? What is a reasonable negotiation?

In answer to this, one participant stated his belief that all licensing agreements should have some language guaranteeing public-sector pricing. There must be some agreement at the outset that the price will be cost, plus a small amount. Some other participants strongly disagreed that such an approach is feasible. One stated, “there are many factors that go into that decision and to assume that it can be set at the outset is perhaps naïve.” Another noted that to have the terms set at the outset might present some problems. “Confidentiality. Deals change. I would offer as a consideration that it’s good to have an idea of where you want to get but you have to understand the nature of business agreements.”

Another participant concurred, stating that such a simplistic approach carries the assumption that there is a one-to-one ratio between patent and product. In fact, treatments typically are based on a number of patents often held by a variety of organizations. Adjuvants, drug ingredients whose function is to facilitate or modify the action of the principal ingredient, are cross licensed, for example. Nonprofit institutions and universities do not usually have the rights to all the pieces, or even the primary piece of a therapy. “We are committed to providing low-cost drugs, but there are tons of constraints and our negotiating position is weak.”

One participant gave the example of his institution’s attempt to guarantee low prices for the public sector.

“We had in our collaborations reasonable pricing clauses but we found that they drove away potential collaborators,” he said. “It was more effective to drop that clause and try to facilitate tiered royalty rates, or to put in language for indigent access programs.”

In addition to providing drugs at low cost to people in the developing world, some participants argued forcefully for products to be made available to low-income people in the United States, noting that the poor in the U.S. are often overlooked. Other participants disagreed with this point of view, saying that it would be unfair for the wealthy U.S. to “throw their poor into the same basket” as poverty-stricken people in the developing world. A heated debate ensued and no consensus was reached.

Alternative Models of Differential Pricing for Medicines

The final segment of the day featured a videotape of Patricia M. Danzon, Professor of Health Care Systems and Insurance and Risk Management at the University of Pennsylvania Wharton School, presenting a talk on differential drug pricing through confidential rebates. Discussion of the video was moderated by Ernst R. Berndt, Professor of Applied Economics at the Massachusetts Institute of Technology Sloan School of Management and the National Bureau of Economic Research.

The question of differential pricing has emerged in two contexts. One is making existing drugs, particularly HIV/AIDS drugs, affordable and available in developing countries. Additionally, in the U.S. there have been concerns about “parallel trade,” the importation of drugs from countries where prices are low to countries where prices are high.

As mentioned earlier in the meeting, there is general agreement that the prices paid in poorer countries should be lower than the prices paid in richer countries (although there is no consensus about what the appropriate differentials are or how to implement them). However, there is less agreement as to what the differential pricing should be within and among industrial-

ized countries and where middle-income countries would fit. Danzon’s presentation focused on an innovative strategy for providing price differentials in various settings.

Companies’ ability to provide differential prices has been eroded by two phenomena. First, parallel trade and, second, extensive referencing by governments that regulate their prices based on prices in other countries. A study conducted by Danzon found that drug price differentials relative to per capita income were roughly appropriate within the industrialized or more affluent countries, but for the two middle-income countries in her study—Mexico and Chile—prices were out of line relative to per capita income.

MIRENA®: IMPROVING ACCESS TO A NEW PRODUCT

Discussion arose among participants about ways to make Mirena® more accessible to women in developing countries and to poor women in the United States.

Mirena is a levonorgestrel-releasing intrauterine system (IUS) that was developed by Population Council biomedical researchers with some government funding. Mirena is licensed to Schering AG and marketed in the United States by its subsidiary, Berlex Inc. The IUS is registered as a contraceptive in more than 100 countries and is available on all continents; it was approved for use in the United States in December 2000. It combines the best features of hormonal contraceptives and intrauterine devices (IUDs), delivering the progestin levonorgestrel directly to the uterus and providing highly effective contraception for up to five years. Mirena also reduces bleeding, including the excessive menstrual bleeding experienced by some women. One participant noted that this decrease in menstrual bleeding greatly reduces the risk of anemia, thus making Mirena doubly important in the developing world.

In its licensing agreements the Population Council arranged for the creation of two independent foundations (Berlex created the ARCH Foundation, operating solely in the U.S., and Schering created the

International Contraceptive Access [ICA] Foundation) to provide Mirena to low-income women. In 2005, the ARCH Foundation provided more than 12,000 Mirena units to poor women in the United States, and in 2006 it will provide 13,000. Schering AG has allocated approximately 150,000 Mirena units to the ICA Foundation through 2006; approximately 37,000 of these are at no charge and the remainder are at a very low price. The Foundation has transferred 3,800 units to public-sector agencies in Ecuador at no cost, where it has also sponsored insertion training and introductory studies. It is also in the process of sponsoring training and studies with and transferring free units to agencies in Nigeria, Kenya, and Indonesia.

One participant contended that the foundations are distributing only token numbers of Mirena and are not meeting the need that they are set up to provide. Another attendee countered that these foundations are “priming the pump.” Since Mirena is a relatively new product, the demand for it in the developing world is comparatively low. An information campaign is needed to raise its profile. Even in places where it is available, local-

level challenges may need to be addressed. Local agencies, for example, may not want to replace the Copper T 380A IUD (a popular nonhormonal contraceptive product that was also developed by the Population Council). The health systems themselves may have major problems with staffing, distribution capacity, and other issues. One attendee argued that these foundations provide a way to learn about the issues, but ultimately may not be the best mechanism for widespread distribution to poor women.

There was further debate about the cost to manufacture Mirena. Although the current cost to produce an individual unit of Mirena was not discussed, one attendee expressed his belief that it would be possible to manufacture the product for less than 10 dollars per unit. Another participant noted other costs associated with Mirena, among them provider training, preinsertion pregnancy tests, and insertion of the device. A third participant said that in frustration her foundation had considered developing a low-cost generic version of Mirena, but would prefer that Mirena itself could be made more readily available to poor women.

There are two currently discussed approaches to achieving differential pricing. One is a system of mandated discounts calculated as a percentage off some benchmark price (the EU Commission proposed a 75 percent discount off the average OECD price, restricted to drugs for treating certain diseases, such as HIV/AIDS, malaria, and tuberculosis). The other approach is a markup, perhaps 15 percent, based on marginal cost. But this raises the question of which marginal cost. What if additional production capacity is required, for example?

There is no consensus on which approach is economically appropriate and politically acceptable. And, even if governments could agree, there is no guarantee that companies would be willing to supply drugs at these prices. This is the case in part because price differentials would be visible and, thus, the threat of parallel trade and of external referencing would remain. Furthermore, having a set of regulated prices would establish certain benchmarks and discourage competition below those prices.

Danzon and her colleagues have proposed a system of achieving differential prices by permitting and encouraging confidential rebates. In this system, manufacturers would sell their products to wholesalers who would then distribute the drugs at a uniform price worldwide. The manufacturers would negotiate rebates with the final purchasers and these rebates would be paid conditional on purchases being made. This is the same model that is used in the U.S. in which HMO benefit managers negotiate different discounts with manufacturers and those rebates are made electronically. The manufacturers sell at a uniform price but price differentials exist because of these rebates.

With this system, price differences are not observable to other people. Thus, manufacturers are able to give lower prices to low-income countries, knowing that those prices will not spill over to the high-income countries. That ability to segment markets is assured because parallel trade and external referencing are not possible. This system is flexible across drugs and countries. It also encourages competition.

The primary objection to the idea of confidential rebates is that developing countries lack the bargaining power to negotiate them. However, Danzon suggested that third parties (e.g. nongovernmental organizations or governments) bargain on behalf of consumers in low-income countries and that part of this bargaining could include price-volume contracts. In this sort of system, if demand is really price sensitive, it is in the interest of manufacturers to give deep discounts, provided that those discounts do not then spill over to high-income markets.

A second objection to this sort of system is that if prices are not observable, then the system is open to corruption. This is particularly a concern where subsidies from various government agencies might be involved. This concern, however, can be addressed by arranging for audits by a third party and the discounted prices would not be observable to governments in other countries. This proposal applies equally well to price differ-

ences within the industrial world where there are real differences in income.

One participant commented that “loose lips” could sink the confidential rebate system by allowing for parallel trade. Other attendees suggested additional innovative approaches. They acknowledged that a challenge that needs to be addressed is that U.S. law stipulates that the government gets the lowest offered price. Genzyme circumvents this issue by either charging full price for its drugs or giving them away. Another participant proposed that pharmaceutical companies should have to decide in advance whether they are going to sell their products in the developed or the developing world. If they are going to sell in the developed countries, they would lose all patent protection in the developing countries, and this would allow for the manufacture of inexpensive, generic versions of the drugs. Another participant suggested that a way to encourage companies to work on treatments for tropical diseases would be for foundations or governments to make advance purchase commitments.

In its licensing agreements, the Population Council arranged for the creation of two foundations to provide its Mirena® intrauterine contraceptive system to low-income women. Under its Mirena contract, Berlex Inc., established the not-for-profit ARCH Foundation to assist low-income women in the United States who do not have insurance coverage for Mirena. Schering AG and its Finnish subsidiary, Schering Oy—the manufacturers of Mirena and its marketers outside the United States—have established the International Contraceptive Access (ICA) Foundation, which provides Mirena at reduced prices to selected public-sector organizations in order to help serve the needs of poor women and families, primarily in developing countries. The ICA Foundation is the first foundation for the specific purpose of supplying products at reduced prices internationally. Controversy over the availability and cost of Mirena in the developing world prompted a spirited debate among workshop participants.

Conclusion

It is possible to draw several conclusions from the day's discussion about the public-sector pricing of pharmaceutical products and the work that remains to be done. Among them:

1. Big pharmaceutical companies possess chemical libraries that may include compounds that could be useful. (Several organizations in attendance are beneficiaries of donations of rights to such compounds.)
2. Intermittent funding does not enable organizations to pursue drug development; new approaches and mechanisms are needed to assure consistent funding.
3. Clinical trials conducted in developing countries need to benefit the local population; something must be left behind, such as health infrastructure improvement, if not a drug.
4. The cost associated with taking a pharmaceutical product from the point at which a publicly funded organization would license it to a pharmaceutical company to its market introduction is many times larger than and far outweighs the cost and public funding preceding licensing.
5. Pharmaceuticals are not widgets. Companies in this industry have a greater societal responsibility than companies in other industries.
6. A major task is to find appropriate ways for donors to subsidize important pharmaceutical products for those unable to afford them.
7. License agreements from publicly supported research organizations can include reasonable pricing clauses, tiered royalty rates, and indigent access programs.
8. Funding of liability protection for not-for-profit research entities is a significant concern that needs to be addressed with donor organizations.
9. As is the case with funding for development, funding for commodity purchase must be consistent and long-term in order for pharmaceutical companies to commit the resources needed to supply the public sector; advance purchase commitments provide a mechanism.
10. Getting new products to the dock at a low price in a developing country does not solve the problem. Product introduction, adequate distribution channels, and infrastructure for delivery are also required. Attending to these issues requires time and money.

Participants

Sandra P. Arnold

Vice President, Corporate Affairs Division
Population Council

Carmen Barroso, Ph.D.

Regional Director
IPPF Western Hemisphere Region
International Planned Parenthood Federation

Ernst R. Berndt, Ph.D.

Louis B. Seley Professor of Applied Economics
Sloan School of Management
Massachusetts Institute of Technology

Howard W. Bremer, J.D.

Emeritus Patent Counsel
Wisconsin Alumni Research Foundation

Klaus Brill

Head of Portfolio Management & Strategy G&A
Schering AG

George F. Brown, MD, MPH

Director, Health Equity
The Rockefeller Foundation

Arthur Caplan, Ph.D.

Chair, Dept. of Medical Ethics
Center for Bioethics
University of Pennsylvania

Douglas S. Colvard, Ph.D.

Director, Extramural Research
CONRAD Program
Eastern Virginia Medical School

Charles S. Craig, J.D.

Chairman
Craig Capital Corporation

Vanessa E. Cullins, MD, MPH, MBA

Vice President-Medical Affairs
Planned Parenthood Federation of America

Peter Donaldson, Ph.D.

President
Population Council

Steven M. Ferguson, MBA

National Institutes of Health
Director, Division of Technology Development and Transfer
Office of Technology Transfer

Charles Gardner, Ph.D.

Associate Director, Health Equity
The Rockefeller Foundation

Victoria Hale, Ph.D.

Chief Executive Officer
Institute for OneWorldHealth

Peter Hall

Consultant, Sexual and Reproductive Health

Stephen Heartwell, Ph.D., MPH

Associate Professor and Director
University of Texas
Southwestern Medical Center of Dallas
Div. of Community Women's Health Care

Anrudh Jain, Ph.D.

Acting Vice President and Director
International Programs Division
Population Council

Elof Johansson, MD, Ph.D.

Vice President, Center for Biomedical Research
Population Council

Ulrich Koch, Ph.D.

Vice President, Corporate Business Development
Schering AG

Rita Leavell, MD, MBA

Project Director
Private Sector Partnerships One
Abt Associates

Ruth B. Merkatz, Ph.D., RN, FAAN

Project Director, Contraceptive Development
Population Council

Paul Model, Esq.

Attorney

Cristina Muñoz, MD

Clinical Assistant Professor of Obstetrics & Gynecology
Director, Ambulatory Clinical Practice
University of North Carolina

Zeda Rosenberg, Sc.D.

Chief Executive Officer
International Partnership for Microbicides

Allan Rosenfield, MD

Dean and DeLamar Professor of Public Health
Mailman School of Public Health
Columbia University

James Sailer, MPP

Senior Director, Corporate Affairs Division
Population Council

F. M. Scherer, MBA, Ph.D.

Aetna Professor Emeritus
John F. Kennedy School of Government
Harvard University

Sara Seims, Ph.D.

Director, Population Program
The William and Flora Hewlett Foundation

E. Jonathan Soderstrom, Ph.D.

Managing Director, Office of Cooperative Research
Yale University

J. Joseph Speidel, MD, MPH

Adjunct Professor, Dept. of Obstetrics,
Gynecology & Reproductive Sciences
Director for Communications, Development and
External Relations
UCSF Center for Reproductive Health Research and Policy

Jeffrey Spieler

Division Chief for Research
USAID

Tari Suprpto, Ph.D.

Technology Manager
Office of Technology Transfer
The Rockefeller University

John Townsend, Ph.D.

Program Director
FRONTIERS
Population Council

Ilari Vainio

Director, Business Development & Public Markets
Schering Oy

Patricia Vaughan, Esq.

General Counsel
Population Council

George M. Young, MBA

Senior Business Analyst
Population Council

Recommended Reading

These readings were made available to participants in advance of the meeting to inform and enhance the day's discussion.

- Arno, Peter and Michael Davis. 2001. "Why don't we enforce existing drug price controls? The unrecognized and unenforced reasonable pricing requirements imposed upon patents deriving in whole or in part from federally funded research," *Tulane Law Review* 75: 631–693.
- Arno, Peter and Michael Davis. 2002. "Paying twice for the same drugs," Op-Ed in *Washington Post*, 27 March, page A21.
- Arrow, Kenneth J., Hellen Gelband, and Dean T. Jamison. 2005. "Making antimalarial agents available in Africa," *New England Journal of Medicine* 353: 333–335.
- Bayh, Birch and Bob Dole. 2002. "Our law helps patients get new drugs sooner," Letter to the Editor of the *Washington Post*, 11 April, page A28.
- Bremer, Howard W. 1998. "University technology transfer: Evolution and revolution," Council on Governmental Relations: 50th Anniversary Journal of Papers.
- Gates, Bill. 2005. Prepared remarks to the 2005 World Health Assembly, Geneva Switzerland, 16 May.
- Gladwell, Malcolm. 2004. "High prices: How to think about prescription drugs," *The New Yorker*, 25 October.
- Gordon, Mark L. 2004. "University controlled or owned technology: The state of commercialization and recommendations," *les Nouvelles: Journal of the Licensing Executives Society*, December, pp. 152–163.
- Hale, Victoria. 2005. "Private-sector mercy," *The New York Times*, 19 August.
- "Increasing people's access to essential medicines in developing countries: A framework for good practice in the pharmaceutical industry." March 2005. A UK Government policy paper, publication of the UK Department for International Development.
- Jack, Andrew. 2005. "An antidote to neglected diseases," *The Financial Times*, 16 September.
- Oehler, Joachim. 2004. "The role of milestones in licensing deals to assure access to health products in developing countries," *IP Strategy Today* 10: 59–70.
- Salicrup, Luis A., Rachele F. Harris, and Mark L. Rohrbaugh. 2005. "Partnerships in technology transfer: An innovative program to move biomedical and health technologies from the laboratory to worldwide application," *IP Strategy Today* 12: 1–12.
- Scherer, F.M. 2004. "The pharmaceutical industry: Prices and progress," *New England Journal of Medicine* 351: 927–932.
- Scherer, F.M. 2005. Comment on the Medical Research and Development Treaty.
- Stix, Gary. 2004. "Making drugs, not profits: A married couple attacks neglected diseases of the developing world," *Scientific American*, 26 April.
- "The new landscape of neglected disease drug development." 2005. Publication of the Pharmaceutical R&D Policy Project.
- U.S. Government Printing Office. 1980. "Patent and Trademark Law Amendments Act (Bayh-Dole Act)," 35 U.S.C. 200-212. Washington, D.C.: U.S. Government Printing Office.
- Wagner, Judith L. and Elizabeth McCarthy. 2004. "International differences in drug prices," *Annual Review of Public Health* 25: 475–495.

STAFF

Writer: Gina Duclayan

Designer: Y. Christina Tse

Editor: Sandra P. Arnold

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One Dag Hammarskjold Plaza
New York, New York 10017
www.popcouncil.org