

Funding Pharmaceutical Research While Reducing the Cost of Drugs: Separating R&D from Manufacture and Sale*

Speaker: James Love

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The speaker asserted that the way we fund pharmaceutical research and development (R&D) today is seriously flawed. The high cost of drugs is a direct consequence of an economic model that requires the individual patient's payment to cover the cost of manufacturing a medication, its marketing, and its R&D. He argued that this results in a pharmaceutical market that is economically inefficient, morally repugnant, and politically corrupt. In countries like the United States that lack a universal health care program with controls on drug pricing, the high cost of pharmaceuticals leaves many unable to afford the basic medicines needed to sustain life. Love's solution goes to the heart of the way R&D is financed, leading to a restructuring of the pharmaceutical market, lower prices, more equitable trade, and, most importantly, facilitating access to medications for all who need them.

The Current Pharmaceutical Market: High Prices and limited Access to Drugs

Currently, with R and D costs paid by the drug's developer, this company charges high prices to cover these costs. Competitors, who might want to manufacture generic copies, could sell them at much lower prices. To avoid this unfair situation, the U.S. government grants drug companies a 20-year patent-based monopoly, allowing them to protect their R&D investment while setting the price at any level they choose.

A similar policy has been adopted internationally as the World Trade Organization (WTO) has implemented the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. This requires that member countries issue 20-year patents in all fields of technology as a means of providing incentives for R&D. Regional and bilateral trade agreements have added to this protection for intel-

lectual property, limiting the alternative of compulsory licensing which, until now, has enabled governments to bypass patent rights and broaden distribution, in exchange for compensation to the drug companies. Love declared that the more widespread these TRIPS agreements become, the more prices for the consumer will go up, and the greater will be the worldwide problem of lack of access to medications.

The TRIPS system rewards the discovery of a new drug with a monopoly on the market and no limits on pricing. As Love illustrated in his talk, the business goal of maximizing profit – as opposed to maximization of health benefit – together with this market monopoly leads prices to skyrocket and locks out patients who cannot afford such luxuries as medicine. Research itself is discouraged, since products that might not be profitable will not be sought or discovered (CIPR 2002; Royal Society 2003). We get too much investment in copycat products and too little in innovative medications, vaccines, and treatments for diseases that primarily afflict the poor. Love pointed out that, of nearly 1400 new drugs approved worldwide between 1975 and 1999, only 16 were developed for the tropical diseases and tuberculosis that account for 11% of the global disease burden (Love 2003).

This economic model skews the budgets of pharmaceutical companies, with only about 10% of drug revenues actually going toward R&D, and less than a fifth of that – just 2% of the total – going toward truly innovative products. The rest of the R&D funds are spent on existing products or “me too” drugs that are not significantly better than existing ones (Angell 2004, Love 2003). In fact, only about 25% of new drug approvals are rated by the Food and Drug Administration to have any therapeutic benefit over existing treatments (NIH-CM 2002).

Clearly, as Love showed, the current method of
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finance is defective. Reliance on R&D performed by for-profit firms driven by the potential for a 20-year patent-protected payoff leads to the inhibition of research, limited access to drugs for many low-income populations, and investment in drugs that have the potential for profit but not necessarily for maximum therapeutic benefit. One consequence has been conflicts over the price of anti-leukemia drugs in South Korea, fluconazole in Thailand, and AIDS drugs in South Africa.

Separating the Funding of Drug R&D from Manufacture and Sales

Love argued that the solution is to separate the funding of R&D from the conduct of drug manufacture and marketing. This would allow drastic reductions in the price of drugs while permitting better choices of R&D objectives. The focus of drug R&D would shift from the protection of intellectual property to where it should be, the provision of new health-promoting pharmaceuticals. And drugs could be sold at prices near their actual manufacturing or marginal cost, usually a small fraction of their current price.

Practically, Love continued, this translates into new national policies supported by trade agreements that would encourage participating countries to promote R&D in both their private and public sectors. Trade agreements are needed because pharmaceutical companies are multinational entities that operate in many countries, with drug R&D and manufacture taking place across the globe. Within such agreements, each individual country would devise its own mechanism for financing R&D. Examples Love provided included direct public sector funding, prize models in which government rewards innovative development with financial compensation, intermediate non-manufacturing companies competing for research funding, or a combination of such models.

Central to this approach, Love argued, is the openness of R&D and the sharing of scientific data and technology. Existing examples of such cooperation include international projects like the Human

Genome Project, the SNP Consortium, BioSPICE, and the Open Bioinformatics Foundation, among many that publicly share information contributing to cooperative discoveries and the elimination of duplicative research.

Love's proposal does not ignore the protection of intellectual property, the prime concern of the present system. Rather, the rights of discoverers would be protected through new mechanisms. These might include patent buyouts or lump sum payments by government for a public license. The goal would be to reward the development of new products but not restrict their availability or raise their price.

Love concluded that the current way pharmaceutical research and development is conducted prevents broad access to necessary drugs and limits the potential for innovative research. It should be the responsibility of governments to enable, through appropriate national programs and trade agreements, access to affordable efficacious drugs while supporting broad R&D programs. These new models for developing and marketing drugs are not only morally necessary: they will be highly beneficial to society as a whole. It is time to do better in making the advances of pharmaceutical science available to the world's people in an affordable manner.

For more information, see the Consumer Project on Technology website, www.cptech.org.

** This report was prepared and edited by members of the NY Metro Chapter of PNHP, including Gary Schwartz, Albert Einstein College of Medicine, Class of 2006, Einstein Student Chapter Coordinator, PNHP, and is the sole responsibility of the Chapter.*

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