

The de-linkage of R&D costs and drug prices through the Prize Fund for HIV/AIDS will cost less, expand access, accelerate and improve innovation, and replace an incentive system that is expensive, inefficient and unsustainable

Testimony of James Packard Love

Hearing before the United States Senate, Committee on Health, Education, Labor and Pensions, Subcommittee on Primary Health and Agency

on

The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative

**May 15, 2012
Washington, DC**

My name is James Packard Love. I am pleased to testify today in support of S.1138, the Prize Fund for HIV/AIDS.

I am the Director of Knowledge Ecology International (KEI), a non-profit organization that is concerned with the management of knowledge and human rights. A significant part of our work focuses on the development of and access to new medicine technologies, including in particular new medicines, vaccines and diagnostic devices. KEI was created as a new corporation in 2006 to carry out the work done earlier by the Consumer Project on Technology (CPTech) and the Taxpayer Assets Project (TAP), two projects of the Center for the Study for Responsive Law (CSRL). Including the work for KEI, CPTech and TAP, I have worked extensively on issues relating to medical innovation since 1991, when I was asked to review an agreement between Bristol Myers Squibb (BMS) and the National Institutes of Health (NIH) for the commercial development and sale of Taxol, a drug for cancer invented by the NIH.¹ Since 1991, I have been involved in more than two decades of research and analysis into various aspects of the drug, vaccine and medical device industries, including, for example, the economics of discovery and commercial development, the efficacy, efficiency and fairness of various incentives mechanisms to stimulate investments in private sector R&D, the pricing of medicines and vaccines (including products developed with government support), the setting of research and development priorities, intellectual property right policies, and new approaches to supporting research and development, including those that encourage more open systems of innovation. A list of several publications on these topics are available at <http://keionline.org/jamie>.

Since 1994, I have worked on both domestic and international aspects of these issues. Since 2000, I have been a consultant, advisor or expert for the World Bank, the United National Program on Development (UNDP), the World Health Organization (WHO), UNITAID, the UN Human Rights Council, the World Intellectual Property Organization (WIPO), the Global Fund

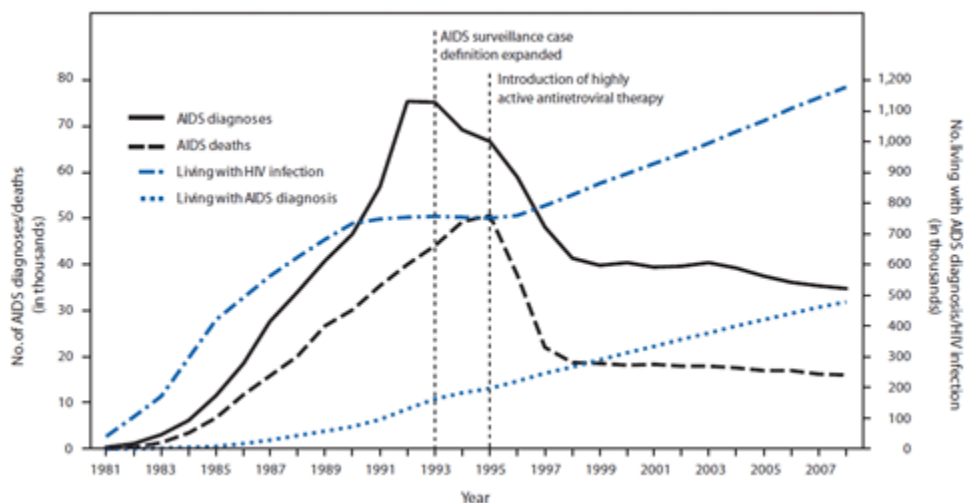
¹ Subcommittee on Regulation, Business Opportunities, and Energy, of the Committee on Small Business, U.S. House of Representatives. *Exclusive Agreements between Federal Agencies and Bristol-Myers Squibb Co. for Drug Development: Is the Public Interest Protected?* July 29, 1991. Hearing Record. Serial No. 102-35.

for HIV/AIDS, Tuberculosis and Malaria (TGF) , regional intergovernmental bodies including the European Parliament, the European Patent Office (EPO), the African Union (AU), and several national governments and NGOs. I am the U.S. Co-chair of the Trans Atlantic Consumer Dialogue (TACD) Policy Committee on Intellectual Property, the Chairman of Essential Inventions, the Chairman of the Union for the Public Domain, and a member of a number of committees, and task forces, such as the 2.3(c) Committee (to implement paragraph 2.3c of the WHO Global Strategy on Public Health, Innovation and Intellectual Property).

The current and looming crisis in the market for new drugs for HIV/AIDS

My earliest work on treatments for HIV/AIDS drugs was focused on the pricing of AIDS drugs in the United States, including cases where the United States government had played an important role in funding the research and development. One insight was that the pricing of drugs invented with extensive public support was at least as aggressive as the pricing of products developed without such support, and indeed, often the government supported inventions were more expensive. Another insight was that the pricing of a product had almost no relationship to actual private sector outlays on research and development for that product, or to its costs of manufacturing. In the absence of competition, typically due to some type of government enforced monopoly such as the exclusive rights associated with patents, orphan drug designations, pediatric testing, or regulatory test data reliance, prices were set according to the seller's perception of the patient's willingness to pay. For treatments for AIDS, a potentially lethal disease, the better the drug, the higher the price, moderated only by the unwillingness of insurance companies, employers and governments to reimburse high priced drugs. In the early days of the HIV/AIDS pandemic, the combination of a politically influential patient community and a relatively small number of persons receiving treatment made it possible for drug companies to be very aggressive in terms of prices, as the costs of the drugs were absorbed by the larger population. In the United States, after 1996, when effective three drug antiretroviral therapy (ART) was first introduced, the number of AIDS related deaths plummeted. With fewer deaths and but thousands of new infections each year, there was a steady rise in the number of persons living with HIV, which today the Centers for Disease Control and Prevention (CDC) estimates to be more than 1.2 million persons in the United States.

FIGURE. Estimated number of AIDS diagnoses and deaths and estimated number of persons living with AIDS diagnosis* and living with diagnosed or undiagnosed HIV infection† among persons aged ≥13 years --- United States, 1981—2008.
Source: HIV Surveillance --- United States, 1981--2008, Morbidity and Mortality Weekly Report (MMWR), June 3, 2011 / 60(21);689-693



At present, CDC estimates there are roughly 50 thousand new infections per year, many of them relatively young, and 16 thousand AIDS related deaths. Depending upon assumptions regarding deaths from other causes, the number of persons living with HIV continues to grow by several thousand per year.

The Cost of Antiretroviral Drugs

Since 1987, the FDA has approved 25 new molecular entities in six classes of antiretroviral drugs, or roughly one new product per year. These drugs are normally taken in 3 or 4 drug combinations, according to the relevant treatment guidelines. Over time, patients may develop resistance or suffer from the side effects of a particular regime. Given the advantages of some of the newer drugs, and the continued monitoring of treatment, the standard of care is periodically revised. Some of the older AIDS drugs have gone off patent, and are available from generic suppliers, but as the standard of care has evolved, there is a focus on the newer drugs that are still protected by patents or other intellectual property rights.

For US consumers, the cost of commonly used AIDS drug regimes has increased significantly. In 2000, the combination of d4T+3TC+NVP was available at just over \$10,000 per year. Today the four recommended regimes for treatment naive patients range have an average wholesale price of \$25 to \$35 thousand per year, and “salvage” regimes for patients that have developed resistance to several drugs are often far more expensive.

Table 1: Average Wholesale Prices (March 2012), selected Antiretroviral Therapy regimes

Products	Brand names	Monthly	Annual
<i>Preferred, treatment naive patients</i>			
EFV/TDF/FTC	Atripla	\$2,080.97	\$24,971.64
ATV/r + TDF/FTC	Reyataz, Norvir(100), Truvada	\$2,865.17	\$34,382.04
DRV/r + TDF/FTC	Prezista, Norvir(100x2), Truvada	\$3,238.85	\$38,866.20
RAL + TDF/FTC	Isentress, Truvada	\$2,562.75	\$30,753.00
LPV/r + ZDV/3TC	Kaletra + Combivir	\$1,906.48	\$22,877.76
<i>Alternative Regimes</i>			
EFV + ABC/3TC	Sustiva, Epzicom	\$1,808.42	\$21,701.04
RPV/TDF/FTC	Complera	\$2,195.83	\$26,349.96
RPV + ABC/3TC	Isentress, Epizcom	\$2,290.20	\$27,482.40
ATV/r +ABC/3TC	Reyataz, Norvir(100), Epzicom	\$2,603.73	\$31,244.76
DRV/r + ABC/3TC	Prezista, Norvir(100x2), Epzicom	\$2,966.30	\$35,595.60
FPV/r + TDF/FTC	Lexiva (700x2), Norvir(100x2), Truvada	\$2,914.99	\$34,979.88
FPV + TDF/FTC	Lexiva(700x4), Truvada	\$3,204.13	\$38,449.56
LPV/r + TDF/FTC	Kaletra + Truvada	\$2,262.79	\$27,153.48
TPV/r + TDF/FTC	Aptivus, Norvir(100x4), Truvada	\$3,959.99	\$47,519.88
T20 + TPV/r + TDF/FTC	Fuzeon, Aptivus, Norvir(100x4), Truvada	\$7,208.71	\$86,504.52

The AWP of the products bears no relationship to the costs of manufacturing. The range of prices for products varies considerably, particular when expressed as the price per formulated active pharmaceutical ingredient (API). (See Table 2)

In the United States, the leading HIV drug Atripla (TDF/FTC/EFV) sells for more than \$57 thousand dollars per formulated kilo of active pharmaceutical ingredient (API). Pfizer and GSK's sell Maraviroc in both 150 and 300 mg tables, for the same price. Depending upon the dose, the price ranges from \$63 thousand to \$126 thousand per kilo of API. J&J's drug rilpivirine is sold for \$9,653 per year in the United States, or \$1.058 million per formulated kilo of API. In contrast, outside of the United States, the best prices for the most commonly used generic AIDS drugs are between \$212 and a \$1,101 per kilo of API.² If rilpivirine, a drug with a daily dose of only 25 mg per day, was available from competitive suppliers as a generic drug in large quantities, it would likely be available for less than \$10 per year from manufacturers.

2 Prices for generic drugs outside the United States depend upon economies of scale and the number of generic suppliers. Because of the complicated intellectual property rights for AIDS drugs, the number of patients who were treatment naïve, and the severe resource constraints in most developing countries with significant incidence of HIV infections, only a handful of the current set of antiretroviral drugs are manufactured in large quantities in developing countries, and all of these these products now available at less than one thousand dollars per kilo of API. If the US was to adopt the HIV/Prize Fund legislation, the number of affordable generic antiretroviral drugs would be expanded, and include more of the products registered by the FDA since 2005, the year the WTO required patents be granted for pharmaceutical products.

With efficient procurement and distribution, it would not be difficult to obtain generic supplies of many AIDS drugs from manufacturers for one to three percent of the US prices, or less than \$1,000 per formulated API.

Table 2: US Average Wholesale Price Compared to MSF best global generic price, annual and per kilo of API

<i>Product</i>	<i>Daily dose in mg</i>	<i>US Average Wholesale Price, March 2012</i>		<i>MSF UTW, best global generic price, July 2011</i>		<i>Percent of US AWP</i>
		<i>Annual</i>	<i>Per Kilo API</i>	<i>Annual</i>	<i>Per Kilo API</i>	
Single drugs						
Abacavir (ABC)	300 x 2	\$7,698	\$35,151	\$195	\$890	2.5%
Atazanavir (ATV)	300	\$13,981	\$127,684	\$250	\$2,283	1.8%
Darunavir (DRV)	600 x 2	\$14,762	\$33,704			
Efavirenz (EFV)	600	\$8,274	\$37,782	\$52	\$237	.6%
Efuviritide (T20)	90 x 2	\$38,985	\$593,374			
Emtricitabine (FTC)	200	\$6,052	\$82,910	\$61	\$836	1%
Etravirine (ETV)	100 x 4	\$11,744	\$80,436			
Fosamprenavir (FPV)	700 x 2	\$10,876	\$21,284			
Maraviroc (MVC)	150 x 2	\$13,778	\$125,826			
Maraviroc (MVC)	300 x 2	\$13,778	\$62,913			
Nevirapine (NVP)	200 x 2	\$8,677	\$59,431	\$31	\$212	.4%
Raltegravir (RAL)	400 x 2	\$14,056	\$48,136			
Rilpivirine	25	\$9,653	\$1,057,815			
Ritonavir (r)	100	\$3,703	\$101,458	\$183	\$2,507	2.5%
Tenofovir (TDF)	300	\$10,479	\$95,702	\$83	\$758	.8%
Tipranavir (TPV)	250 x 4	\$16,022	\$43,895			
Fixed dose combinations						
ABC/3TC	600/300	\$13,427	\$40,873	\$112	\$341	.8%
AZT/3TC	300/150 x 2	\$12,421	\$37,813	\$101	\$307	.8%
Lopinavir/ritonavir (LPV/r)	200/50 x 4	\$10,456	\$28,647	\$402	\$1,101	.3.8%
Rilpivirine/TDF/FTC	25/300/200	\$9,653	\$50,372			
TDF/FTC	300/200	\$16,697	\$91,493	\$116	\$636	.7%
TDF/FTC/EFV	300/300/600	\$24,972	\$57,013	\$219	\$500	.9%

Lack of Price Competition in US Market

Even with the extensive intellectual property rights protection in the United States for antiretroviral drugs, one might expect more price competition, particular for similar drugs within the same therapeutic class, available from eight different manufacturers. The US FDA has approved eight Nucleoside Reverse Transcriptase Inhibitors (NRTIs), eleven protease inhibitors (PIs), five Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs), and drugs in three new

classes of drugs (fusion inhibitors, entry inhibitors – CCR5 co-receptor antagonists, and HIV integrase strand transfer inhibitors). Even though these products have medical differences, there is enough similarity and substitutability to expect some price competition, but prices are still quite high, and have increased over time, despite the growth of registered products and the expiration of patents for some older products. There are several explanations for the paucity of price competition among manufacturers, including the fact that end users are often insulated from price differences by third party reimbursement agents, and because the medical differences can be important for some patients, and it is unwise to frequently switch drug regimes, among and between classes of antiretroviral drugs. However, another reason is that there is a great deal of collusion between drug manufactures, both for AIDS drugs and treatments for other diseases. BMS, Gilead, Merck, Pfizer, J&J, GSK and Abbott all cross license products from each other. Pfizer and GSK recently combined their HIV products to be managed by ViiV Healthcare. For several products, global rights for the same drug are split among companies in different parts of the world. For example, BMS sells EFV in the US as a standalone product under the brand name Sustiva, and combines EVF with two other drugs in Atripla, a combination product sold by Gilead. Merck sells EFV outside of the United States under the brand name Stocrin. Roche sells Viracept in Europe, and ViiV sells the drug elsewhere, including in the United States. The fixed dose combination Complera includes rilpivirine, a J&J product, with the Gilead drugs TDF and FTC. GSK and Gilead have an agreement to commercialize TDF for chronic hepatitis B in several Asian countries. Abbott, Pfizer, GSK and Merck recently announced various collaborations to develop diagnostic tests for cancer. These are just a few of the cross licensing and marketing agreements between the companies that “compete” in the US antiretroviral market.

Rate of Growth of market for antiretroviral drugs

In 2011, IMS reported sales of \$9.782 billion for the top 15 antiretroviral drugs for HIV/AIDS, based upon average wholesale receipts, before off invoice discounts and rebates. This is up from \$8.799 billion in 2010, an increase of 11.2 percent in one year, following a trend of double digit increases in national outlays on antiretroviral drugs.

Table 3: Rate of Increase in US ARV Sales

Year	Increase from previous year ³
2007	10.7%
2008	14.5%
2009	15.5%
2010	12.2%
2011	11.2%

Assuming 1.2 million persons living with HIV, and 36 percent of the current HIV+ population receiving ARV drugs, this amounts to \$8,151 per HIV+ person, and \$22,643 per person receiving ARV drugs. Any effort to implement treatment as prevention would dramatically change the

³ This table combines data from two different IMS reports.

rates of increase.

Patients Receiving Treatment

Historically, several factors have influenced the numbers of persons on treatments. In the past, given the high cost of drugs and the side effects from taking drugs, the primary consideration were the patient CD4 count or other measures of patient health, as well as patient awareness of infections. Over time, there have been stronger arguments for beginning ART earlier, both to improve patient outcomes, and also lower rates of reinfection. New “treatment as prevention” norms may lead to a dramatic increase the numbers of patients who would be using drugs, including in some scenarios, patients who are not HIV+ themselves, but who are having sex with persons who are HIV+.

Estimates of the number of patients actually receiving treatments in the United States vary. CDC estimates that more than one in five persons living with HIV do not even know they are infected. One recently published study estimated that only 24 percent of persons living with HIV in 2006 were regularly receiving ART.⁴ The CDC recently estimated the number of persons receiving ART to be about 36 percent of the HIV positive population.⁵ The Kaiser Foundation puts the percent of persons “in regular care” at 50 percent of those diagnosed with HIV⁶, or about 40 percent of persons who are HIV+.

Some health experts are calling for dramatic increases in the numbers of persons receiving antiretroviral drugs.

One obvious factor in access to treatment is the availability of insurance or reimbursements for the many persons living with HIV that have low incomes. Many of those patients now seek to obtain treatment from various federally funded or subsidized programs, including the state run and co-funded AIDS Drug Assistance Programs, known as ADAPs.

ADAP Cost-containment

In recent years, the ADAP programs have face a difficult crisis in funding. One aspect of the crisis has been waiting lists in several states. According to the National ADAP Monitoring Project, in 2011, 14 states reported waiting lists for treatment, reaching 9,298 individuals by September 1, 2011. Since then, special federal appropriations were made available which helped at least temporarily lower the numbers on waiting lists. As of May 3, 2012, there were 2,704 individuals who have registered and qualified for treatments, but are on wait lists in 10 states.

Since September 2009, six state ADAP programs have lowered the standards for financial

4 Gardner EM, McLees MP, Steiner JF, Del Rio C, Burman WJ., The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. *Clin Infect Dis.* 2011 Mar 15;52(6):793-800.

5 New Hope for Stopping HIV, CDC VitalSigns, December 2011
<http://www.cdc.gov/VitalSigns/HIVtesting/index.html>

6 Fact Sheet: The HIV/AIDS Epidemic in the United States, March 2012.

eligibility, in order to control costs. Illinois, North Dakota, Ohio and South Carolina lowered the eligibility level to 300 percent of the Federal Poverty Level (FPL). Utah now uses 250 percent of FPL, and Arkansas uses 200 percent. The previous standard was 400 percent of the FPL. The changes lead to the disenrollment of 445 individuals in Arkansas (99), Ohio (257), and Utah (89). Illinois, North Dakota, and South Carolina grandfathered existing clients, and will only apply the new income standards to new applicants.

As demand “has not dwindled,” *ADAP Watch* predicts “the waiting lists will likely plateau and grow again in the coming months,” and more cost containment measures are anticipated.

In addition to wait lists and lowered standards for incomes, *ADAP Watch* reports the following cost control strategies have been implemented in from April 1, 2009 to April 11, 2012:

- Alabama: reduced formulary, capped enrollment
- Arkansas: reduced formulary
- Florida: reduced formulary, transitioned 5,403 clients to Welvista from February 15 to March 31, 2011
- Georgia: reduced formulary, implemented medical criteria, participating in the Alternative Method Demonstration Project
- Illinois: reduced formulary, instituted monthly expenditure cap (\$2,000 per client per month),
 - disenrolled clients not accessing ADAP for 90-days
- Kentucky: reduced formulary
- Louisiana: discontinued reimbursement of laboratory assays
- Nebraska: reduced formulary
- North Carolina: reduced formulary
- North Dakota: capped enrollment, instituted annual expenditure cap
- Puerto Rico: reduced formulary
- Tennessee: reduced formulary
- Utah: reduced formulary
- Virginia: reduced formulary, restricted eligibility criteria, transitioned 204 clients onto waiting list
- Washington: instituted client cost sharing, reduced formulary, only paying insurance premiums for clients currently on antiretrovirals
- Wyoming: capped enrollment, reduced formulary, instituted client cost sharing
- ADAPs Considering New/Additional Cost-containment Measures (before March 31, 2013***)
- Alaska: reduce formulary
- Arizona: instituting client cost sharing
- California: instituting client cost sharing
- Georgia: instituting client cost sharing
- Virginia: enrolling clients into PCIPs

At present, the USA faces a growing crisis in treatment for HIV/AIDS, and it is directly associated with the intellectual property right system. What was once a relatively small population of persons with a “rare” disease is now a health condition for more than 1.2 million persons. As the population of persons living with HIV grows, and the prices for products rise, patient face increasing barriers to access, and society as a whole finds harder to bear the cost. It is highly unlikely that the US will achieve adequate coverage of patients, at best standards of care, unless we try something radically different.

The HIV/AIDS Prize Fund Approach

The HIV/AIDS Prize Fund Approach is a radical change from the existing system, and for HIV/AIDS, that is a good thing. By de-linking R&D costs from drug prices, the Prize Fund makes it possible to eliminate price sensitive drug formularies and other ADAP cost-containment measures, dramatically reduce the burden on employers and others who pay for AIDS drugs, and make the new “treatment as prevention” strategies feasible. The Prize Fund would also dramatically reform and improve the economic incentives for drug developers, including by providing new incentives to open source and share research on new treatments for AIDS.

The Old Incentive System

At present, we grant time limited legal monopolies to make, sell, distribute and use new drugs and vaccines. Following extensive lobbying by drug developers, the time limits on these monopolies continues to grow, as do the many ways that such monopolies can be claimed. For AIDS drugs, patents on new compounds, new uses of old compounds, methods of heat stabilization, the use of gel tabs and enteric coatings on pills, fixed dose combinations, and countless minor improvements in products receive patent protection, exclusive rights to test data, orphan drug exclusive marketing rights, and other legal monopolies. Collectively these monopolies lead very predictably to high prices, aided by both tacit and explicit collusion among leading AIDS drug developers. Faced with aggressive monopolies on the selling side, reimbursement agencies either shift huge costs to others, or find ways to limit access to treatment. The cost of legal monopolies for AIDS drugs in the United States was probably well over \$8 billion in 2011. Despite the huge outlays, only about one new drug per year has been registered, and most of these have been medically unimportant me-too products. If the annual cost of the monopoly is currently more than \$8 billion, and growing, this is an expensive way to pay for innovation.

The New Incentive System

The Prize Fund for HIV/AIDS proposes more than \$3 billion per year in prize fund rewards. This would provide ample incentives for the development of new products, and also implement a much more efficient reward design, by tying innovation rewards to improvements in patient outcomes, when benchmarked to existing medicines. This single change in the incentive system

would dramatically refocus private sector R&D toward projects that were medically more important.

The \$150 million in open source dividends would dramatically enhance the speed at which we introduce medically superior treatments.

If implemented in the United States, the prize fund would dramatically expand access, allowing us to reverse the rate of growth in infections, stimulate development of better products, and potentially save taxpayers and employers more than \$5 billion per year.

The size of the prize fund for HIV/AIDS would be 0.02 percent of the gross domestic product of the United States. The money for the prize fund would come from governments and health insurance providers, according to:

The ratio of the number of persons receiving treatments for HIV/AIDS that are insured in the private sector to the number of persons receiving treatments for HIV/AIDS who received insurance or reimbursements or care from the public sector.

Prize Design

The prize fund money would be used to pay for :

End product prizes. These are rewards for products that receive FDA approval and which are used in the market. To be eligible to receive an end product prize a person shall be-

- (1) in the case of a qualifying treatment for HIV/AIDS that is a drug or biological product, the first person to receive market clearance with respect to the drug or biological product;
- (2) in the case of a manufacturing process for a qualifying treatment for HIV/AIDS, the holder of the patent with respect to such process;

Section (b) of the bill sets out a number of criteria for such prizes. Among them:

- A new product or process is eligible to receive such prizes for 10 years.
- The prizes would be based upon the number of patients using products, and the "incremental therapeutic benefit of the qualifying treatment," benchmarked against existing therapies, or for the benefits of the new process.
- There would be a cap on the amount that any single product could receive.

Open Source Dividend Prizes. At least 5 percent of the prize money will be allocated to "open source dividends," to reward "the persons or communities that openly shared knowledge, data, materials, and technology on a royalty-free and nondiscriminatory basis." The system for managing the open source dividends would include "time-limited period of nominations for persons or communities whose contributions were considered useful, including the evidence to support such nominations to describe the significance of the contribution." These prizes, which

would be greater than \$150 million per year at current levels of GDP, would create a powerful economic incentive to open source knowledge, data, materials and technology, which should directly benefit product developers.

Decentralized management of upstream prizes, by competitive intermediaries. The prize fund will have the possibility of authorizing multiple non-profit entities to manage parts of the prize fund, to either manage some of the funds for the open source dividend prizes, or to give prizes for upstream R&D projects. This money will be given to "communities that provide open, nondiscriminatory, and royalty-free licenses to relevant intellectual property rights."

The competitive intermediaries would be funded by private sector employers.

Section 10(a). Such intermediaries shall compete for funding from non-Federal entities that co-fund the Fund.

Background on the Prize Fund Approach

The ideas presented in S.1138, for rewarding innovation with cash prizes rather than monopolies, are both old and new. KEI has a web page with extensive background on the use of innovation inducement prizes here: <http://www.keionline.org/prizes>. While prizes have been used to stimulate and reward innovation both before and after the patent system was developed, interest in prizes as a mechanism has increased sharply in recent years.

Academic work on innovation prizes was reinvigorated by the work by Brian Wright in 1983, and Michael Kremer, Steven Shavell and others in the 1990s,⁷ as well as by the pioneering efforts of Michael Kremer and his collaborators to fashion new prize type mechanisms (the Advance Purchase Commitment and Advanced Marketing Commitment models) to reward development of new treatments for malaria and other diseases. Also, following interest in the crisis in the AIDS market, Dean Baker began to question to economic efficiency of monopoly rewards for new drug development – proposing as an alternative expanded direct government funding of drug development.

In 2002, Tim Hubbard and I were invited by Aventis, the pharmaceutical and life sciences company now owned by Sanofi, to meet with top level executives to develop scenarios for drug development that did not depend upon patents or other legal monopolies. By the end of 2002, Tim Hubbard and I developed, with the collaboration of several Aventis executives, a new paradigm for drug development that included three major features – a global R&D treaty to address the need to address the sustainable sharing of R&D costs, the use of innovation

7 1983. Brian Wright. The Economics of Investment Incentives: Patents, Prizes, and Research Contracts. *American Economic Review*. 73: 691-707. 1998. Michael Kremer. "Patent Buyouts: A Mechanism for Encouraging Innovation." *Quarterly Journal of Economics* 113: 1137-67. 2001. Steven Shavell and Tanguy van Ypersele. "Rewards versus Rights." *Journal of Law and Economics*. 44: 525-547. Previously published as "Rewards versus Intellectual Property Rights." 1998 Harvard Law School, Olin Center for Law, Economics & Business, Discussion Paper No. 246. Also, see: <http://keionline.org/prizes/cites>

inducement prize funds to reward successful innovations, and the creation of new “competitive intermediaries” funded by employers, insurance companies, or individuals (under mandates), to provide funding for various open source and upstream R&D projects or achievements. This was meant to co-exist and complement existing government grant and contract programs, like those administered by the NIH. This work was further developed in articles and research papers and presented at a series of workshops and seminars and in from 2002 to 2004, including two at Columbia University with Jeffrey Sachs.

The notion of de-linking drug development incentives from product prices was independently being developed by others, such as the economist Burton Weisbrod, who wrote an editorial in the Washington Post on the topic in August 2003.⁸ Will Masters was also developing similar prize fund models to reward innovations in agriculture.

The key challenges in developing the prize fund approach were to address the sources of sustainable funding for the prize fund, and to explain how prize payments were set when the path to innovation was uncertain, the risk adjusted costs of development was unknown and/or variable, and the true value of the products are unknown at the time of product development.

Hubbard and I proposed a competitive model, where the amount of the prizes themselves would be determined by the supply and demand for innovation, by competing for shares of a prize fund of a fixed size. Anticipating that valuation of innovations was difficult when products were new, Hubbard and I proposed a system whereby innovations were eligible to compete for prize fund shares every year for 10 years, adjusting claims each year on the basis of best evidence of utilization and benefits of innovations.

The valuation of the “end product” prizes would be based upon the incremental impact of the innovations on health outcomes, compared to older bench-marked products, subject to the flexibility to have non-linear payoffs, caps on rewards, the use of option pricing models to capture the benefits of redundancy for products that might fail or be held in stockpiles, and other nuances. Given the stochastic nature of innovation, and the ability of developers to pool risks, the system would work if the size of the prize fund was large enough, and if the *anticipated* payoffs were closely enough correlated to social values of innovation.

To address the challenges of valuing pre-commercial innovations, Hubbard and I proposed systems of competitive intermediaries, that need only justify their valuations to entities (employers, insurers or individuals) that choose the intermediary.

In 2004, Representative Sanders expressed interest in drafting a bill to implement a version of the prize fund approach for the US market. HR 417 was subsequently introduced in the 109th Congress. The Sanders bill included core ideas that have been incorporated in several subsequent proposals on prize fund:

The bill did not eliminate the patent system, but did eliminate the patent monopoly once products

⁸ Burton Weisbrod. "Solving The Drug Dilemma." Washington Post, August 22, 2003.

were registered for sale with the FDA. Patents still could be used to establish claims on the prize fund rewards, and drug developers could also receive rewards even without patents. The valuation was based upon the incremental value of the innovation, benchmarked against older products,

Products participated in the prize fund for 10 years, competing against each other for shares of a fund of fixed size.

Subsequent to the development of the Sanders bill, there was a proliferation of various prize fund proposals, including several in 2008 and 2009 in the context of the work of the World Health Organization (WHO) on public health, innovation and intellectual property rights, a 2004 proposal by Aidan Hollis for a voluntary mechanism that was later transformed into the 2009 Health Impact Fund proposal with Thomas Pogge, and a growing literature on medical prizes from a diverse group of other academics, practitioners and journalists, including for example, Joe Stiglitz, Carl Nathan, Thomas Erren, Ron Marchant, Joseph DiMasi, Henry Grabowski, Stan Finkelstein, Peter Temin, Sara E. Crager, Matt Price, Jorn Sonderholm, Paul Hynek, Talha Syed, Terry Fisher, Thomas Erren, Adam Mann, Hafiz Aziz ur Rehman, Paul Wilson, Amrita Palriwala, Richard Bergström, A Gandjour, N Chernyak, Jan Keunen, Evert van Leeuwen, Gert-Jan van der Wilt and Tina Rosenberg, to mention a few.

Among the several papers on this topic that I have co-authored, particularly relevant are:

- 2009. James Love and Tim Hubbard. "Prizes for Innovation of New Medicines and Vaccines." 18 *Annals of Health Law*. 155.
- 2007 November. James Love and Tim Hubbard. "The Big Idea: Prizes to Stimulate R&D for New Medicines." *Chicago-Kent Law Review* Vol. 82 no. 3.
- 2005. James Love and Tim Hubbard. "Paying for Public Goods." In *Code: Collaborative Ownership and the Digital Economy*. Edited by Rishab Aiyer Ghosh. MIT Press, Cambridge. 207-229.
- 2004. James Love and Tim Hubbard. "A New Trade Framework for Global Healthcare R&D." *PLOS Biology*. 2(2): e52.
- 2003. A New Trade Framework for Global Healthcare R&D, Access to Medicines and the Financing of Innovations in Health Care, Paper presented at Workshop Hosted by the Program on Science, Technology, and Global Development, The Earth Institute at Columbia University, and the Consumer Project on Technology, Washington D.C. December 4th.
- 2003. James Love. "From TRIPS to RIPS: A Better Trade Framework to Support Innovation in Medical Technologies." Paper for the Workshop on Economic issues related to access to HIV/AIDS care in developing countries, Agence nationale de recherches sur

le sida, Marsielle, France, May 27.

The 2009 articles in the *Annals of Health Law* provides the most concise explanation of the evolution of the core prize fund design features that are incorporated the S.1138, including the bill's open source dividend and competitive intermediaries proposals. The rationale for competitive intermediaries is also discussed in the article in *Code*.

I also highly recommend the new April 2012 report by the World Health Organization's Consultative Expert Working Group on R&D, which discusses the issue of de-linkage at some length.

The International Dimension

While my testimony has focused on the domestic aspects of S.1138, the international dimension is quite important. There are tens of millions of poor people living in developing countries who are HIV+ and who will die without sustainable access to treatment. Since the WTO rules on drug patents were enforced in 2005, it has become increasingly difficult to obtain affordable generic version of AIDS drugs in developing countries. Not only would S.1138 greatly benefit people living in the US, but it would radically transform the market for AIDS drugs throughout the world, and make a vast contribution to the struggle to make treatment for HIV/AIDS sustainable for tens of millions of poor people living outside the United States.