

**Statement of James Love**  
**The Economics of the Pharmaceutical Market in the United States**

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**Introduction**

There was a time when pharmaceutical costs were a fairly minor part of national health care expenditures, and not a great burden on patients and public and private insurers. Those days are gone. In the past two years national expenditures on pharmaceutical drugs increased by 31 percent, and total outlays are now approaching about 2 percent of GDP. Globally, US consumers represent nearly half of the world market for pharmaceutical drugs, spending far more per capita than most countries, including those with similar incomes.

The prices for drugs have soared, and investors are pushing firms to charge ever-higher rollout prices. Conditions that recently were treated for \$2.50 per day now see prices for new drugs at more than \$4 per day. For severe illnesses, prices can be much higher. Each class of anti-retroviral drugs has been priced higher than the previous class. The new HIV drug T-20 is priced at \$20,000 per year for a single drug. An AIDS patient needs at least three. T-20 by itself is priced nearly twice as high as a three drug cocktail based upon d4T+3TC+Zidovudine. Gleevec, a new drug for Leukemia, is priced at more than \$160 per day. Ceredase was introduced in the market at a price of more than \$.5 million for the first year of treatment. .

How high will prices go, and how much can we afford, and why do US consumers pay more than everyone else for medicines? Today I will briefly examine the basic characteristics of the pharmaceutical market, mention that typical measures that could be undertaken to obtain better prices, and finally to suggest it is time to consider a new trade framework that would permit every country to take measures to protect consumers, while ensuring we continue to support high levels of R&D to development new medical inventions.

**The Economics of the Pharmaceutical Market**

What are the most important features of the pharmaceutical market?

1. Products have high fixed costs of R&D, but often low marginal costs of production.
2. Most new products are protected by strong intellectual property protection, granting long marketing monopolies.
3. Innovation is decentralized and highly competitive. Big pharma typically acquires its technology from smaller firms or non-profit research institutions.
4. Marketing is expensive, requires large fixed costs, and is dominated by handful of large firms.

5. There is considerable evidence that firms can avoid price competition even when there is competition within a therapeutic class. A good example of this is the market for anti-retroviral drugs, where prices for each mature class of drugs used in a HAART regime are quite similar (within the three classes of nucleoside, non-nucleoside and protease inhibitors).
6. Firms engage in much non-price competition, and spend enormous energy and resources to influence physicians, and bias the evidenced base for prescribing.
7. There is a very inefficient private R&D agenda, which can be explained by well-known problems in the markets for innovation. Firms have incentives to invest too much in "me-too" products, and too few incentives to invest in truly innovative products.
8. The patent system is costly to administer, prone to many errors, and is subject to abuse and frequently used to achieve anticompetitive ends.
9. There are huge benefits from extending monopolies, and firms will invest huge efforts and resources to do so. A 2 year extension of a top selling drug can now be worth more than \$15 billion, and with incentives like that, there is little wonder we observe astonishingly energetic efforts to not only game the rules, but to constantly change the rules.

### **The need for more transparency of drug development costs**

There is considerable controversy over the costs of new drug development. The latest industry-supported, published estimate for R&D of a "big pharma" new drug pegs the cost at \$802 million (DiMasi, et al, 2003), more than three times the estimate the same authors published a little more than a decade ago. In contrast, the Global Alliance for TB Drug Development October 2001 report, *The Economics of TB Drug Development*, estimates that a new TB drug can be discovered and developed for \$115 to \$240 million, including the costs of failures. For some classes of drugs, costs appear to be even lower. The easiest figures to verify are those associated with the costs of clinical trials. DiMasi and colleagues claim nearly \$300 million for the risk-adjusted costs of clinical trials, before capital costs and a half billion after capital costs. The TB Alliance figures are far less. For some products the costs associated with clinical trials may be fairly small. For example, the US Internal Revenue Service (IRS) reports that expenditures on pre-approval clinical trials are a little more than \$10 million per approved Orphan product.<sup>1</sup> (But even the smaller costs of Orphan Drug development has increased significantly in the past ten years.) Interestingly, the IRS reports lower outlays for R&D on new products than is reported by the annual PhRMA survey, a fact rarely mentioned by analysis who tend to rely almost entirely on PhRMA's own surveys and experts for data on these issues, ignoring independent data even when it is available.

We have attempted to reconcile some of the conflicting data regarding costs by asking DiMasi and his co-authors to provide two simple numbers. In the DiMasi et al. study, what are:

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<sup>1</sup> James Love, "What do US IRS tax returns tell us about R&D investments? Van ontwikkelen tot slikken, Pharma Selecta congres.

1. the average number of patients in clinical trials, and
2. the average cost per patient in the trials?

If we have these two numbers (which have not been provided) we can better evaluate the reasonableness of their claims regarding costs.

With regard to R&D costs, our own analysis of IRS data suggests that firms invest less than 10 percent of turnover on development of new products.<sup>2</sup>

Understanding better the actual costs of the R&D process is important, but it is also important to understand the character of investment flows, and to evaluate the productivity of those investments.

Despite increased public and private investment in R&D, the number of new chemical entities approved by the U.S. Food and Drug Administration has not changed markedly, and many of the newer products only offer marginal improvements over existing therapies. Over the past three years, the US FDA determined that two thirds of new chemical entities were did *not* represent a significant improvement compared to existing marketed products for the treatment, diagnosis, or prevention of a disease.

**Table 1**  
**USA FDA NME APPROVALS**  
**2000 to 2002**

	2000	2001	2002	Total
Priority	9	7	7	23
Standard	18	17	10	45
Total	27	24	17	68
% Priority	33%	29%	41%	34%

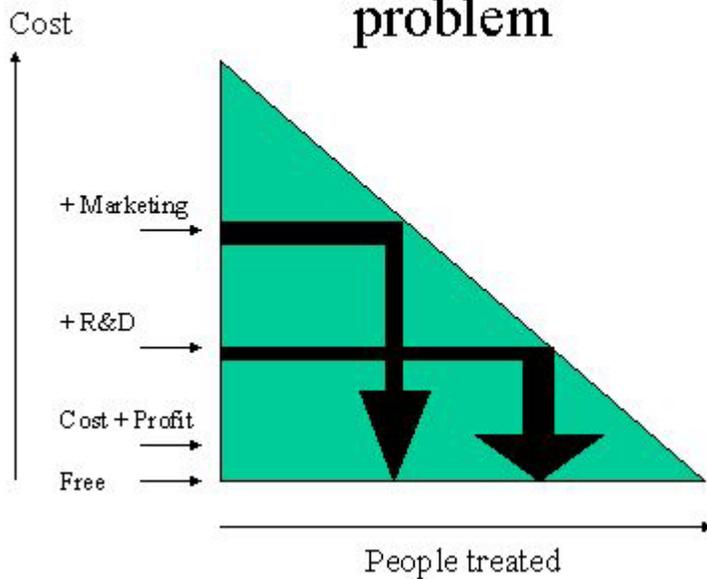
*Source: FDA Center for Drug Evaluation and Research.*

It should be emphasized that that firms spend much more on marketing and distribution than is spent on R&D, and this is a consequence of the patent system, which finances R&D in part by providing firms a long marketing monopoly. Tim Hubbard has illustrated the consequences of this system in this simple demand curve analysis.

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<sup>2</sup> James Love, "What do US IRS tax returns tell us about R&D investments? Van ontwikkelen tot slikken, Pharma Selecta congres.

## Tim Hubbard's demand curve problem



### What to do about high prices

The fundamental problem is that while we depend upon a mixture of public and private financing for drug development, we nearly always end up with a private monopoly marketing the product. Left to their own devices, firms seek to maximize profits, and that means, charging what the market will bear. Government in nearly every developed economy use their buying power to bargain or to set prices for medicines. If you don't do that, you have to take an inventory of the areas where you can make markets more competitive. Remember, competition is your friend. Monopoly leads to high prices. This is not a profound statement, but it is important.

### Parallel Trade

This hearing is largely about parallel trade in pharmaceuticals, and it should look at the issue much broader than just the North American market. Our own view is that parallel trade is a good thing for US consumers, and it should be expanded to Europe and other developed economies. But we do not think that parallel trade or referencing pricing should extend to poor countries. We recommend that parallel trade extend to countries that meet the World Bank classification for high-income countries.

There are two legal issues should receive more attention in the parallel trade debate.

1. First, the committee should study the *Jazz Photo Corporation v. International Trade Commission* court decision to determine if the court has eliminated the first sale doctrine for patented products.
2. Second, determine if Article 6 of the WTO/TRIPS agreement permits applying the first sale doctrine selectively to only countries of similar incomes.

### **Eliminate or reform wasteful non-patent *Sui Generis* IP rights**

Many of the barriers to competition are created by the US Congress, and they include an ever expanding number of extensions of patents and regulatory barriers to entry. It would be a nice start to take an inventory of those barriers to competition, and ask two simple questions:

1. How much do they cost in terms of higher US prices, and
2. What do we get back in terms of R&D?

### **Better Management of Publicly Funded Inventions**

We have asked OMB to ask the DHHS and the Veterans Administration why the US government has failed to ever take advantage of the existing US government rights to use patents funded by the federal government to acquire generic medicines in cases where the government pays for the medicines. There are many drugs in this category, including for example, d4T, and HIV drug that sells for less than \$50 per year outside the USA, and nearly \$4,000 per year in the United States. The US government has a royalty-free right in the patent on the new \$20,000 HIV drug T-20. The federal government has rights in many patents, but never uses them to buy generic drugs.

### **New Trade Framework for funding R&D**

The TRIPS accord and hundreds of bilateral and regional trade agreements focus on patent and other intellectual property rights, but none of them deal directly with the important issue of R&D. US consumers pay for about half of the private sector funded R&D, but also probably 80 percent of the global expenditures on publicly funded R&D, nearly \$100 per capita.

What makes far more sense for the trade framework is to require countries to fund a certain amount of the GDP for health care R&D, say 10 to 15 basis points on GDP. This would allow countries more flexibility in meeting trade obligations, but still deal efficiently with free rider problem.

If this was done, we could look at the larger issue. If the cost of the patent system for the pharmaceutical sector is now greater than \$200 billion per year, and we are only

financing about \$20 billion in R&D on new products (based upon IRS data, and excluding R&D funded by foreign consumers), then it may be too inefficient. It is costing us at least \$150 billion per year to have patents, and we are only getting back about \$20 billion in R&D, and most of that on products that are not particularly innovative. When the prices of medicines were much lower and we were spending less than 1 percent of GDP on medicines, such inefficiency might have been acceptable. It will clearly not be acceptable in the future. We need to look at new business models for funding R&D, and in particular, we need a business model that separates the market for development of new productions from the post market entry life of a product. It makes more sense to impose obligations on insurers to funding R&D through annual lump sum fees, invested in competitive R&D enterprises, but have post development products be priced closer to marginal costs. You could easily double private sector R&D spending, while making sure that seniors and others could buy every product as a generic. No realistic cost benefit analysis could justify the status quo, which is why it has been defended as dogma, rather than on pragmatic grounds..