

## **Avoiding a Prescription Drug Development Crisis: A Proposal for a New International Development Reimbursement Procedure**

Lance Gentry

Colorado State University-Pueblo, USA

[lance.gentry@colostate-pueblo.edu](mailto:lance.gentry@colostate-pueblo.edu)

### **ABSTRACT**

*The cost of developing new drugs is enormous, recent estimates show that the average research and development (R&D) costs exceed \$800 million dollars and are growing at an annual rate of 7.4% above inflation. A free rider situation exists, where American consumers pay a majority of the R&D costs for new prescription drugs. Recent events make it foreseeable that the American consumer will no longer be willing or able to continue to pay a disproportionate percentage of R&D costs. If a solution to this problem is not found, new drug development could be severely retarded. A potential solution is proposed and discussed.*

**Keywords:** *Pharmaceutical Development, Public Policy, Free Rider*

## **INTRODUCTION**

Every year, new prescription drugs become available. Prescription drugs are used to treat both physical and mental problems ranging from treating acne, managing pain, fighting mental depression, and treating otherwise terminal diseases. While treatments are still needed for many problems, the global pharmaceutical industry has made great progress toward treating many human ailments. Developing new molecular entities (i.e., prescription drugs) is an expensive process that is disproportionately born by a small portion of the world's population. Recent events, both political and financial, raise the potential that the current funding model for new prescription drug development may be in jeopardy. The literature is reviewed to test these assumptions. The findings are discussed and a proposal is offered for a new funding model for international drug development.

## **LITERATURE REVIEW**

### **The Cost of Developing Drugs**

Developing new drugs is expensive. Danzon (1997) found that the American pharmaceutical industry standard of spending 21% of sales revenue on research and development greatly understated the percentage of R&D expense as a percentage of the total costs of developing and producing new drugs, because the R&D in the numerator pertains to future drugs whereas the sales in the denominator pertains to drugs for which the R&D occurred many years previously. Thus, these measures discount the time value of money of the development funds during the time drugs were being developed and successful drugs were being approved. As Danzon (1997) noted, these are enormous opportunity costs when you consider the average time for drug development was 15.3 years for drugs approved from 1990 to 1995. Pharmaceutical firms are

spending billions of dollars on research and development, but how much does it cost to develop just one new successful drug?

DiMasi et al (2003) evaluated sixty-eight new drugs from ten pharmaceutical companies in an attempt to answer this question. They determined that the average new drug cost was \$802 million in year 2000 dollars and that this cost was growing at an annual rate of 7.4% above inflation. Adams and Brantner (2006) replicated DiMasi et al's research and found that the average cost per new drug was \$868 million. Further, they found that that the variance was large with new drug development costing between \$500 million to more than \$2 billion.

### **The Free Rider Problem**

Economists define free riders as those who benefit from the work of others without making a proportional contribution. Common knowledge has it that the American consumer pays for the majority of the R&D costs of new drugs while other governments regulate the price of drugs so that their citizens only pay a bit more than the production cost of these drugs. Drug companies go along with this because they still generate some profits by selling to citizens in these nations (so long as the marginal costs of increased production is less than the regulated selling price of the drug) and because they drug companies fear that if they do not agree, the governments will just nationalize the rights to drug patents and produce the product themselves (Pilon, 2004). The free rider problem occasionally comes up in the mainstream media (e.g., Zuckerman, 2004), but the discussion is usually raised by the government. In his speech before the First International Colloquium on Generic Medicine, Food and Drug Administration McClellan (2003) summarized the prescription drug free rider problem.

*This year, Americans, who account for a fraction of prescription drug use worldwide, will pay for about half of all pharmaceutical spending worldwide. By contrast, citizens in the world's third largest economy, Germany, paid less than five percent. The same kind of drug payment disparity is true for many other developed nations who have about as much ability to pay as Americans do.*

*Yet on the whole, people in these other nations are getting most of the same kinds of drugs and the many of the same kinds of health benefits as Americans. And it's not only Americans that seem to be paying an unfair share. Drug prices on average are significantly higher in countries like Poland than they are in France and Germany – even though people in those countries have significantly less economic wealth than the countries of Western Europe.*

*Why does this happen? After the usually long and extensive development process to show that a drug is safe and effective, all of the R&D costs have been spent. All that's left are the production costs of making and distributing the medicines themselves. But the remaining production costs only account for about 25 to 50 percent of the total cost of developing and providing a new medicine for a particular country. Obviously, each country would like to pay only this additional cost to obtain the drug for the additional patients in that country. Nobody wants to pay for all the rest of the costs – all the money that has already been spent researching and developing a new medicine and researching and developing its production and labeling.*

*And some of the world's richest nations are driving the world's hardest bargains. In fact, many developed countries are in effect banding together to get the same price. For example, many high-income countries regulate their prices by setting them equal to those in other countries that already have rigid price controls. This system is used in Canada, informally in*

*Japan, and in some countries in Europe. By linking together, they may get even more power to only pay for cost of making additional pills. As a result, many relatively wealthy countries are moving away from covering any significant part of the costs of research and development. They are leaving development costs for nations with less ability or will to extract lower prices.*

*But unless someone covers the cost of R&D investment, which accounts for 20 percent or more of the revenue from pharmaceuticals, that investment will slow or stop, and so will the improvements in health that we've become used to seeing in recent decades.*

*The United States is now covering most of these costs of developing a new drug to the point where it can be used by the population of the world.*

The US Department of Commerce (2004) found ample evidence that prescription drug free riding existed and estimated that this free-riding in the form of price controls directly resulted in diminished returns to pharmaceutical companies of \$18 billion to \$27 billion dollars annually. To put this into perspective, eliminating this free-riding could have funded 22 to 33 new prescription drugs per year using the average cost of \$802 million dollars for each new drug (DiMasi et al, 2003). Of course, this figure assumes that all of the increased revenue would indeed go into research and development. The Department of Commerce was much more conservative and estimated that the elimination of free-riding would generate three to four new molecular entities annually. Alternatively, if the citizens of these other countries started paying a more proportionate share of the research and development costs, the price for American consumers could be reduced accordingly.

Surprisingly, few academic researchers have seriously investigated the free-riding prescription drug situation other than to use it as an example of free-riding. Light and Lexchin (2005) and Keyhani & Ross (2007) each offered briefs that claimed the entire free rider concept

was a myth. However, these researchers missed the distinction that the free ride was being had by non-American *consumers*, not non-American pharmaceutical *companies*. Both Light & Lexchin and Keyhani & Ross concluded that there was no free-ridership because European and Canadian pharmaceutical companies were also spending money on R&D and were creating new molecular entities. Their argument is specious since these researchers were looking at firms, not consumers. The R&D costs of virtually all major pharmaceutical companies – whether the firms are American, European, or other – are predominately born by the American consumer because other countries strictly regulate the price of these products. On the other hand, Gilbert and Rosenberg (2004) concluded that the European consumers' free ride was not quite free after all. While they agreed that the American consumer was paying a disproportionately large share of the industry's R&D costs, they pointed out that Europe was starting to pay other social and economic costs because of their pricing controls. For example, because the margins on new pharmaceuticals are much higher in the States, drug companies naturally launch products there first. Thus, American consumers have more immediate access to new drugs than other consumers, even if they have to pay more for this privilege. Gilbert and Rosenberg credited this situation, along with the desire to be closer to their most profitable market, as the reason why many European pharmaceutical firms (i.e., Swiss-based Novartis) are moving their R&D centers to the States. Thus, one of the social costs of free ridership may result in a substantial brain drain as some of the best and brightest researchers relocate to the States. The Novartis Corporation stated that *OECD governments get a "free ride" by imposing artificially low drug prices at home, while assuming that the U.S. market will continue to underwrite the development of new drugs* (US Department of Commerce, 2004).

## Prescription Drugs

For the purposes of simplicity, this paper assumes that Americans pay one price for prescription drugs. The actual situation in the United States is more complex as pricing varies quite a bit for new prescription drugs. For example, it is conservatively estimated that cash payers spent at least 14.6 percent more than third-party payers did for the same drugs (Frank, 2001). However, no matter what price an American pays for a brand-name prescription drug, it is likely to be more than consumers pay elsewhere. Danzon and Furukawa have been studying international drug pricing in a series of articles which are highly recommended for more detail about international drug pricing. After controlling for differences in strength (milligrams of active ingredient) and formulation (US drugs are more likely to be long-acting formulations such as tablets and capsules, which substitute quality for quantity), Danzon and Furukawa (2008) concluded that brand-name prescription drugs are between ten and thirty percent lower outside of the United States in a recent study of drug prices in twelve countries. The academic research was consistent with that of the US Department of Commerce (2004), which found that patented drugs were between eighteen to sixty-seven percent less in the Organization for Economic Cooperation and Development (OECD) countries compared to the United States.

However, when it comes to generic drugs and over-the-counter (OTC) drugs, the efficiencies of the American market reassert themselves. Danzon and Furukawa found that the US is the least expensive place to buy both generics and OTC drugs. The pricing for unbranded generics varied dramatically in other countries: *all foreign prices are higher, ranging from 14 percent higher in Chile to threefold higher in Australia and fivefold higher in Canada.* Similar findings occurred in the OTC comparison: *OTC prices are at least 80 percent higher in all countries than in the United States and more than three times higher in Italy, Japan, Spain, and Chile.*

Thus, the literature supports the claim that Americans pay a disproportionate share of the R&D cost of new prescription drugs. However, after the R&D costs are recouped (presumably in the period the drug is covered by patents), Americans then pay less for generic and OTC drugs than consumers in other countries.

### **THE UPCOMING CRISIS**

The literature-supported finding that the American consumer funds a disproportionately large share of new prescription drug development is the Achilles' heel of the pharmaceutical industry. Should the American consumer quit shouldering this disproportionate contribution, either by choice or necessity, the development of new molecular entities would slow dramatically unless the consumers in free-rider countries started paying more for their prescription drug consumption. While estimating the probability of free-rider countries raising or eliminating their prescription drug price controls is outside the scope of this paper, the author does not believe this would be a likely outcome.

There are two potential paths for the American consumer to quit contributing a disproportionate share to prescription drug development. The first path is political, the American consumer may simply refuse to pay more than other consumers for new prescription drugs. For example, the American government could follow the example of most industrialized countries and simply impose price limits. Alternatively, Americans could simply allow consumers to import prescription drugs from other countries and allow market forces to bring domestic prices down. Some arbitrage already exists; consumers who live near Canada and Mexico often buy drugs in these countries.

The second path is financial, the American consumer may no longer have the ability to pay a disproportionately high price for pharmaceutical. While a discussion of American financial problems is outside the scope of this article, it is readily apparent that the US government is dramatically increasing its national debt to the point that external bondholders are concerned about the safety of their investment. Should Americans take either of these paths, a new solution will be needed to finance the development of new prescription drugs.

### **A PROPOSED SOLUTION**

For the sake of simplicity, all population and Gross Domestic Product (GDP) numbers in this document were obtained from the CIA World Factbook (2009). The GDP numbers quoted were adjusted by the CIA to reflect purchasing power parity (PPP) since this is the accepted practice of most economists when discussing the use of resources across countries. This CIA World Factbook is one of three sources commonly cited for this information. The other two sources are the International Money Fund and the World Bank. Since these numbers involve some estimation, especially for less industrialized nations, the figures from these sources vary from one another. Should this proposal be implemented, it is suggested that these three sources be averaged to create the numbers used to determine minimum payments to the pharmaceutical firms.

Individual cost sharing, where the consumer pays a percentage of the prescription cost, is often suggested as a method to reduce healthcare costs. In their meta-analysis of 132 articles on the subject, Goldman et al (2007) indeed found that for each 10% increase in individual cost sharing, prescription drug spending decreases by 2% to 6%, depending upon class of drug and condition of the patient. Unfortunately, they also found an association between increased

individual cost sharing and discontinuation of therapy and lower rates of drug treatment. Even if cost sharing did not have any negative health associations with it, the purpose of individual cost-sharing is to reduce health-care costs, so the more successful cost-sharing might be, the more it would decrease revenues available for new prescription drug development under the current system. Ideally, a system for funding new prescription drug development should separate the financial incentives for developing a new drug from the price of the drug itself. Otherwise, the more successful the efforts to reduce healthcare costs, the less the funding to develop new molecular entities. A system that separates these issues is proposed.

Instead of individual cost sharing, a system of country cost sharing is proposed. In addition to separating the financial incentives for developing new prescription drugs from the drug production, this proposal was also designed to consider the ability to pay. The desire was to create a proposal where wealthier countries who wanted to provide these drugs to their citizens would pay a fair price to cover drug development and where poorer countries would receive a free ride until their economic situation allowed them to also contribute.

Given these objectives, two economic indicators were considered, the country's GDP and the country's GDP per capita. The GDP was included because only considering GDP per capita would omit some of the largest economies in the world (i.e., China and India). GDP per capita was included because only considering GDP would omit small countries such as Liechtenstein who boast some of the highest standards of living in the world. Any country that had a GDP of fifty billion dollars or had a GDP per capita of thirty thousand dollars is automatically added to the list of participating countries. These cutoffs are somewhat arbitrary, but were picked as reasonable indicators of ability to pay and result in 105 participating countries as documented in Table 1. A desired contribution of \$1.5 billion was set, assuming approximately two-thirds of

the participating countries would desire to make any given drug available to their citizens. This means that approximately one billion dollars would be provided to a pharmaceutical company for a typical new drug.

Table 1: Proposed Contributions per Participating Country

Country	GDP (PPP) in millions	Population in thousands	GDP (PPP) per capita	Minimum Contribution	Contribution per capita
Algeria	\$233,500	34,178	\$6,832	\$5,107,442	\$0.15
Andorra	\$3,660	84	\$43,630	\$80,057	\$0.95
Angola	\$112,800	12,799	\$8,813	\$2,467,321	\$0.19
Argentina	\$575,200	40,914	\$14,059	\$12,581,586	\$0.31
Australia	\$802,900	21,263	\$37,761	\$17,562,162	\$0.83
Austria	\$331,200	8,210	\$40,340	\$7,244,474	\$0.88
Azerbaijan	\$77,790	8,239	\$9,442	\$1,701,533	\$0.21
Bahamas, The	\$9,352	309	\$30,250	\$204,560	\$0.66
Bahrain	\$26,890	728	\$36,948	\$588,176	\$0.81
Bangladesh	\$226,400	156,051	\$1,451	\$4,952,140	\$0.03
Belarus	\$114,300	9,649	\$11,846	\$2,500,131	\$0.26
Belgium	\$390,200	10,414	\$37,468	\$8,535,005	\$0.82
Bermuda	\$4,500	68	\$66,335	\$98,430	\$1.45
Brazil	\$1,998,000	198,739	\$10,053	\$43,703,076	\$0.22
British Virgin Islands	\$853	24	\$34,845	\$18,667	\$0.76
Brunei	\$19,580	388	\$50,439	\$428,281	\$1.10
Bulgaria	\$93,980	7,205	\$13,044	\$2,055,663	\$0.29
Burma	\$55,270	48,138	\$1,148	\$1,208,943	\$0.03
Canada	\$1,303,000	33,487	\$38,910	\$28,501,055	\$0.85
Cayman Islands	\$1,939	49	\$39,543	\$42,413	\$0.86
Chile	\$245,100	16,602	\$14,764	\$5,361,173	\$0.32
China	\$7,992,000	1,338,613	\$5,970	\$174,812,304	\$0.13
Colombia	\$396,000	45,644	\$8,676	\$8,661,871	\$0.19
Croatia	\$82,580	4,489	\$18,394	\$1,806,306	\$0.40
Cuba	\$108,400	11,452	\$9,466	\$2,371,078	\$0.21
Czech Republic	\$264,800	10,212	\$25,931	\$5,792,079	\$0.57
Denmark	\$204,100	5,501	\$37,106	\$4,464,363	\$0.81
Dominican Republic	\$78,190	9,650	\$8,103	\$1,710,282	\$0.18
Ecuador	\$108,000	14,573	\$7,411	\$2,362,328	\$0.16
Egypt	\$444,800	83,083	\$5,354	\$9,729,293	\$0.12
Equatorial Guinea	\$23,000	633	\$36,310	\$503,088	\$0.79

Country	GDP (PPP) in millions	Population in thousands	GDP (PPP) per capita	Minimum Contribution	Contribution per capita
Ethiopia	\$70,230	85,237	\$824	\$1,536,170	\$0.02
Falkland Islands	\$105	3	\$33,471	\$2,299	\$0.73
Finland	\$194,000	5,250	\$36,950	\$4,243,442	\$0.81
France	\$2,133,000	64,058	\$33,298	\$46,655,987	\$0.73
Germany	\$2,925,000	82,330	\$35,528	\$63,979,729	\$0.78
Gibraltar	\$1,066	28	\$38,025	\$23,317	\$0.83
Greece	\$343,800	10,737	\$32,019	\$7,520,079	\$0.70
Guatemala	\$68,750	13,277	\$5,178	\$1,503,797	\$0.11
Guernsey	\$2,742	66	\$41,627	\$59,977	\$0.91
Hong Kong	\$307,300	7,055	\$43,557	\$6,721,699	\$0.95
Hungary	\$196,700	9,906	\$19,857	\$4,302,500	\$0.43
Iceland	\$12,870	307	\$41,964	\$281,511	\$0.92
India	\$3,304,000	1,166,079	\$2,833	\$72,269,751	\$0.06
Indonesia	\$916,700	240,272	\$3,815	\$20,051,356	\$0.08
Iran	\$843,700	66,429	\$12,701	\$18,454,597	\$0.28
Iraq	\$90,230	28,946	\$3,117	\$1,973,638	\$0.07
Ireland	\$189,000	4,203	\$44,966	\$4,134,075	\$0.98
Isle of Man	\$2,719	77	\$35,537	\$59,474	\$0.78
Israel	\$203,400	7,234	\$28,118	\$4,449,052	\$0.62
Italy	\$1,827,000	58,126	\$31,432	\$39,962,723	\$0.69
Japan	\$4,340,000	127,079	\$34,152	\$94,930,606	\$0.75
Jersey	\$5,100	92	\$55,661	\$111,554	\$1.22
Kazakhstan	\$176,200	15,399	\$11,442	\$3,854,095	\$0.25
Kenya	\$61,650	39,003	\$1,581	\$1,348,496	\$0.03
Korea, South	\$1,338,000	48,509	\$27,583	\$29,266,625	\$0.60
Kuwait	\$149,500	2,691	\$55,552	\$3,270,075	\$1.22
Libya	\$87,720	6,310	\$13,901	\$1,918,736	\$0.30
Liechtenstein	\$4,160	35	\$119,674	\$90,993	\$2.62
Lithuania	\$63,370	3,555	\$17,825	\$1,386,118	\$0.39
Luxembourg	\$39,470	492	\$80,260	\$863,344	\$1.76
Macau	\$18,140	560	\$32,402	\$396,784	\$0.71
Malaysia	\$385,200	25,716	\$14,979	\$8,425,638	\$0.33
Mexico	\$1,567,000	111,212	\$14,090	\$34,275,636	\$0.31
Morocco	\$137,900	34,859	\$3,956	\$3,016,343	\$0.09
Netherlands	\$673,500	16,716	\$40,291	\$14,731,743	\$0.88
New Zealand	\$116,600	4,213	\$27,673	\$2,550,440	\$0.61
Nigeria	\$336,200	149,229	\$2,253	\$7,353,841	\$0.05

Country	GDP (PPP) in millions	Population in thousands	GDP (PPP) per capita	Minimum Contribution	Contribution per capita
Norway	\$276,300	4,661	\$59,285	\$6,043,624	\$1.30
Oman	\$66,870	3,418	\$19,564	\$1,462,675	\$0.43
Pakistan	\$431,200	176,243	\$2,447	\$9,431,815	\$0.05
Peru	\$247,900	29,547	\$8,390	\$5,422,419	\$0.18
Philippines	\$318,200	97,977	\$3,248	\$6,960,120	\$0.07
Poland	\$670,700	38,483	\$17,429	\$14,670,497	\$0.38
Portugal	\$237,300	10,708	\$22,161	\$5,190,561	\$0.48
Puerto Rico	\$70,230	3,971	\$17,686	\$1,536,170	\$0.39
Qatar	\$91,550	833	\$109,866	\$2,002,511	\$2.40
Romania	\$272,000	22,215	\$12,244	\$5,949,568	\$0.27
Russia	\$2,271,000	140,041	\$16,217	\$49,674,517	\$0.35
San Marino	\$1,662	30	\$54,808	\$36,354	\$1.20
Saudi Arabia	\$577,900	28,687	\$20,145	\$12,640,644	\$0.44
Serbia	\$79,770	7,379	\$10,810	\$1,744,842	\$0.24
Singapore	\$237,900	4,658	\$51,078	\$5,203,685	\$1.12
Slovakia	\$119,800	5,463	\$21,929	\$2,620,435	\$0.48
Slovenia	\$59,490	2,006	\$29,661	\$1,301,249	\$0.65
South Africa	\$492,200	49,052	\$10,034	\$10,766,093	\$0.22
Spain	\$1,402,000	40,525	\$34,596	\$30,666,523	\$0.76
Sri Lanka	\$92,090	21,325	\$4,318	\$2,014,322	\$0.09
Sudan	\$88,370	41,088	\$2,151	\$1,932,953	\$0.05
Sweden	\$345,100	9,060	\$38,092	\$7,548,514	\$0.83
Switzerland	\$318,100	7,604	\$41,831	\$6,957,932	\$0.91
Syria	\$99,060	20,178	\$4,909	\$2,166,780	\$0.11
Taiwan	\$713,700	22,974	\$31,065	\$15,611,054	\$0.68
Tanzania	\$54,380	41,049	\$1,325	\$1,189,476	\$0.03
Thailand	\$548,700	65,905	\$8,326	\$12,001,941	\$0.18
Tunisia	\$81,980	10,486	\$7,818	\$1,793,182	\$0.17
Turkey	\$903,900	76,806	\$11,769	\$19,771,377	\$0.26
Ukraine	\$338,600	45,700	\$7,409	\$7,406,337	\$0.16
United Arab Emirates	\$206,300	4,798	\$42,993	\$4,512,485	\$0.94
United Kingdom	\$2,236,000	61,113	\$36,588	\$48,908,948	\$0.80
United States	\$14,440,000	307,212	\$47,003	\$315,852,062	\$1.03
Uzbekistan	\$71,840	27,606	\$2,602	\$1,571,386	\$0.06
Venezuela	\$356,300	26,815	\$13,287	\$7,793,497	\$0.29
Vietnam	\$242,300	86,968	\$2,786	\$5,299,928	\$0.06
Yemen	\$55,410	23,823	\$2,326	\$1,212,006	\$0.05

It is expected that most countries would pay the minimum required amount. However, some countries may wish to increase the motivation of pharmaceutical companies to develop a new molecular entity to treat a condition for which there is currently no effective treatment. In this case, one or more countries may publically announce an increase in their contribution for the first firm that develops a new drug to treat this condition that is approved by the appropriate government agencies.

In exchange for receiving payments from participating countries, the pharmaceutical firms would not have exclusive rights to produce these drugs. Any drug manufacturer could produce these drugs and sell them in any participating country that approved the drug as well as in any and all free rider (poorer) countries. This competitive pricing arrangement would result in low costs to the consumer, while encouraging drug companies to develop new drugs. It would require international cooperation to dissuade cheaters from disrupting the scheme. A cheater would be a participating country (as defined in this document) who allowed the drug to be sold within their country without paying the pharmaceutical firm that created it. However, this would be fairly easy to police by existing international bodies.

In summary, the proposed system of country cost sharing would put the development of new prescription drugs on safe fiscal ground. It would allow poorer countries to receive state-of-the-art drugs at close to their production costs while wealthier countries would pay their fair share of development costs, while also benefiting from very competitive pricing for individual prescriptions. The amounts suggested in this proposal would need to be periodically reviewed by the appropriate regulatory agencies to keep up with inflation and changing economic trends, but would be a much fairer and more stable process than the current situation.

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