Hidden Price Tags: Disease-Specific Drug Donations: Costs and Alternatives*

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Summary

One-third of the world's population lacks access to essential drugs, often because of cost. These drugs could prevent or treat many of the communicable diseases that are killing 14 million people each year. As a response, some multinational pharmaceutical companies have initiated drug donations to combat specific diseases. Yet in its experience, Médecins Sans Frontières has witnessed serious drawbacks and problems with these donation programs. This paper examines the costs borne by the donor countries for drug donations. It also examines after-tax gains to the donor company and the impacts of tax incentives. The donation model is also compared with other models that can improve access to essential medicines, including the purchase of generics, concessionary pricing, discounted pricing, and differential pricing. The data show that drug donations can cost the public sector of a donor country (in this case, the United States) more than four times as much as other models that achieve the same end result; these models are to purchase either the lowest-priced quality generic on the world market, or the branded drug at a differential price. The data also show that the donor company does not have an incentive to lower its prices to a level affordable to the developing world, although its real manufacturing costs may allow it. The current system of incentives encourages drug donations over better policy options that would be more sustainable and less costly to the public. These other options also offer support to the generic industry and greater autonomy to developing countries in meeting their drug needs. In light of the numerous drawbacks to drug donations, they should neither be relied upon nor portrayed as a long-term solution to the ongoing crisis of access to essential medicines. National governments, NGOs, and intergovernmental organisations including the WHO, the World Bank, UNICEF, and UNAIDS, should promote solutions that are more sustainable than donations for the access crisis, such as encouraging generic production and negotiating dramatically reduced differential pricing for branded products. They should invest in the development of generic production and facilitate the use of TRIPS-compliant safeguards where appropriate. Finally, they should create a favorable policy framework that encourages differential pricing by proprietary pharmaceutical companies.

Introduction

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One-third of the world's population lacks access to essential drugs. In the most impoverished parts of Africa and Asia, this figure is over 50%. Yet infectious and parasitic diseases continue to kill 14 million people each year, 97% of these deaths occurring in developing countries.[1] The vast majority of deaths from infectious diseases are preventable. Effective vaccines and treatment to counter many of these diseases either already exist or could be developed on the basis of our current knowledge and technology. The lack of access to essential medicines underlines the existence of two different worlds in a global economy. In the industrialized world there is a huge choice of medicines, including those for non life-threatening ailments such as baldness and impotence. In the developing world, in contrast, there is no access to the most basic, life-saving medicines. The price of medicines remains a fundamental obstacle.

There are a number of strategies that could be aimed at addressing this access crisis, including stimulation of generic production or negotiation of meaningful price reductions. However, in recent years, the pharmaceutical industry's response to the access crisis has largely been to launch disease-specific drug donations. Why has the industry chosen this particular approach? What influences a company to give a donation? And finally, is this the best way to address the ongoing access crisis?

Médecins Sans Frontières (MSF) works in more than 85 countries and witnesses daily the consequences of the lack of access to lifesaving medicines. In addition, over the years, MSF has worked directly or indirectly with many drug-donation programs and has observed firsthand the problems inherent to this model. While MSF's field experience has uncovered a number of weaknesses in the drug-donation model, this paper will focus on one specific aspect—the relative costs of donation programs as compared to other possible measures, and the implications for future policy.

Background

Disease-specific drug donations: A new trend

There has been a noticeable increase in disease-specific drug-donation programs by major pharmaceutical companies in recent years. Among the best known are: Merck & Co.'s Mectizan donation program to treat onchocerciasis (river blindness) started in 1987 (and in which MSF has participated since 1998); Glaxo Wellcome's Malarone program for drug-resistant malaria, started in 1996; The International Trachoma Initiative, founded by Pfizer Inc. and the Edna McConnell Clark Foundation, which has provided the Pfizer product Zithromax since 1998; and the Global Programme to Eliminate Lymphatic Filariasis (also known as elephantiasis), a program initiated in 1998 by the World Health Organization and SmithKline Beacham to distribute SmithKline Beacham's product albendazole.

A recent survey[2] of 97 of the largest 150 companies in the United States (based on annual revenue as ranked by *Fortune*) indicated that US-based pharmaceutical companies account for a disproportionate share of corporate-product donations. The five pharmaceutical companies that responded represented more than 55% of the product donations of all 97 surveyed companies, but only 7% of the total cash donations.

According to the survey, Merck & Co., Johnson & Johnson, and Pfizer Inc. reported product donations worth more than US$ 100 million, and were the top three corporate donors in 1999. In contrast, not one pharmaceutical company figures among the top 20 corporate cash donors.

The five pharmaceutical companies in the survey reported product donations worth 66.1 to 85.7% of their total donations, and product donations were the fastest-growing segment of their philanthropy. Their combined product donations jumped from US$ 415 million in 1997 to US$ 611 million in 1999, a 47% increase in two years. Why are companies increasingly making such large product donations? What incentives exist for giving donations?[3] Finally, what are the costs and benefits to the recipients, public, and donors with these types of programs?

Drug donations: The Pros and Cons

There are a number of types of drug donations, including short-term responses to emergencies, such as natural disasters or wars; donations of existing inventory; or donations in response to specific diseases. (A number of studies stress that drug donations are not always appropriate.[4, 5, 6, 7, 8]) In addition to providing drugs, these programs may contain other components, such as administration and distribution systems, health education, training, and related medical services. This paper will focus on the product-donation component of disease-specific donation programs.

In some cases, drug donations can genuinely improve access to a medicine.[3] For example, when recipients—whether governments, NGOs or individual patients—cannot afford to pay for the drugs, or when no therapeutically equivalent generic is available, a drug donation can fill the gap for a limited period of time. However, data measuring actual improvements to access as a result of donation programs are scarce, since most of the major disease-specific drug donations have only been launched in the past few years.

One of the few figures available—from Merck's Mectizan donation program, the oldest such program—estimates that in 1998, 25 million people were treated with the drug in 32 countries. One of the program's strong points, which is unique to the Mectizan program, is the company's commitment to donate the drug "wherever needed for as long as needed." The Merck donation was implemented with a number of NGOs, whose work also was supported with public funding. Notably, onchocerciasis is endemic to a limited geographic area, can be eradicated, and has a simple treatment protocol, making an open-ended donation feasible. For many diseases, these favorable conditions do not apply.[9, 10]

One of the greatest dangers of donation programs is that they become relied upon and can lend the appearance that the problem of drug access has been solved, when, in fact, they do not address the problem adequately. Some drawbacks to the donation model include:

Sustainability

Because donations are completely contingent on the donor, they cannot be seen as long-term, sustainable solutions. As the current CEO of Merck & Co., Raymond Gilmartin, declared, "Giving our medicines away in general is an unsustainable and unrealistic answer because, at the end of the day, we must earn an adequate return on our investment in order to fund future research."[11]

Scale

The volume of donations by multinational pharmaceutical companies can only fill a fraction of the needs. For example, 95% of the 40 million people infected with HIV live in poor countries. Most people with AIDS in the developing world cannot afford the US$ 10,000 per year price of antiretroviral (ARV) treatment. Companies clearly do not have the capacity to donate ARV treatment (at US prices) to every patient in need. Likewise, the sheer scale of epidemics such as

TB and malaria precludes the possibility that donations alone can adequately address the problem.

Geographic and Quantitative Restrictions

Donors often restrict the number of regions or patients that can receive the donation, despite the existence of a greater level of need. Pfizer's offer to donate fluconazole to South Africa prompted Chris Ouma, MD, an MSF physician at Mbagathi Hospital in Nairobi, Kenya, to say, "We're very happy for the South Africans, but for me, as a Kenyan doctor, and for the Kenyan patients dying from cryptococcal meningitis, it doesn't help much." In Kenya, where Pfizer continues to hold the patent on fluconazole, the drug remains prohibitively priced, and the majority of patients diagnosed with cryptococcal meningitis die without treatment.

Indication Restrictions

Donors often restrict the indications for which the drug can be used, despite its broader usefulness. For instance, Pfizer's Zithromax donation, which is limited to trachoma, could also be used to treat sexually transmitted diseases (STDs) or acute respiratory infections.

Time Restrictions

Donors may restrict the duration of the donation. Such restrictions may be completely unrelated to public health objectives, such as target dates for disease eradication. The question inevitably arises, what happens after the donation ends?

Burden on Public Health Structures

Donations are often given through disease-specific (vertical) programs that require extensive administrative work for the receiving country and divert scarce human resources from existing health structures.[12] Donations should be integrated into the recipient country's drug procurement system, and not require the creation of separate programs.[3]

Distortion of Rational Drug Use

Public health priorities in recipient countries can be distorted by donations.[9] While drug prescriptions should be based on medical evidence, donated products can easily distort rational drug use, especially in resource-poor settings. For example, if a doctor has no first-line antibiotic available, but there is a donated third-generation antibiotic sitting on the shelf, rational drug use is very likely to be ignored. The wisdom of Glaxo Wellcome's donation of malarone—a second or third-line treatment for drug-resistant malaria in sub-Saharan Africa—has been questioned with regard to resistance-prevention.[13, 14, 15] Similarly, many questions have been raised at the WHO as to whether sufficient clinical evidence exists for using SmithKline Beacham's donated albendazole for lymphatic filariasis.[3]

Harmful Competition

Donations may negatively affect the development of the generic manufacturing industry in developing countries, as these producers cannot compete against free products. The developing world's capacity to manufacture quality, affordable generics will be a key part of the long-term solution to the access crisis, and the generic industry should be developed and allowed to compete on fair terms.

Delays

Access to donated medicine can be delayed by protracted negotiations, since agreements between donors and recipients tend to be more complex than standard commercial transactions. For example, Pfizer's fluconazole donation was announced in April 2000, but as of the writing of this paper, more than six months later, no patient in South Africa had received the drug. In contrast, patients participating in MSF projects in Cambodia and Guatemala, for example, have already started treatment with fluconazole, which has recently become available as an affordable, quality generic in their countries. For serious, life-threatening infections—such as those treated with fluconazole—delays mean not only extended suffering, but the difference between life and death.

Methodology

This paper will focus on comparing costs for several models aimed at increasing access to life-saving drugs for patients in developing countries. Information for this analysis was taken from a review of existing literature, publicly available figures on the pharmaceutical industry, personal interviews (see acknowledgments), and data from industry sources. The models are intended to demonstrate the public-sector costs of a drug-donation program and the incentives that are available to the donating company. In addition, the models look at several alternatives to donations (such as generic-drug purchasing, concessionary pricing, discounted pricing, and differential pricing) and examine how costs are distributed under these alternative models.

The following models are examined:

Model 1: Generic Purchasing

Public funds are used to purchase the lowest-cost, quality equivalent generic drug on the world market, in line with the WHO essential drugs policy.[16]

Model 2: Drug Donation

A pharmaceutical company carries out a disease-specific drug donation program.

Model 3: Concessionary Pricing

A pharmaceutical company provides a "concessionary price" for a specific drug, selling a relatively small proportion at full price and donating the rest (*e.g.*, 1 tablet at full price; 9 provided free).

Model 4: Price Reduction

4a Discounted pricing: A pharmaceutical company offers a price for developing countries that is discounted from the price charged in industrialized countries.[17]

4b**:** A pharmaceutical company offers a "differential price"—a dramatically reduced price that brings it within the range of affordability in the developing world. (By "differential pricing" this paper refers specifically to the level of price reduction that is currently used for some vaccines and contraceptives as defined by Pan-American Health Organization, WHO, and United Nations Population Fund.)

All models will be compared and the cost and the distribution of the cost analysed.

The examples will create a hypothetical situation in which a life-saving drug (DrugX), patented and sold by a US-based company (PharmaZ), is provided to a least-developed country (CountryY) that cannot otherwise afford it. We will assume that PharmaZ is governed by US tax law, and that the US government is the public body that will purchase DrugX for CountryY.

The analysis in this study is based on a number of assumptions.

1. PharmaZ is a profitable corporation that pays tax on its US income.
2. The company's drug donations make it eligible for an enhanced tax deduction, and the company claims the deduction to which it is entitled.
3. The cost of producing a branded drug for donation can be estimated as the marginal cost of production.
4. The "cost of goods" figure, which is an average of all of a company's products and is published in its annual report, is used as an estimate of the cost basis of the donated drug.
5. The average manufacturing cost is one-quarter of the cost of goods.
6. The marginal cost of production is 1 to 5% of full market value (FMV).
7. With economies of scale, marginal cost of production is much lower than average manufacturing cost.
8. Packaging and shipping costs for drugs, whether generic or branded, are assumed to be equivalent for all options.
9. The recipient country is a least-developed country (LDC).
10. The LDC's intellectual property laws allow the import of the lowest-cost generic.

Methodology of cost calculation

The analysis of all models will focus on the following issues:

- The cost of producing the drugs (packaging and shipping costs are assumed to be equivalent in all options)
- The cost to taxpayers in the donor country
- The after-tax gains to the donor company
- The costs incurred by the recipient country

Cost of producing the drugs:

Branded Drugs: The real manufacturing cost (as well as R&D and other costs) of a branded drug is a tightly guarded secret that is unavailable to the public and is considered proprietary information. In addition, no aggregate data are available for real manufacturing costs for the entire pharmaceutical industry.[18, 19] Therefore, this study relies on actual figures, estimates based on industry sources, and averages that can be taken from industry-wide materials, to arrive at conservative estimates of costs.

The cost of producing a branded drug for donation can be estimated as the marginal cost of production, because investments are computed on the basis of anticipated sales, not on donations. Therefore,

Cost of donated drug = Marginal cost of production

In order to deduce an estimate of the marginal cost of production, we will rely on the "cost of goods," a figure that is publicly available in a company's annual report. The cost of goods for research-based pharmaceutical companies excludes R&D expenses, marketing, and administrative costs, and typically ranges from 15 to 30% of sales.[20] Since the manufacturing cost of branded drugs is not publicly known,[18, 19] industry analysts estimate average manufacturing cost at a quarter of the cost of goods, *i.e.*, between 4% and 7.5% of sales, depending on the company.[21]

Cost of goods = 15 to 30% (sales)
Average manufacturing cost = 25% (cost of goods)
Average manufacturing cost = 25% (15 to 30%) (sales)
= 4 to 7.5% of sales

However, with economies of scale, this average manufacturing cost is much higher than the marginal cost of production, since many costs are fixed or have increasing returns to scale, and the industry does not operate at full capacity.[22] Depending on the drug and the company, we estimate that marginal cost of production ranges from 1 to 5% of the fair market value (FMV) of a proprietary product.

Marginal cost of production = 1 to 5% of FMV

An alternative way to estimate the manufacturing cost is to compare it to the selling price of the cheapest generic when there is significant competition in the market. For example, patent holders for ciprofloxacin and fluconazole sell their products in the United States at prices 40 to 68 times more than the lowest-cost available generic. (See appendix 1)[23] Assuming that the profit margin on the lowest-cost generic is 10%, then the production costs of the lowest-cost generics range from 1.3 to 3% of the fair market value of a proprietary product, which is in line with the 1 to 5% estimate above.

<u>Cost to taxpayers of the donor country:</u>

Model 1: Cost to US taxpayers: generic purchases

If the US government provides CountryY with a grant to purchase the cheapest quality generic drugs on the world market, the cost to US taxpayers will be the selling price of the cheapest generic manufacturer.

Cost to US taxpayer = Quantity (generic price/tablet)

Model 2: Cost to US taxpayers: drug donations

The cost to US taxpayers of product donations by a pharmaceutical company is the tax reduction (the amount by which the company's tax bill is reduced as a result of the donation).

Cost to US taxpayer = Lost tax revenue

Lost tax revenue = Tax reduction (for donor company)

A company can take a tax deduction only if it makes a profit, and deductions for donations of goods out of the inventory of a business are generally limited to the cost or basis of the goods. However, qualified contributions of pharmaceutical drugs can earn "enhanced deductions"[24] that are greater than the general deductions allowed for donated inventory. If the donation meets certain conditions,* the enhanced deduction will be based upon the lesser of:

1. The cost basis plus half the difference between the cost basis and FMV (FMV is the manufacturer's selling price in the United States):

Deduction = Cost basis + ½ (FMV – cost basis)

2. Twice the cost basis.

Deduction = 2 (cost basis)

Generally, the second option is the lesser number, so we will assume that the corporation is allowed to deduct up to twice the cost basis of the donated product from its taxable income. As the maximum corporate tax rate in the US is 35%, the company can lower its US income tax bill by up to 70% of the cost basis.

Deduction	=	2 (cost basis)
Tax reduction	=	35% (deduction)
	=	35% (2)(cost basis)
	=	70% cost basis

In this study we assume that the reported cost of goods—an aggregate figure covering the total costs to a company of producing all products—can be used as an estimate of the cost basis for one specific product. As the cost of goods typically ranges from 15 to 30% of sales,[25] the cost basis will likewise range from 15% to 30% of sales, and the tax reduction will then range from 10.5% to 21% of sales.

Cost of goods	=	Cost basis
Cost of goods	=	15% to 30% of sales
Cost basis	=	15% to 30% of sales
Tax reduction	=	10.5% to 21% of sales

*Pharmaceutical donations must meet the following conditions to qualify for an "enhanced deduction": The donated product is used solely for the care of the ill, needy or infants; the recipient must provide the donor a written statement that the donation is for qualified purposes; the recipient must be a US Code section 501(c)(3) corporation classified as a public charity. It can transfer the drugs to another exempt US organization, or a non-US organization that meets the same standards. The donor must be a C Corporation that pays the corporate income tax. The donated product must comply with FDA rules (such as expiration dates). The donated product cannot be resold or exchanged for property at any point. (From US Tax Code, Section 170(e)(3), amended 1986.)

Since sales are equal to FMV:

Cost basis = 15 to 30% of FMV
Tax reduction = 10.5 to 21% of FMV

Therefore, the cost to the taxpayer is 10.5% to 21% of the FMV of the donated product. However, it should be noted that a corporation might not be able to take advantage of the tax reduction in full, since deductions for charitable contributions are capped at 10% of a company's taxable income. Also, some companies may choose not to claim the tax deductions.

Model 3. Cost to US taxpayers: concessionary pricing

Cost to US taxpayer = Lost tax revenue – Price of drugs + Tax (price of drugs)

Model 4. Cost to US taxpayers: price reductions

Cost to US taxpayer = Price of drugs – Tax (price of drugs)

<u>After-tax gains to the donor company:</u>

In calculating the after-tax gains to the donor company, we will exclude the real manufacturing cost to the company.

Model 1. For generic purchases, after-tax gain is not applicable.

Model 2. For drug donations, after-tax gains will be computed as follows:

After tax gains = Tax reduction

Model 3. For concessionary pricing, after-tax gains will be computed as follows:

After tax gain = Tax reduction + Additional income – Tax (additional income)

Model 4. For price reductions, after-tax gains will be computed as follows:

After tax gain = Additional income – Tax (additional income)

<u>Costs incurred by the recipient country:</u>

Drugs Purchased: There is no additional cost to the recipient country if the US government gives a grant to purchase products that simply substitute for products that would have been imported anyway and if the consignment is handled by the national drug procurement system.

Drugs Donated: Additional costs incurred by the recipient country for the donation of drugs by a pharmaceutical company include the direct cost of complying with specific donor requirements such as separate distribution or management systems, wherever applicable. Other indirect costs

result from the stretching of scarce human resources, such as technical and administrative staff of health structures,[26, 12] since they are diverted from their normal duties. However, these costs are difficult to quantify and require further research.

Data Presentation

The following examples are provided to illustrate the relative costs of various models for improving poor patients' access to essential medicines in the developing world. The examples are hypothetical. Examples will be based on equations taken from the Methodology section and the following data:

Table 1 Summary of Cost Calculations

Summary of equations	**Data**
Cost of donated drug = Marginal cost of production Marginal cost of production = 1 to 5% of FMV Deduction = 2(cost basis) Tax reduction = 70% (cost basis)	Generic DrugX: US$ 0.30/tablet Branded DrugX: US$ 12.00/tablet PharmaZ's average cost of goods: 15% of sales (using the lower end of the average-cost-of-goods range)

Note: These prices are based on real price differences between generics produced in a competitive market and proprietary products.[23]

Table 2 Summary of Drug-Delivery Options

#	Model	Example
1	**Generic purchase:** Public funds are used to purchase the lowest-cost, quality equivalent generic drug on the world market, in line with WHO essential drugs policy.	The US government gives a grant to CountryY for the purchase of 100 million tablets of DrugX at the lowest price available for a quality generic, US$ 0.30/tablet.
2	**Drug Donation:** A pharmaceutical company carries out a disease-specific drug donation program.	PharmaZ donates 100 million tablets of DrugX to CountryY.
3	**Concessionary pricing:** A pharmaceutical company provides a "concessionary price" for a specific drug, selling a relatively small proportion at full price and donating the rest, *e.g.*, 1 tablet at full price; 9 given free.	PharmaZ offers a concessionary price, selling 2.5 million tablets of DrugX at the full US manufacturer's selling price—US$ 12/tablet—and donating another 97.5 million tablets, for a total of 100 million tablets to CountryY.
4	**Price Reductions:**	
4a	**Discounted Pricing:** A pharmaceutical company offers a price for developing countries that is discounted from the price charged in industrialized countries.	PharmaZ offers a 90% discount off the full US manufacturer's selling price of DrugX (US$ 12/tablet) Note: The 90% figure is based on the percentage often cited in the media following the May 2000 announcement of price reductions for AIDS drugs; the five companies who made the announcement did not specify the exact discounts to be offered).[27]
4b	**Differential Pricing:** A pharmaceutical company offers a "differential price"—a dramatic reduction that brings it to affordable levels for the developing world.	PharmaZ offers a differential price—US$ 0.30/tablet—for DrugX, which matches the lowest generic price.

Example 1. Generic Purchase: The US government gives a grant to CountryY for the purchase of 100 million tablets of DrugX at the lowest price available for a quality generic—US$ 0.30/tablet.

The purchase of 100 million tablets will cost the US government US$ 30million. This represents the cost (excluding packaging and shipping costs) borne by US taxpayers.

Cost to US taxpayer = Quantity (generic price/tablet)
= 100 million tablets (US$ 0.30/tablet)
= US$ 30 million

Example 2. Drug Donation: PharmaZ donates 100 million tablets of DrugX to CountryY.

If PharmaZ donates 100 million tablets, the donation will be valued at US$ 1.2 billion, based on the fair market value of US$ 12 per tablet.

FMV = 100 million tablets (US$ 12/tablet)
= US$ 1.2 billion

Assuming that PharmaZ's published average cost of goods, 15%, is similar to its cost basis for DrugX, the company can claim a deduction of twice its cost basis. That is,

Cost basis = (Cost of goods)(FMV)
= 15% (US$ 1.2 billion)
= US$ 180 million

Deduction = 2 (cost basis)
= 2 (US$ 180 million)
= US$ 360 million

PharmaZ's tax bill can be reduced by 35% of the deduction, so its after-tax gain is US$ 126 million.

Tax reduction = 70% (cost basis)
= 70% (US$ 180 million)
= US$ 126 million

The cost of this donation to the US government, and therefore to the US taxpayer, is US$ 126 million in lost tax revenue.

Exploring Incentives: Donations vs. Price Reductions

In addition to its various donation programs, the pharmaceutical industry may also offer price reductions for developing countries that cannot otherwise afford essential medicines. In May

2000, five major pharmaceutical companies, in conjunction with UNAIDS (which comprises the WHO, UNICEF, and World Bank), announced just such a price reduction for AIDS drugs.[28, 29] While "discounted pricing" and "differential pricing" both refer to price reductions, this study makes a key distinction between the two based on the extent of the reduction.

Example 3. Concessionary Pricing: PharmaZ offers a concessionary price, selling 2.5 million tablets of DrugX at the full price of US$ 12/tablet and donates another 97.5 million tablets, for a total of 100 million tablets to CountryY.

We assume here, for the sake of comparison, that the concessionary price will result in an average price per tablet that matches the cheapest generic price of US$ 0.30/tablet. If PharmaZ sells US$ 30 million worth of DrugX at full price and donates the remainder, it will mean 2.5 million tablets sold at US$ 12/tablet and 97.5 million tablets donated.

2.5 million tablets (full price) + 97.5 million tablets (donated)	=	100 million tablets
2.5 million tablets (US$ 12/tablet) + 97.5 million tablets (US$ 0/tablet)	=	US$ 30 million
Average price per tablet	=	US$ 0.30

PharmaZ's tax reduction for the donated tablets will be US$ 122.85 million, computed as follows:

FMV of donation	=	97.5 million tablets (US$ 12/tablet)
	=	US$ 1170 million (or US$ 1.17 billion)
Cost basis	=	15% (FMV)
	=	15% (US $1.17 billion)
	=	US$ 175.5 million
Tax reduction	=	70% (cost basis)
	=	70% (US$ 175.5 million)
	=	US$ 122.85 million

In addition to the tax reduction, PharmaZ has received US$ 30 million in payments from the US government for the 2.5 million tablets, which will then be taxed at 35%. Therefore, the total after-tax gain to PharmaZ is US$ 142.35 million, which can be computed as:

After tax gain	=	Tax reduction + Additional income – Tax (additional income)
	=	US$ 122.85 million + US$ 30 million – 35% (US$ 30 million)
	=	US$ 142.35 million

The cost to the US taxpayer will be US$ 142.35 million, which can be computed as:

Cost to US taxpayer	=	Lost tax revenue – Price of drugs + Tax (Price of drugs)
	=	US$ 122.85 million - US$ 30 million + 35% (US$ 30 million)
	=	US$ 142.35 million

Example 4a. Price Reductions: Discounted Pricing.: PharmaZ offers a 90% discount from the full price of DrugX (US$ 12/tablet).

PharmaZ chooses to offer a discount on DrugX, selling it at a 90% discount to developing countries. CountryY buys 100 million tablets with funding from the US government at a cost to US taxpayers of US$ 78 million, computed as follows:

Price of drugs	=	90% discount of US$ 12/tablet
	=	10% (US$ 12/tab.)
	=	US$ 1.20/tablet (100 million tablets)
	=	US$ 120 million
Cost to US taxpayer	=	Price of drugs – Tax revenue(price of drugs)
	=	US$ 120 million – 35% (US$ 120 million)
	=	US$ 78 million

The after-tax gain to PharmaZ is also US$ 78 million, computed as follows:

After-tax gain	=	Additional income – Tax (additional income)
	=	US$ 120 million – 35% (US$ 120 million)
	=	US$ 78 million

Example 4b. Price Reductions: Differential Pricing. PharmaZ offers a differential price of US$ 0.30/tablet for DrugX that matches the lowest generic price.

PharmaZ offers a differential price, reducing its price to US$ 0.30/tablet and matching the generic price. The cost to CountryY, and therefore to the US taxpayer, is US$ 19.5 million.

Price of drugs	=	US$ 0.30/tablet (100 million tablets)
	=	US$ 30 million
Cost to US taxpayer	=	Price of drugs – Tax revenue(price of drugs)
	=	US$ 30 million – 35% (US$ 30 million)
	=	US$ 19.5 million

The after-tax gain to PharmaZ is also US$ 19.5 million, computed as follows:

After tax gain	=	Additional income – Tax (additional income)

= US$ 30 million – 35% (US$ 30 million)
= US$ 19.5 million

Incentives and Costs

Having examined the options for reduced prices, it is useful at this point to determine the price level below which there is no tax incentive for PharmaZ to reduce prices. To match the financial incentive of a donation, a sale at reduced price would have to generate an after-tax gain of US$ 126 million, or in other words, additional income from sales of US$ 193.85 million.

Net gain ≥ US$ 126 million, if
Income ≥ US$ 193.85 million, since
After tax profit ≥ US$ 193.85 million – 35% (US$ 193.85 million)

This means that the company has no financial incentive to sell DrugX below US$ 1.94 a tablet (price reduction of 84%), since:

100 million tablets ($ **X**/tablet) ≥ US$ 193.85 million
X ≥ US$ 1.94/tablet
Price per tablet must be ≥ US$ 1.94/tablet

Although PharmaZ has no incentive to lower its price below US$ 1.94/tablet, its estimated marginal costs of production fall far below that, to US$ 0.12 to US$ 0.60/tablet. Referring back to the methodology section, we can estimate real manufacturing cost for a donation (based, again, on industry analysts' estimations of marginal costs of production, which are not publicly known) as follows:

Real manufacturing cost = Marginal cost of production
Marginal cost of production = 1 to 5% (US$ 1,200 million)
= US$ 0.12 to US$ 0.60/tablet

Table 3 Compiled Results from Examples 1-4b (in US$)

#	Model	Cost to US taxpayer	After tax gain to PharmaZ*	Marginal cost of production
2	Drug Donation	$126 million	$126 million	$12 - $60 million
3	Concessionary Pricing	$142.35 million	$142.35 million	$12 - $60 million
4b	Discount Pricing	$78 million	$78 million	$12 - $60 million
4b	Differential Pricing	$19.5 million	$19.5 million	$12 - $60 million

*Production costs of the 100 million tablets have not been included in the calculations; the main purpose here is to highlight the difference in potential gain between a donation and price reduction generated by existing US tax law. Calculations do not include the marginal cost of production to the company.
** This figure assumes that the generic manufacturer is making a profit.

Sensitivity Analysis

There are three variables in the models discussed in this paper. These are:

- The basis cost of goods on which the deduction is based
- The marginal cost of production; and
- The difference between the selling prices of the patent holder in the US and the lowest-cost generic manufacturer.

The first two are not publicly known, as this is proprietary information of pharmaceutical companies.
Our estimate for the basis cost of goods (on which the deduction is based) ranges from 15% to 30% of the fair market value of the drug. Our example, based on the lower figure, offers a conservative view of the tax reduction the company claims, and is the lower estimate of the cost of a donation to US taxpayers. If the basis cost of goods is higher than 15%, the cost-effectiveness of models 2 and 3 (donation and concessionary prices) decreases further.
We estimate that the marginal cost of production ranges from 1% to 5% of the fair market value of a drug. Our example, based on the higher figure, is at the higher end of the estimated cost of production for the company. If the marginal cost of production is less than 5%, the cost of the donation to US taxpayers remains unchanged, and so does its cost-effectiveness when compared with the purchase of a generic. However, the overall gain for the company increases.
The difference between the selling prices of the patent holder in the US and the lowest-cost generic manufacturer has been estimated at between 30x and 68x. In our example, we have assumed that it is 40x. If the difference is higher, the cost of the donation to US taxpayers increases, and its cost-effectiveness further decreases when compared with the purchase of the lowest-cost generic. In contrast, the difference between the selling prices of the patent holder in the United States and the lowest-cost generic manufacturer may be lower than 40x. However, for the donation option to be more cost-effective than the lowest-cost generic in our example, the generic would have to cost at least US$ 1.26, *i.e.*, a price difference of 9.5x with the branded product. This is much lower than the price difference for drugs currently donated, including azithromycin, ciprofloxacin, or fluconazole. However, where there is less competition among generic manufacturers, the donation option could remain cost-effective for US taxpayers until competition among generic manufacturers brings prices down.

Discussion

These examples demonstrate that, of the various options for delivering DrugX to CountryY, the least expensive options for the US public are either to buy the lowest-price quality generic on the world market (Model 1), or to buy the drugs from PharmaZ with differential pricing (Model 4b). The three other options will cost the public sector considerably more. The most expensive option for the public is for PharmaZ to offer a concessionary price (Model 3), closely followed by the option to make a donation (Model 2). The next most expensive option is for PharmaZ to discount its price by 90% (Model 4a).

What do these examples indicate about the system of incentives to the pharmaceutical industry? If generics are purchased from another manufacturer, PharmaZ does not gain anything (Model 1). But there is a significant after-tax gain for the company if it offers a concessionary price (Model 3) or makes a drug donation (Model 2). Likewise, the company will still have an after-tax gain if it engages in discounted pricing or differential pricing. However, there is no financial incentive for PharmaZ to lower its price below the US$ 1.94/tablet level. It has much more to gain from making a donation than from selling at a differential price. Finally, if we look at the estimates of marginal cost of production, PharmaZ's after-tax gains exceed the

manufacturing costs in all cases except under the differential-pricing model, which was inconclusive.

Our analysis dwells on the comparison of theoretical models. The actual cost of drug donations to US taxpayers remains unknown, as IRS figures do not provide a breakdown between cash and product deductions. According to the IRS, as reported by the General Accounting Office,[30] many companies do not take advantage of enhanced deductions. In addition, a given corporation may not be able to take advantage of tax reductions in full, as deductions for charitable contributions are capped at 10% of a company's taxable income. But it should also be noted that the drug industry has the lowest average effective tax rate of all industries (16.2% for 1993 to 1996 according to Congressional Research service).[31]

This study is meant to illustrate the relative costs of various models and cannot demonstrate why companies choose to make product donations. Companies may have motivations other than philanthropic ones for donating products, including: improving public image,[32, 33, 34] protecting patents, or responding to public pressure. These issues require further investigation. Also, since tax laws regulating donated drugs differ considerably by donor country, further study should focus on other countries with sizeable proprietary pharmaceutical companies.

However, the existing system of financial incentives reinforces, if it does not significantly impact, a company's decision to initiate a drug donation program. At the same time, the tax-incentive system discourages the use of the least expensive options for the public sector—the purchase of generics or differential pricing. It is also possible that donations create a disincentive toward local generic production. These effects may be limited in countries with little drug-manufacturing capacity, but decisive in other developing countries, which are unable to compete in their export markets with drugs entirely subsidized by rich countries. Perhaps policy makers should re-examine the consequences of the current system of incentives, and examine alternatives for the better use of public funds. It may also be the case that, because of the tight scrutiny of the foreign aid budget by the US Congress, the US government has favored a more costly option, since the cost of tax breaks is much less visible to voters. Policy changes should be considered that would actually encourage, rather than deter, differential pricing or generic purchasing.

Examined through the lens of cost, drug donations are not a wise use of scarce public resources. Looking at the wider picture, it becomes even more apparent that donation programs cannot be considered a solution to the global access crisis. For example, donations undercut, rather than encourage, the independence of developing countries. More and more, developing countries are actively taking a larger role in determining their own affairs, including in the area of public health. Engaging in differential pricing so that developing countries can buy their own medicines, or encouraging the generic industry so that they can produce them, means that these countries retain more control over their drug supply.

The landscape for the generic industry will soon be changing. With the implementation of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which will be complete for all WTO member countries by 2006, producers will not be able to manufacture generic versions of newer medicines since new patents will be valid for a minimum of 20 years. This change will leave fewer choices for developing countries, *i.e.*, drug donations, significant differential pricing, and TRIPS-compliant safeguards. National legislation in developing countries should protect public health by making full use of allowances under TRIPS, such as generic drug production under voluntary or compulsory licensing (the granting of a license to a third party without the consent of the patent holder) and parallel importing (which allows a

country to import a branded drug from another country where it may be sold for less). Faced with a narrowing field of options, it is essential that we examine now the most sustainable and least expensive options.

It is also important to note that the examples in this paper focused on a very specific situation: foreign aid from the United States to a least-developed country, focusing on the cost to the donor country. When examining drug donations and other mechanisms for improving access to medicines, key differences between least-developed and developing countries should be taken into account. For emerging economies such as those of South Africa, Brazil, India, and Thailand, a separate study is needed to assess the costs of the various models for individual governments.

The question of cost also should be examined from the perspective of developing and least-developed countries, as drug donations can be both beneficial and burdensome to the countries receiving them. For example, more AIDS patients in South Africa will have access to fluconazole if Pfizer's donation program is implemented as currently designed, but the onerous documentation requirements of a vertical program may put serious burdens on the health structure.[35] However, further study is needed to weigh the costs and benefits of these donations to the recipient countries.

Recommendations and Conclusions

Based on this study's findings and MSF's extensive experience with drug-donation programs in the developing world, MSF has made the following recommendations to national governments, NGOs, and intergovernmental organizations including the WHO, World Bank, UNICEF, and UNAIDS:

1. Single-disease drug donations should not be encouraged as solutions to the global access problem. These programs are unsustainable, restrictive, harmful to the development of long-term solutions like generic production, and cost more to donor countries than other approaches. Rather, incentives should be designed to encourage strategies such as generic production and differential pricing, which maximize scarce public resources and donor funds.

2. The purchase of quality generics on the world market is one of the most promising models for improving access to medicines in the long-term. Therefore, the development of generic industries in the developing world should be encouraged. After the implementation of TRIPS is completed in 2006, countries' efforts to implement public health safeguards should also be promoted and facilitated.

3. Differential prices for the developing world for proprietary drugs should be promoted. The success seen with differential pricing for vaccines and contraceptives should be built upon for essential medicines (see Appendix 2). A policy framework favorable to differential pricing by proprietary pharmaceutical companies should be created and supported by all actors, including national governments, NGOs and intergovernmental bodies.

Further research is needed. The examples included in this report were hypothetical situations based on the most accurate estimates feasible, given the information available. Much additional research is needed on:

How donation programs directly impact access in reality—are there measurable improvements or consequences? Further information is needed about programs that have been initiated in the last few years, including assessments of the distribution of costs to all actors involved. The direct and indirect costs and benefits of donations to recipient countries, addressing the issues of distortion of rational drug use, disruption to existing public health structures, and diversion of scarce health resources. The impact of drug donations on the development of the generic industry.
Accurate assessments of costs within the proprietary pharmaceutical industry, including detailed estimates of real manufacturing costs, R&D expenditure, and tax deductions.

For many infectious diseases devastating the developing world today, effective treatments exist but remain out of reach because they are too expensive. At the same time, public resources devoted to combating these diseases are limited and should be spent in the most effective way. The relatively higher costs of drug donations to the donor country make them an ill-considered policy option. While donations can certainly be useful in the short term, they are also saddled with multiple drawbacks. Generic production and differential pricing present major advantages over drug donations. Both options would decrease costs to donor countries and diminish reliance on donors. As an organization that witnesses daily the human consequences of the lack of affordable medicines, MSF has called on responsible parties to prioritize the best, sustainable solutions to the access crisis.

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Appendix 1: Selected Proprietary and Generic Drug Prices

(From: Pérez-Casas, Carmen et. al. "HIV/AIDS medicines pricing report. Setting objectives: is there a political will?" Médecins Sans Frontières, 6 July 2000.)

Best price found for drugs produced by reliable manufacturers, in US$

	Ceftria-xone 1 g vial	**Ciproflo-xacin** 250 mg tablet	**Didano-sine** 100 mg capsule	**Efavi-renz** 200 mg capsule	**Flucona-zole** 200 mg capsule	**Lamivu-dine** 150 mg capsule	**Nevira-pine** 200 mg capsule	**Stavu-dine** 40 mg capsule	**Zidovu-dine** 100 mg capsule	**Zidovu-dine +lamivu-dine** 300+150 mg capsule
Brazil	N/A	N/A	**0.5**	2.3	N/A	**0.8**	2.5	**0.3**	**0.2**	**0.7**
Colombia	7.2	**0.05**	**0.8**	3.3	**0.4**	**1.7**	4.3	2.4	**0.7**	N/A
Guatemala	**1.8**	**0.05**	2.3	3.4	**0.6**	2.4	N/A	4.2	**0.4**	**3.9**
India	**1.8**	N/A	N/A	N/A	**0.6**	**0.5**	**2.1**	**0.6**	**0.2**	**0.9**
South Africa	10.9	0.40	*0.7	*2.4	4.1	1.1	*3.0	*2.5	0.4	1.5
Thailand	**1.7**	**0.06**	**0.7**	2.7	**0.3**	2.5	3.5	**0.4**	**0.2**	2.3
Uganda	*4.4	***0.14**	1.3	N/A	*1.3	1.6	*4.7	3.1	0.7	3.7
US (wholesale price)	N/A	3.40	1.8	4.4	12.2	4.5	4.9	4.9	1.7	9.8
Price differential: US vs best price		**68.0 x**	**3.6 x**	**1.9 x**	**40.6 x**	**9.0 x**	**2.3 x**	**16.3 x**	**8.5 x**	**14.0 x**
Price differential:US vs best price (%)		98%	72%	48%	98%	89%	56%	94%	88%	93%

Prices of drugs produced by a manufacturer other than the originator of the brand drug are highlighted in **bold**.
N/A indicates that prices were not available at the time this report was written.
* non-institutional prices

Appendix 2: Vaccine and Contraceptive Price Tables

(From Pérez-Casas, Carmen et. al. "HIV/AIDS medicines pricing report. Setting objectives: is there a political will?" Médecins Sans Frontières, 6 July 2000.)

Comparison of 1999 vaccine prices per paediatric dose
US domestic vs PAHO Prices

Vaccine	OPV (Oral Polio Vaccine)	MMR (1-dose vials)	Measles (1-dose vials)	Recombinant Hepatitis B (1-dose vials)	Hib (10-dose vials)
US private sector (catalogue) price/dose*	$ 10.93 (1-dose vials)	$ 27.46	$ 10.40	$ 24.20	$ 15.88
US government (CDC) price per dose*	$ 2.90 (1-dose vials)	$ 14.69	$ 6.51	$ 9.00	$ 4.75
price differential: US private vs public sector	3.8 x	1.9 x	1.6 x	2.7 x	3.3 x
PAHO price per dose	$ 0.087 (10-dose vials)	$ 0.88	$ 0.68	$ 0.92	$ 2.18
price differential: US government vs PAHO prices	33.3 x	16.7 x	9.6 x	9.8 x	2.18 x
price differential: US private sector vs PAHO prices	125.6 x	31.2 x	15.3 x	26.3 x	7.3 x

Source: PAHO (Pan-American Health Organization), WHO - 1999

Comparison of 2000 contraceptives prices US domestic vs UNFPA prices

US $	Condoms	Oral contraceptives	Injectable contraceptives
UNFPA	0.02 / pc	0.14-0.23 per cycle	0.70 / dose
US wholesale	0.59 / pc	24 / cycle	35 / dose
US retail	0.83 / pc	30 / cycle	65 / dose
price differential US retail vs UNFPA	42 x	130-214 x	93 x

Source: UNFPA, 2000