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Center for Science in Public Policy

The Pharmaceutical Industry's Contributions to The United Nations Millennium Development Goals

Jeremiah Norris

Carol Adelman

Yulya Spantchak

Kacie Marano

Hudson Institute
1015 15th Street, NW
6th Floor
Washington, DC 20005
www.hudson.org

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I. Introduction

Member States of the United Nations unanimously endorsed the Millennium Declaration on September 8, 2000. One of its provisions resolved “to encourage the pharmaceutical industry to make essential drugs more widely available and affordable to those who need them in developing countries.”¹ Then, in late September, the UN established the Millennium Development Goals (MDGs), drawing its authorization from the original Declaration. There are eight goals that address a variety of global issues, including education, poverty, environment, and health. The Goals were set to be achieved by 2015, with indicators applied to measure progress. For example, to measure poverty reduction, the number of people living under \$1.25 per day is tracked. To measure progress in reaching universal education, primary school enrollment is tracked.

While most of the MDGs have concrete and measurable indicators, MDG 8 presents a more ambiguous goal to build a global partnership for development. It has numerous components including increasing access to markets, increasing official development assistance, easing the debt burden for developing nations, improving cooperation with the private sector, and increasing cooperation with pharmaceutical companies to provide access to affordable essential drugs. Within Goal 8, Target 8E is particular to the Declaration’s provisions on the pharmaceutical industry. It states: “In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries.” Target 8F also has applications to the pharmaceutical industry in that it seeks to achieve the MDGs “in co-operation with the private sector [and] make available the benefits of new technologies.” Thus, the Millennium Declaration and goal 8 of the MDGs constitute an effort by the UN to engage the pharmaceutical industry in alleviating disparities in global access to medicines.

This White Paper by Hudson Institute’s Center for Science in Public Policy (CSPP) is the outcome of a comprehensive research effort conducted over a period of 18 months to measure pharmaceutical companies’ contributions over a 12 year period, from 2000 through 2011. We looked at how and in what manner the pharmaceutical industry broadly responded to the Millennium Declaration. This paper discusses past attempts to measure progress in achieving the MDGs and the gap in evaluation that this paper begins to fill. The study provides the global monetary and non-calculated values of pharmaceutical contributions from 2000 through 2011. We hope that this research can provide lessons learned for other disease categories, including non-communicable diseases, which may challenge the capabilities of developing countries. The pharmaceutical companies’ past response to the Millennium Declaration may well be seen as a platform from which the global health community can extend its expertise for continued improvements in the lives of millions of people.

¹. UN General Assembly, *United Nations Millennium Declaration, Resolution Adopted by the General Assembly*, 18 September 2000, A/RES/55/2

II. Background

A recent document that measures MDG progress, the *Millennium Development Goals Report 2012*, reviewed all eight of the MDGs.² While some components of MDG 8 were assessed, the portion that addressed the pharmaceutical industry was not mentioned. Thus, the actual cooperation with the pharmaceutical industry in supplying drugs and providing access to essential medicines has not been measured or reported on.

When developing the MDGs, the United Nations created a set of indicators to measure progress on achieving these goals. To measure MDG Target 8E, the UN's indicator is to gauge the percentage of the population having sustainable access to affordable essential medicines.³ According to *MDG Gap Task Force Report 2011* on MDG 8, only 42% of public sector facilities and 64% of private sector facilities had made essential medicines available to the public. Furthermore, in developing countries the cost of medicine both in the public and the private sectors is significantly higher than the international price for the medicine. While generic drugs are cheaper, many providers in developing countries do not trust the validity of generic drugs. Despite the setbacks in drug availability, the report also noted that pharmaceutical companies are taking numerous steps to help achieve Target 8E. For example, pharmaceutical companies have taken on valuable public-private partnership programs to improve access and development for essential medicines, and most companies also take into consideration economic discrepancies when pricing their medicines.⁴

While the United Nations has evaluated the percentage of the population that has access to essential medicines, few assessments have been made to measure the total contributions of the pharmaceutical industry to reaching MDG Target 8E. Many other factors, such as government transparency and distribution, affect the availability of medicines. For instance, supply chain management is a perennial problem. It can take as long as six months between the time an order is placed with an international drug supplier and its arrival in country. Government procurements usually are shipped into a central warehouse before being disbursed to clinics and hospitals in a timely manner. This is often referred to as the 'last mile' before a drug actually reaches a patient. At the 2006 World Health Assembly, the WHO released findings from a two year study which showed that taxes and duties on medicines, as well as mark-up applied, often contribute

² United Nations Department of Economic and Social Affairs. *The Millennium Development Goals Report 2012*. United Nations. Web.
<<https://www.unfpa.org/webdav/site/global/shared/documents/publications/2012/MDG%20Report%202012.pdf>>

³ United Nations Development Group. *Indicators for Monitoring the Millennium Development Goals*. Rep. no. ST/ESA/STAT/SER.F/95. United Nations, 2003. Web.
<<http://www.undp.or.id/mdg/documents/MDG%20Indicators-UNDG.pdf>>

⁴ United Nations, *Millennium Development Goal 8: The Global Partnership for Development: Time to Deliver. MDG Gap Task Force Report 2011*, 2011, Web.
<http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2011/mdg8report2011_engw.pdf>

to the final price more so in comparison to the manufacturers original price.⁵ For these reasons, using the percentage of the population that has access to essential medicines is not necessarily a good indicator for “cooperation” of the pharmaceutical industry, which has been instrumental in contributing to improving healthcare in developing countries.

Since the launch of the MDGs, the pharmaceutical industry has engaged in a variety of activities to increase access to medicines. While the United Nations has focused on estimating the availability of medicines, which is often dependent on factors outside of the pharmaceutical industry’s control, efforts to measure the actual contributions of the industry towards Target 8E have been lacking.

A previous attempt at measuring pharmaceutical industry’s contributions to the MDGs was published in a 2006 study by the London School of Economics. The study was commissioned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).⁶ The IFPMA conducted a survey on the cash and in-kind commitments made by the pharmaceutical industry. This report attempted to assess the value of in-kind drug donations and the number of “positive health interventions” made by the industry. Interestingly, the study noted that assessing the value of monetary contributions is difficult due to the various in-kind contributions that are not assigned a value, such as training of professionals. Furthermore, some initiatives are carried out by third party organizations, making the assessment of an individual company’s contribution difficult. This report did not include research and development costs due to a difficulty in measuring such contributions. As a result, the authors noted that the results of the report were an underestimation of the pharmaceutical industry’s total contributions to the MDGs. Another example of the reports’ lack of comprehensive data was that the report only covered members of the IFPMA, rather than all global pharmaceutical firms. According to the study, IFPMA members contributed a total of \$4.4 billion to MDG related projects by the end of 2005.⁷

In 2010, the IFPMA followed up with a subsequent study. While it did not publish any global monetary figures on industry’s contributions to access to medicines, it was much more detailed on members’ specific programs by disease category. In some cases, the IFPMA provided a monetary value to each member’s project, while in others they were discussed only in narrative form. This 2010 study by the IFPMA was a key source of data for this White Paper.⁸

⁵ World Health Organization. *The Price, Availability, and Affordability of Medicines for Chronic Diseases*. World Health Organization. Geneva, 2006.

⁶ Kanavos, Panos, PhD, Tony Hockley, and Caroline Rudisill. "The IFPMA Health Partnerships Survey: A Critical Appraisal." The London School of Economics & Political Science, Mar. 2006. Web. <http://www.policy-centre.com/downloads/IFPMA_LSE_Report_08Mar06.pdf>.

⁷ Ibid.

⁸ International Federation of Pharmaceutical Manufacturers and Associations. *Developing World Health Partnerships Directory 2010*. Web. <http://www.ifpma.org/fileadmin/content/Publication/IFPMA_Partnerships_Directory_Full_2010.pdf>

III. Research Description

Since a significant amount of the industry's contributions have not been reported, this report attempts to fill this gap and add to previous research. The study details some of the ways in which pharmaceutical companies have contributed to achieving MDG Target 8E and 8F. Specifically, it assesses the dollar value of all contributions made by the pharmaceutical industry to international global health over a 12 year period. To assess the pharmaceutical industry's role in the UN Millennium Declaration, Hudson Institute reviewed corporate social responsibility reports, corporate press releases, published reports on public-private partnership initiatives in global health, and conducted phone calls with individuals within the companies reviewed. We then compiled all available data on pharmaceutical companies' contributions from the MDG Declaration in 2000 through 2011.

To ensure the best estimate possible, the study looks at the following categories of contributions: product donations, cash contributions, other in-kind donations and items for which monetary values are not calculated. In addition to monetary contributions, Hudson went further to measure areas of pharmaceutical contributions that are often overlooked. The non-monetary items include the following: voluntary license transfers, royalty-free license transfers, providing medical compounds for libraries, clinical trials for neglected diseases and institutional capacity building.

While collecting this data, we encountered several issues. In general, companies do not have strict reporting requirements for their contributions. While individual initiatives are well documented, overall company involvement had to be pieced together through various reports and interviews. In some cases, a value could not be estimated for certain types of contributions. It is not that these items are without value; rather the values were not fully recorded by companies. Often they were presented in narrative form, absent of any monetary values. Secondly, many in-kind donations did not have monetary values placed. Therefore, Hudson made conservative estimates for these donations. All estimates are explained thoroughly in the methodology. Because of the difficulty in finding companies' total contribution amounts and the conservative estimates of in-kind donations; the total amount reported is likely to be underestimated. Yet, our figures are substantially higher than the previously mentioned IFPMA study, largely because Hudson's study covers global pharmaceutical firms rather than just companies that are part of one membership organization.

Hudson Institute's analysis found an estimated total of over \$94.8 billion in contributions by 29 pharmaceutical companies since the creation of the MDGs in 2000 through 2011. This report demonstrates that the pharmaceutical industry has contributed both product donations and a wide array of capacity building interventions that have strengthened local healthcare institutions. The pharmaceutical industry's involvement in global health illustrates the importance of combining treatment with the strengthening of local capacity and institutions. The global health community is now coming to the realization that institution building should be a key priority.

IV. Findings

To assess the pharmaceutical industry's role in the UN Millennium Declaration, Hudson Institute analyzed both monetary and non-monetary contributions from pharmaceutical companies. Table 1 provides the total values of contributions delineated by category covering the period of 2000 through 2011. The monetary values are broken down into the following: product donations, cash donations, and other in-kind donations. Non-monetary values include voluntary license transfers, royalty-free license transfers, library of medical compounds, number of clinical trials for neglected diseases and institutional capacity building. In total, the sector provided over \$94.8 billion from 2000 through 2011.

Table 1. Monetary & Undetermined Values of Pharmaceutical Contributions 2000 - 2011

Contribution	(Billions of US\$)	(Specified units)
Product Donations	\$75.740	
General Product Donations	\$74.220	
Discounted Products and not-for-profit pricing	\$1.520	
Cash Donations	\$8.910	
General Cash Donations	\$7.680	
Capital Investments in Capacity Building	\$0.725	
Operating Costs of Capital Investments	\$0.503	
Other In-Kind Donations	\$10.180	
Transfers of Production Technology	\$0.070	
Volunteerism	\$0.002	
Number of healthcare staff trained/educated	\$0.006	1,190,800 individuals
Costs-Avoided in Pre-clinical ARV Drug Development by generic producers	\$10.100	
Voluntary License Transfers*	-	54 licenses
Royalty-free license transfers*	-	11 licenses
Library of Medical Compounds*	-	50,000 medical compounds
Clinical Trials for Tropical Diseases*	-	10 clinical trials
Institutional Capacity Building*		14 institutions
TOTAL	\$94.830	

* The monetary value for these contributions are undetermined.

In all, Hudson was able to identify contributions from 29 different pharmaceutical companies, representing 75% of the top twenty Pharmaceutical companies in the world based on 2010 revenue.⁹

Abbott Laboratories	Merck
AstraZeneca	Novo Nordisk
Bayer Healthcare LLC	Novartis
Becton, Dickinson & Company	Otsuka
Boehringer Ingelheim	Pfizer
Bristol-Myers Squibb	Ranbaxy
Cumbre Pharmaceuticals Inc.	Roche
Daiichi Sankyo, Co.	Sanofi-Aventis
Eisai Co, Ltd.	Schering-Plough
Eli Lilly and Company	Takeda Pharmaceuticals
Gilead Sciences	TULIPE
GlaxoSmithKline	United Therapeutics
Japan Pharmaceutical Manufacturers Association	Wyeth Pharmaceuticals
Johnson and Johnson	ViiV Healthcare
Lundbeck Inc.	

Hudson Institute's identification of over \$94.8 billion in pharmaceutical contributions is quite significant, especially when compared to government aid allocations for global health. For example the U.S. Congress allocated \$20 billion to USAID for global health activities from 2001 – 2010, far less than contributions from pharmaceutical companies in a similar time period.¹⁰ In 2005, the Millennium Project estimated between \$82-152 billion of additional dollars needed to reach the MDGs by 2015.¹¹ The pharmaceutical industry has already contributed over 60% of this figure.

An important component in this study is not only the dollar value of donations by pharmaceutical companies, but also the types of contributions mentioned that are often overlooked. Each category of contributions is broken down, assessed, and described below.

⁹ Roth, Gil Y. "The Top 20 Pharmaceutical Companies." *Contract Pharma*. N.p., 14 July 2011. Web. <http://www.contractpharma.com/issues/2011-07/view_features/the-top-20-pharmaceutical-companies/>

¹⁰ Salaam-Blyther, Tiaji. "USAID Global Health Programs: FY2001-FY2012 Request." Congressional Research Service, 30 June 2011. Web. <[://www.fas.org/sgp/crs/misc/RS22913.pdf](http://www.fas.org/sgp/crs/misc/RS22913.pdf)>.

¹¹ McNair, David. "Who's Going to Pay for the MDGs?" *The Guardian*. Guardian News and Media, 29 Jan. 0023. Web. 11 Feb. 2013. <<http://www.guardian.co.uk/global-development/poverty-matters/2012/jan/23/whos-going-to-pay-for-mdgs>>.

V. Specific Contributions to MDG Target 8E, Access to Medicines

Product donations category is the largest set of contributions identified, representing almost 80% of all pharmaceutical companies' contributions. The majority of general product donations identified are from data compiled by Hudson Institute's Center for Global Prosperity in its annual publication: *The Index of Global Philanthropy & Remittances*. These figures cover donations from 2004 – 2010 amounting to \$43.0 billion. This data includes corporate estimates for transport, taxes, duties and tariffs, and in-country storage and distribution. Although *Index* data for 2011 were not available, through PQMD we were able to identify almost \$2.2 billion donated from PQMD companies in 2011, this includes estimates for transport, taxes, duties and tariffs. Hudson also found an additional \$31.2 billion from non PQMD pharmaceutical companies and PQMD companies who donated directly to a program, bringing the total to over \$74.2 billion in general product donations.

The sub-category of discounted products includes companies which donated their products at a discounted price and companies which gave their products at not-for-profit prices. In some cases companies did not publicly report the discounted price. Because Hudson Institute did not know the rate of the discount, the value of donation could not be calculated. In cases where not-for-profit prices were used but the figures were not disclosed, Hudson Institute estimated the value of the profit donated.¹² Hudson was able to identify \$1.5 billion in discounted product donations and products sold at not-for-profit pricing.

It is likely that the largest component of discounted product donations is from the United Nations Accelerated Access Initiative (UN/AAI). Hudson, however, was unable to calculate a monetary value for corporations' discounted products given to this initiative. This public-private partnership was organized by various pharmaceutical companies and several UN specialized agencies in 2000 and lasted until 2010. Through this partnership companies offered discounted products to UN supported HIV initiatives in developing countries.¹³ According to the *Developing World Health Partnerships Directory 2010* report 773,803 patients in developing countries were taking one or more medicines supplied at discounted prices by an UN/AAI partner company.¹⁴ Although we were unable to find values for all of the companies' discounted products, an example of the level of discount can be found through ViiV Healthcare, one of the pharmaceutical partners in the UN/AAI program. Through the UN/AAI program ViiV Healthcare reduced its price of *Combivir*, its leading ARV drug, from \$730 to \$197 per patient per year.¹⁵ This 73% decrease of price is most likely indicative of other companies' price discounts, however, we were unable to determine the discounted products value and the quantity donated because data were unavailable.

¹² See Product Donations section in the methodology on page 14 for detailed explanation.

¹³ World Health Organizations, UNAIDS. "Accelerating Access Initiative: Widening Access to Care and Support for People Living with HIV/AIDS Progress Report." 2002

¹⁴ International Federation of Pharmaceutical Manufacturers and Associations. *Developing World Health Partnerships Directory 2010*. Web.

<http://www.ifpma.org/fileadmin/content/Publication/IFPMA_Partnerships_Directory_Full_2010.pdf>

¹⁵ Ibid.

As seen in Table 1, we found over \$75.7 billion dollars in product donations from pharmaceutical companies in 2000 through 2011.

Cash Donations in Table 1 include three sub-categories: general cash donations, capital investments in capacity building, and operating costs of capital investments. Pharmaceutical companies' contributions are often mainly regarded as product donations; however, these companies also contribute heavily in cash donations as well. For instance, Merck & Co. provides annual fiscal support to the Carter Center's River Blindness Program and it does the same in coordination with WHO and GlaxoSmithKline on the Lymphatic Filariasis public-private partnership. In particular, GlaxoSmithKline contributed the most in cash donations, representing 38% of the total \$7.68 billion uncovered.

The second sub-category of capital investments in capacity building totaled \$0.73 billion. This ranges from corporations supporting lab modernization in developing countries, to creating training centers for midwives. The operating costs for initiatives such as various clinics and research institutions added another \$0.50 billion. **Together these subcategories total \$8.9 billion in cash contributions from pharmaceutical companies.**

Other in-kind donations in Table 1 include the monetary value of technology transfer through public private-partnerships, corporate volunteerism, training of healthcare staff, and cost of the pre-clinical development phase of drugs used by other producers. Although corporations spend billions of dollars on these costs, the actual monetary figures are usually unreported or unavailable. Therefore, the total is an underestimation.

The category of technology transfer not only relates to MDG Target 8E, but MDG Target 8F, as well. Target 8F resolves to promote the MDGs "in co-operation with the private sector [and] make available the benefits of new technologies." Hudson Institute was able to obtain a monetary value for only one corporation's technology transfer program. Eli Lilly and Co.'s program transferred multi-drug-resistant tuberculosis (MDR-TB) production technologies to companies in South Africa, India, Russia, and China. These transfers were accompanied by Lilly's provision of engineering staff to assist with training in the use of the manufacturing technologies in each of these four countries, along with quality control staff to ensure that production output met standards of known quality, safety and efficacy. The value for this transfer to technology is estimated at \$70 million.

Regarding volunteerism, only two companies published figures for their volunteer activities, AstraZeneca and Eli Lilly & Company. From these two sources, the total value for volunteerism amounted to \$2 million. It is likely that there are numerous other corporate volunteerism programs for which values could not be obtained.

The third sub-category covers the monetary value of the training of health care staff. There are a number of programs that engage in health care worker trainings, amounting

to 1.19 billion people trained. However, a monetary value for their training was only available for 5 of the 47 programs identified and amounted to \$1.5 million.

The fourth sub-category covers the costs avoided by foreign pharmaceutical companies to produce patented antiretroviral medicines as generic products. Manufacturers producing generic products of already developed ARVs were able to bypass the research and development phase of drug production and thus, the costs as well. Hudson Institute estimated that manufacturers of generic ARVs saved \$10.1 billion from foregoing investments in basic research and other indirect costs of producing generic medicines.¹⁶

Altogether, other in-kind donations totaled \$10.18 billion.

Contributions for which Monetary Values were Undetermined:

Hudson found substantial categories of industry contributions in which only a few companies placed a monetary value against them. The first category of these contributions is pharmaceutical corporations' **voluntary license transfers**. Consistent with pharmaceutical companies' commitment to the UN's Millennium Declaration, and to paragraph 6 of the Amendment of the 2005 TRIPS Agreement on the transfer of production technology, key research-based industry organizations issued voluntary licenses to developing countries for the local production of ARVs, malaria and TB drugs. While we were able to identify over 54 voluntary license transfers from five different companies, these companies have not placed on public record any monetary value to these transfers. Thus, table 1 only provides data on the number of licenses.

The second type of non-monetary contributions is **royalty-free license transfers**. Like voluntary license transfers, companies have not placed on public record any monetary value to this. Thus table 1 only provides data on the number of licenses identified. Hudson Institute identified 11 royalty-free license transfers from four companies, some of these licenses include: the antiretroviral drug maraviroc, efavirenz, license to drugs for Drugs for Neglected Disease Initiative (DNDI), and a license for Medicines for Malaria Venture to pursue the development of investigational drug candidates. Another example is Merck's contribution of small molecule assets and intellectual property via a non-exclusive, royalty-free license to the DNDI. This was used to conduct early developing programs for drug candidates for treatment of neglected tropical diseases, with a primary goal of manufacture and distribution of drugs at low cost to the public sector in developing countries.¹⁷ However, like the other royalty-free transfers identified, no monetary value on this transaction was identified.

Another pharmaceutical contribution often unnoticed is industries allowing access to their **libraries of medical compounds** both to WHO's TDR Programme and to other local research facilities in the developing world. In 2006, Pfizer donated a library of 50,000

¹⁶ See methodology for a detailed explanation of Hudson Institute's estimated calculations.

¹⁷ Merck & Co., Inc. and Drugs for Neglected Diseases initiative Collaborate to Find Treatments for World's Most Neglected Tropical Diseases. Press Release. Merck. Web. 4 Nov. 2012. <<http://www.merck.com/licensing/our-partnership/dndi-partnership.html>>.

medical compounds to the WHO. But like the other contributors mentioned, Pfizer placed no monetary value on its donation. Although Hudson was unable to determine a monetary value for these contributions, their worth is invaluable. Libraries of medical compounds allow researchers to limit the number of promising molecules in the drug research stage and move more quickly in the preclinical phase of drug discovery. According to Bayer HealthCare, this can quickly reduce the average number of test compounds from 10,000 in the drug research stage, which consumes 3 years of the development process, to 250 in the preclinical phase of development. This 97% decrease in number of tests conducted is consequentially a significant savings in time and money.¹⁸

Since passage of the UN Millennium Declaration, pharmaceutical companies have been sponsoring numerous **clinical trials for tropical diseases** in an attempt to bring new drugs to patients in developing countries. These trials, often in collaboration with the WHO, are for HIV/AIDS, TB, malaria, neglected tropical diseases, and MCH conditions. While there are numerous examples of such trials, Hudson Institute included 10 in its dataset. Clinical trials for new drug development are an expensive undertaking in developed countries. Some studies estimate \$802 million to \$1.3 billion to bring one drug to the market.¹⁹ 42% of these costs are in the drug development and preclinical phases, the first steps towards clinical trials and regulatory approval. These trials have a large monetary value which has yet to be estimated.

In addition to these contributions from pharmaceutical companies is their presence in building and promoting **healthcare research and institutional capacity** designed to benefit patients in the developing world. Table 3 provides a list of institutions devoted to research and development in global health. An asterisk indicates the 14 institutions where we identified fiscal support from pharmaceutical companies. It is likely that many of the other institutions listed also received support from pharmaceutical companies, but further research needs to be conducted to confirm. These healthcare institutions constitute a long-term commitment for sustaining the principle of access to medicines. A more exhaustive research effort by the pharmaceutical companies is necessary to document their continuing effectiveness and potential for expansion.

¹⁸ "Processes in Research and Development." Bayer HealthCare, n.d. Web. 22 Dec. 2012. <<http://www.bayerpharma.com/en/research-and-development/processes/index.php>>.

¹⁹ DiMasi, Joseph A., Ronald W. Hansen, and Henry G. Grabowski. "The Price of Innovation: New Estimates of Drug Development Costs." *Journal of Health Economics* 22.2 (2003): 151-85.

Table 3. Institutions Devoted to Research & Development in Global Health

Institution	Country
Academic Model providing Access to Healthcare	Kenya
African Population and Health Research Center	Kenya
Armauer Hansen Research Institute	Ethiopia
Baylor College of Medicine Bristol-Myers Squibb Children's Clinical Center of Excellence*	Uganda
Biomedical Research and Training Institute	Zimbabwe
AIDS Reference Laboratory *	Botswana
Center for Infectious Disease Research in Zambia	Zambia
Center for Infectious Diseases, Stellenbosch University	South Africa
Center for Proteomic and Genomic Research	South Africa
Centre Muraz	Burkina Faso
Ifakara Health Institute*	Tanzania
Infectious Diseases Institute*	Uganda
Institute of Health Sciences Research at Jimma University, Gilgel Gibe Field Research Center	Ethiopia
Institute of Human Virology, Nigeria*	Nigeria
KEMRI-Wellcome Trust Research Programme	Kenya
Makerere University*	Uganda
Malawi-Liverpool-Wellcome Trust Clinical Research Program	Malawi
Medical Research Center	Uganda
Swiss Center of Scientific Research	Cote d'Ivoire
University of Ibadan	Nigeria
Swiss Center of Scientific Research	Cote d'Ivoire
University of Ibadan	Nigeria
Wellcome Trust World Health Organization	Global
Baylor International Pediatric AIDS Initiative At Texas Children's Hospital*	Botswana, Malawi, Swaziland, Uganda, Lesotho, Kenya, Tanzania, Ethiopia, Romania
Africa's first Pediatric AIDS Hospital & Outpatient Clinics*	Botswana
Glaucoma Patients Association for Lagos State Clinics for early detection of Glaucoma*	Nigeria
Children's AIDS Specialty Clinics*	Ten countries in Africa
The Novartis Institute for Tropical Diseases*	Singapore
GSK's Basic Research Centre in Tres Cantos*	Spain
AstraZeneca's Bangalore Research Institute*	India
Novartis Vaccines Research & Development Centre*	Italy

VI. Conclusion

The UN's Millennium Declaration and its follow-on programmatic instrument, the MDGs, are instrumental both in increasing the provision of medicines and in the transfer of technologies to developing countries. This report demonstrates that the pharmaceutical industry is a major player in these efforts.

While the bulk of industry's response is in product donations, the value of these donations goes beyond simply providing products. For one, the \$74.2 billion in product donations obviates the need for Ministries of Finance in recipient countries to use their scarce foreign exchange for similar procurements. An additional benefit from these product donations are in the taxes, duties and tariffs they yield, bringing in a steady flow of foreign exchange to Ministries of Finance. Another advantage of donations is the quality associated with the products. Ensuring quality of drugs continues to be an issue in developing countries, with Interpol estimating that 30% of medicines circulating in Africa are either counterfeit or of inferior quality.²⁰ A recent study by WHO on the quality of anti-malarial medicines in Sub-Saharan Africa revealed that 44% of samples from Senegal and 30% from Madagascar could "be qualified as of inferior quality."²¹ Because of the prevalence of counterfeit drugs, product donations from pharmaceutical companies assure patients in developing countries that their access to medicines in Uganda can yield the same therapeutic benefit as the United States.

In addition, industry has been in the forefront of responding to overall healthcare infrastructure within developing countries. Central to this effort was an understanding that long term sustainability was not possible through the provision of product donations alone. Rather, infrastructure, capacity building, and technology transfers are the key to preserving the gains made in battling diseases. The Infectious Disease Institute in Uganda, financed by Pfizer and now under the operational control of Makerere University, is an example of such activities. It has now provided clinical training in AIDS treatment and care to thousands of caregivers in Africa, Asia, and South America. Astra-Zeneca financed the Infectious Disease Institute in Bangalore, India. This facility not only employs local research expertise, but can also concentrate its research agenda on the causes of disease within its population, rather than rely on external sources. While many people continue to focus on product donations, it is in fact infrastructure, capacity building, and technology transfers that are becoming more and more essential to good healthcare in the developing world and in reaching the Millennium Development Goals.

The use of the pharmaceutical industry's intellectual property has also increased production of many essential medicines, especially for the treatment of ARVs, thus increasing overall access. Today, 30 ARVs are in WHO's Prequalification Programme, classified by the FDA as 'generics'. Most are produced in India. According to Medecins

²⁰ Pharmaceutical Crime. INTERPOL 2013 Web 4 November 2012. <<http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime>>.

²¹ Global Forum on Law, Justice and Development, World Bank Headquarters. *Counterfeit Medicines: Impact and Potential Solutions*. 2 & 3 Oct. 2013.

sans Frontieres, India now supplies 80% of the ARVs going into Africa and it has become a “pharmacy to the developing world”.

The lessons drawn from the pharmaceutical industry’s contributions to the MDGs can be applied to emerging global health issues. For instance, as the UN attempts to address new initiatives on non-communicable diseases, it should take into account the importance of expanding capacity and institutional building efforts in developing countries--a vital factor as the donor community now focuses its funding on the need to “strengthen health systems.” This approach has shown proven results in industry programs over the last decade.

This study provides evidence that the pharmaceutical industry has cooperated with the UN and the international community at large in increasing access to medicines across the globe. While current indicators show that access is not at its most optimal level, the industry has nevertheless taken significant strides to change this. Both the cash and the in-kind contributions show that pharmaceutical corporations have stepped up their efforts and can be regarded as a vital partner in achieving the Millennium Development Goals.

VII. Methodology

While collecting this data Hudson encountered several issues. In general, companies do not have strict reporting requirements for their contributions. While individual initiatives are well documented, overall companies involvement had to be pieced together by various reports and interviews. Secondly, many in-kind donations did not have precise monetary values reported; therefore, when able, Hudson placed conservative estimates on these donations. The breakdown for each estimate is explained below.

Monetary Values

A. Product Donations

The Product Donations category includes general product donations and a sub-category of discounted products.

In some cases, corporations did not specify the monetary value of their contribution. In the cases where the product and number of products was divulged without specifying a monetary value, Hudson Institute used the MSH *International Price Indicator Guide* and other recognized sources to place conservative estimates. When no value was given to the amount and type of product donated, Hudson did not count the contribution.

The largest component of general product donations is from data compiled by Hudson Institute's Center for Global Prosperity and the Center for Science in Public Policy. Data on contributions from 2001-2003 came from Hudson Institute's *Review of Pharmaceutical Contributions* published in 2004.²² Since 2004 the Center for Global Prosperity has been measuring the value of corporate contributions to international development causes through its annual publication: *The Index on Global Philanthropy & Remittances*. From 2004 – 2007, the primary data in the *Index* came from the Partnerships for Quality Medical Donations (PQMD). From 2008 on, the primary source for the data was compiled by the Urban Institute through the review of IRS990 forms submitted by NGOs where organizations report the in-kind medical donations received. This data include corporate estimates for transport, taxes, duties and tariffs, and in-country storage and distribution. From 2001 – 2010, these product donations amounted to \$45.78 billion. Although *Index* data for 2011 was not available, through contacts with PQMD we were able to identify \$2.19 billion donated from PQMD companies in 2011, this includes estimates for transport, taxes, duties and tariffs. The additional contributions identified were from non PQMD member companies and PQMD member companies whose product donations went directly to a program rather than via PQMD and via other reports on product donations. In total, the general product donations amount to over \$74 billion.

²² "Hudson Institute's A Review of Pharmaceutical Contributions, October 2004." *Hudson Institute*. 2004. Web. 1 June 2012. <<http://www.hudson.org/files/publications/AdelmanNorrisPharmCoReview.pdf>>.

The sub-category of discounted products includes companies which donated their products at a discounted price or companies which gave their products at not-for-profit prices. In cases where not-for-profit prices were used but the figures were not disclosed, we estimated the value of the profit donated. To do so, we subtracted the supplier price from the buyer price to estimate the profit the company did not receive. The price of these drugs is calculated based on MSH International Drug Price Indicator Guide.²³

The total value of all product donations is \$75.7 billion.

B. Cash Donations

Cash Donations category includes three sub-categories: general cash donations, capital investments in capacity building and operating costs of capital investments.

Hudson Institute reviewed corporate social responsibility reports, corporate press-releases, published reports on public-private partnership initiatives in global health, and spoke to key individuals within the companies reviewed. Hudson Institute found almost \$7.7 billion in general cash donations, \$0.73 billion dollars donated for capital investments in capacity building and \$0.50 billion dollars for operating costs. Together Hudson Institute identified \$8.9 billion donated.

C. Other In-Kind Donations

Other in-kind donations include the monetary value of the following: technology transfer through public private partnerships, corporate volunteerism, training of healthcare staff, and cost of pre-clinical phase of drugs used by other producers.

Technology Transfer: Hudson Institute was only able to obtain monetary value for Eli Lilly & Company's technology transfer. Eli Lilly's program transferred MDR-TB production technologies to South Africa, India, Russia, and China. These transfers were accompanied by Lilly's provision of engineering staff to assist with the design and construction of plant in each of these four countries, and quality control staff to ensure that production output met standards of known quality, safety and efficacy. This is a different value than the transfer of a license to produce and distribute a patented therapy. The value for this transfer to technology is estimated to amount to \$0.07 billion.

Volunteerism: Only two companies published figures for the hours of volunteer time in their company programs, AstraZeneca and Eli Lilly & Company. Hudson Institute used the Independent Sector's estimated 2010 value of \$21.36 per hour of volunteer time to calculate each company's contributions in volunteer time. From these two sources, the total value for volunteerism amounted to \$0.002 billion.

²³ "International Drug Price Indicator Guide." Management Sciences for Health, n.d. Web. Nov. 2011. <<http://erc.msh.org/mainpage.cfm?file=1.0.htm&id=1&temptitle=Introduction&module=DMP&language=English>>.

Training of Healthcare Staff: While Hudson identified a total of 1.9 billion people trained, the monetary value for training programs was only available for 5 of the 47 programs and amounted to \$0.006 billion.

Costs-Avoided in Pre-clinical ARV Drug Development by generic producers: To arrive at this value, Hudson used previous reports on the average research costs to successfully develop an innovative new drug. Because drug companies producing generic products of already developed ARVs by research-based companies bypassed the research and development phase of drug production, these generic manufacturers did not need to incur these costs. These avoided costs can be estimated as a contribution on the part of the companies that were the innovators of these same drugs.

Hudson relied on a peer-reviewed study published in 2003 in the *Journal of Health Economics*²⁴. This same study was also used by the Congressional Budget Office in its 2006 paper titled *Research and Development in the Pharmaceutical Industry*²⁵. According to both papers, an estimated cost for developing a new drug amounts to \$802 million. Of this total, 43% or \$335 million is spent on the preclinical phase and \$467 million is spent on the clinical trials and FDA approval phase. Because foreign producers manufacturing generic products bypassed the pre-clinical drug development phase, producers were able to save on preclinical costs, amounting to \$335 million per drug.

In order to determine the total costs saved in producing generics, Hudson estimated the number of drugs that have FDA approval and are produced by foreign manufactures as generics. In its 2012 publication titled *Untangling the Web of Price Reductions*, MSF separates ARVs that have had an FDA approval from those that do not, allowing Hudson Institute to determine which of these drugs were produced by foreign manufacturers as generics. In order to determine the value of the R&D industry's contribution to the UN's Millennium Declaration in 2000 via the cost savings by manufacturers producing generics, Hudson Institute identified 30 different classes of ARVs that have received FDA classifications as 'generic' products and which were covered by extant patents and produced in India. Because foreign producers were able to forego the pre-clinical phase of drug development, Hudson Institute estimated that these companies saved \$335 million per generic drug. The estimated cost saved for 30 ARVs amounts to \$10.1 billion.

Therefore, manufacturers of generic ARVs saved an estimated \$10.1 billion from foregoing investments in basic research and other indirect costs of producing generic medicines. To verify this methodology Dr. Stan Finkelstein, Professor of Medicine at the Harvard-MIT Division of Health Sciences & Technology, reviewed and approved the assumptions, including the pre-clinical drug development cost estimate, the number of ARVs produced by generic companies that were certified by the FDA, as reported by

²⁴ DiMasi, Joseph A., Ronald W. Hansen, and Henry G. Grabowski. "The Price of Innovation: New Estimates of Drug Development Costs." *Journal of Health Economics* 22.2 (2003): 151-85.

²⁵ Congressional Budget Office. *A CBO Study: Research and Development in the Pharmaceutical Industry*. N.p., 1 Oct. 2016. Web. <<http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf>>

Medecins Sans Frontieres, and the overall approach used to arrive at the \$10.1 billion figure. In his review, Dr. Finkelstein commented: “I am not aware of any other authoritative source that would afford better estimates.”²⁶

In total, Hudson Institute found \$0.07 billion in technology transfer, \$0.002 billion in volunteerism, \$0.006 billion in training of healthcare staff, and \$10.1 billion in cost of pre-clinical phase of drugs used by other producers. Together these values amounted to \$10.2 billion.

Contributions for which Monetary Values were Undetermined

Non-monetary contributions consisted of voluntary license transfers, royalty-free license transfers, library of medical compounds, and a number of clinical trials for neglected diseases. Items in this category all have narrative descriptions in source documents but are not accompanied by any monetary values.

A. Voluntary License Transfers

Consistent with its commitment to the UN’s Millennium Declaration, and to paragraph 6 of the Amendment of the TRIPS Agreement of 2005 on the transfer of production technology, key research-based industry organizations have issued voluntary licenses to developing countries for the local production of ARVs, malaria and TB drugs, thus increasing access. The companies have not placed on the public record any value to these transfers. Thus the table provides data only on the number of licenses. Hudson Institute identified 54 voluntary license transfers and 11 royalty-free license transfers.

B. Royalty-Free License Transfers

Companies have not placed on the public record any value to these transfers. Thus, table 1 provides data only on 11 royalty-free licenses that Hudson could locate.

C. Library of Medical Compounds

Through the IFPMA’s records, Pfizer donated a library of 50,000 medical compounds to the WHO’s TDR Programme. The monetary value of this transfer was not able to be determined.

D. Clinical Trials for Tropical Diseases

Since passage of the UN Millennium Declaration in 2000, pharmaceutical companies have been sponsoring numerous clinical trials in an attempt to bring new drugs to patients in the developing world. These trials, often in collaboration with the WHO, are for HIV/AIDS, TB, malaria, neglected tropical diseases, and MCH conditions. While there are numerous examples of such trials, Hudson Institute included 10 in its dataset.

²⁶ Finkelstein, Dr. Stan. 11 Jan. 2013. E-mail.

It is known that clinical trials for new drug development are an expensive undertaking in developed countries. Some studies show that of the \$802 million to \$1.3 billion to bring one drug to market, 42% of the costs are in the drug development and Preclinical phases—the first steps towards Clinical Trials and regulatory approval. The 10 trials included in this study have a large monetary value, which has yet to be estimated.

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