

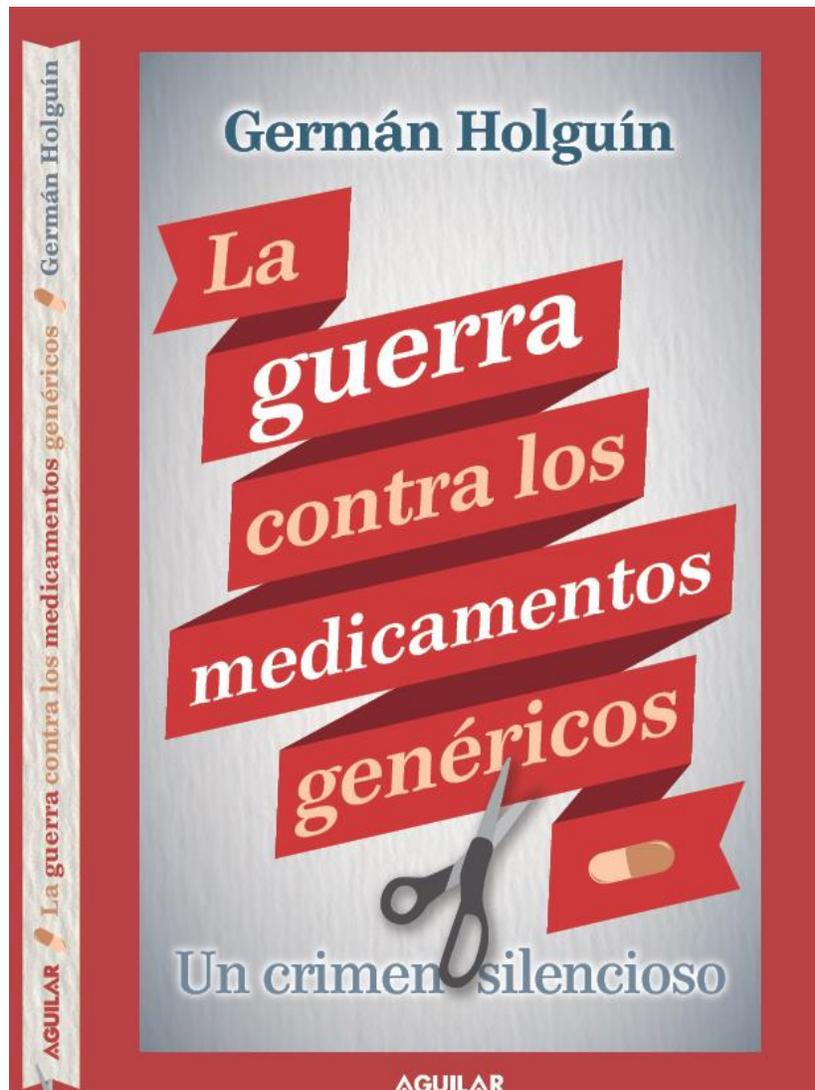
# **THE WAR AGAINST GENERIC DRUGS**

## **A SILENT CRIME**

### **EXECUTIVE SUMMARY**

December, 2014

**German Holguin Zamorano**



**AGUILAR**

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<http://www.libriadelau.com/guerra-contra-los-medicamentos-genericos-.html#.VLgg6iuG-J0>

If you were rich, what would you do?

I would buy a luxury car, a mansion, a farm and...my medicines.



## The Context

The lack of medicines in the developing world, where 80% of the global population lives, is the major public health problem facing the planet today, not only because it compromises the right to health and life, the first and most precious of human rights, but because it affects 2 billion people (one third of the world's population),<sup>1</sup> half of whom are practically unaware of these vital goods, while the other half have no access to them whatsoever when they are needed.<sup>2</sup>

This problem is comparable only to that of the tragedy of hunger and chronic malnutrition, which, according to the Food and Agriculture Organization of the United Nations (FAO), affects 870 million human beings, of whom 98% live in developing countries,<sup>3</sup> and also to the lack of potable water due to its physical shortage, which, according to the World Health Assembly (WHA), affects nearly 884 million people.<sup>4</sup>

The lack of medicines results in high levels of morbidity, suffering, disability, and exclusion, particularly in low- and middle-income countries. According to World Health Organization (WHO) estimates, it leads to the death of 10 million people per year<sup>5</sup>; an alarming figure unsurpassed by even the greatest humanitarian tragedies – including the two world wars and the holocaust.<sup>6</sup>

Latin America is no exception. Of the 580 million inhabitants of the region, 230 million (40%), according to the WHO, have no health insurance and 125 million lack permanent access to basic health services.<sup>7</sup> As a result of these hardships, according to the Pan-American Health Organization (PAHO), approximately 700,000 preventable deaths occur annually in the region.<sup>8</sup>

## Emblematic Diseases

This dearth of medicines is a problem for all the diseases that are prevalent in the developing world. For some diseases, there is absence of medical technology for prevention, diagnosis and treatment, or the existing one is inadequate. For others, there

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<sup>1</sup> WHO. WHO Medicines Strategy – Countries at the Core 2004-2007 [On line] WHO. 2004.

Available at [URL:http://apps.who.int/medicinedocs/en/d/Js5571e/](http://apps.who.int/medicinedocs/en/d/Js5571e/)

<sup>2</sup> Holguin, G. The war against generic drugs: a silent crime. Bogota, Colombia: Penguin Random House Editorial Group, SAS Aguilar.2014:p53

<sup>3</sup> FAO. The state of food insecurity in the world: [On line] Rome: FAO;2012 Oct 9. Available at [URL:http://www.fao.org/docrep/016/i3027e/i3027e.pdf](http://www.fao.org/docrep/016/i3027e/i3027e.pdf)

<sup>4</sup> EFE. The United Nations includes access to water as a Human Right. El Mundo.2010 Jul, 29

<sup>5</sup> WHO. WHO Medicines Strategy – Countries at the Core 2004-2007. Op. cit

<sup>6</sup> Holguin, G., Op. cit

<sup>7</sup> ILO(OIT)/PAHO(OPS). Panorama de la exclusión de la protección Social en Salud en América Latina y el Caribe. 1999. Cited by PAHO. Guía para la Implementación de Estrategias de Medicamentos Genéricos en los Países de América Latina y el Caribe como Mecanismo para mejorar el acceso a Medicamentos. [On line] Washington D.C.: PAHO; 2011 Jun. p.25. Available at: [URL:http://apps.who.int/medicinedocs/documents/s19196es/s19196es.pdf](http://apps.who.int/medicinedocs/documents/s19196es/s19196es.pdf)

<sup>8</sup> PAHO(OPS) Cited by: Departamento de Justicia y Solidaridad. Discípulos Misioneros en el Mundo de la Salud – Guía para la Pastoral de la Salud en América Latina y el Caribe. Bogotá, D.C. Consejo Episcopal Latinoamericano (CELAM); 2010. Point 60

are significant barriers to accessing existing medical technologies (vaccines, diagnostic tests and drugs).

The first group includes the deadliest infectious diseases (AIDS, tuberculosis [TB] and malaria) which lead to four million deaths annually, the majority of them in low- and middle-income countries. Despite the damage these illnesses cause to human health, the levels of research to advance diagnosis and prevention are far below what is needed, and regarding treatment, coverage is minimal: hundreds of thousands of infected patients face pain and death with no medical treatment whatsoever.

Comparable is the case for the 17 neglected tropical diseases (NTDs) recognized by the WHO: cholera, sleeping sickness, yellow fever, leprosy, dengue fever, leishmaniasis and chagas disease, among others. Even though about 1 billion people are infected by these illnesses, 95% of them in developing countries, and while 3 million people die annually from them, effective vaccines, safe diagnostic tests and efficient treatments are wanting.<sup>9</sup>

These illnesses are referred to as “neglected” because despite their morbidity and mortality, the resources assigned to combat them through medical research and development (R&D) are insignificant. A study carried out by Doctors Without Borders (Médecins Sans Frontières or MSF) shows that of the 1,577 medical drugs commercialized throughout the world between 1974 and 2004, only ten, less than 1%, corresponded to the NTD.<sup>10</sup> This is because they are pathologies concentrated especially in the poorest populations of tropical countries, which do not represent a profitable market for the pharmaceutical industry.<sup>11</sup> As stated by Doctors without Borders, “They seem to have fallen into oblivion in the international community”.<sup>12</sup>

Among conditions for which there exist medical technologies, but which are unaffordable, are non-transmissible global diseases, such as cardiovascular diseases and cancer (the two leading global causes of death especially in the developing nations), diabetes, pulmonary diseases, and degenerative illnesses such as Alzheimer’s and Parkinson’s, among others.

*“While we have the technical capacity to provide access to lifesaving medicines, vaccines or other interventions, which are indeed widely available in the developed world,” admits WHO, “Millions of people, including children, suffer and die in developing countries because such means are not available and accessible there”.<sup>13</sup>*

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<sup>9</sup> WHO. Why are some tropical diseases called “neglected”? [On line] 2007 April 17 [cited 2010 Mar. 27] Available at: [URL:http://www.who.int/features/qa/58/en/](http://www.who.int/features/qa/58/en/)

<sup>10</sup> Chirac, P. Torreale, E. Drugs for Neglected Diseases Initiative. Geneva, Switzerland: Medecins Sans Frontieres. For more information consult: [pierchir@club-internet.fr](mailto:pierchir@club-internet.fr)

<sup>11</sup> Holguin, G. Op.cit. p62.

<sup>12</sup> Doctors Without Borders, Proyecto Acceso a Medicamentos Esenciales, México y América Central. Available at: URL:[www.medicossinfronteras.org.mx/web/index](http://www.medicossinfronteras.org.mx/web/index).

<sup>13</sup> Commission on intellectual property rights, innovation and public health. Public health, innovation and intellectual property rights. [Report]. [On line]. 2006. Available at: [URL:http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf](http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf)

## Causes of the problem

It is evident that poverty is a factor underlying this drama, since on the one hand it does not allow countries to invest in medical research that responds to the health needs of their populations, and, on the other hand, it deprives national health systems of acquiring basic health products in sufficient quantities, especially expensive ones, thereby leaving to patients or their families the responsibility of paying out of pocket, which is impossible for those who make less than 2 dollars a day.<sup>14</sup>

Without overlooking this reality, there are two factors that augment the problem and which, because they depend on the will of man, convert it into an issue which is ethically objectionable and legally reprehensible. These are:

- I. The lack of research and development of medical technologies suitable to treat the diseases prevalent in developing countries;
- II. The lack of access to existing medical technologies.

As a result of these deficiencies, in the worldwide pharmaceutical market at present, the “80:20 equation” prevails, whereby 80% of the production of pharmaceuticals is consumed in the developed nations, where less than 20% of the world population lives, leaving only 20% of the pharmaceuticals to be consumed by 80% of the inhabitants of the planet.<sup>15</sup>

## LACK OF R&D FOR ILLNESSES PREVALENT IN THE DEVELOPING WORLD

The reason for this vacuum may be attributed to the current system of incentives for innovation in health, which is based on inventors’ expectations regarding patenting and charging high monopoly prices, which allows recuperating investment costs and obtaining often exaggerated profits.

Obviously then, this incentive system causes resources destined for research to be concentrated on the development of pharmaceuticals that will produce big profits (business medicines), while needs for the rest of the world go unheeded.

A senior executive from Bayer puts it this way, “We did not develop this product for the Indian market, let’s be honest. We developed this product for Western patients who can afford this product, quite honestly.”<sup>16</sup>

To reverse this situation and to promote the development of technologies for diseases affecting disproportionately developing countries, the WHA, after 10 years of reflection and consultations with worldwide groups of experts, has concluded that it is necessary to create an incentive system that is delinked from patents and high monopoly prices. Such a

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<sup>14</sup> According to the WHO, of the 4,800 million people in the developing world, 2,700 million (56%) receive an income of less than 2 dollars a day. Resolution WHA 61.21 2008 May 24. Context No. 2

<sup>15</sup> Holguin, G. Op.cit., p. 76

<sup>16</sup> Gokhale K. “Merck to Bristol Myers face more threats on India Patents”. [On line]. 2014 Jan 28. Available at URL: <http://www.bloomberg.com/news/2014-01-21/merck-to-bristol-myers-face-more-threats-on-india-patents.html>

system could be, for example, an international public fund supplied by a small percentage of the gross domestic product (GDP) of all countries that would award substantial economic rewards to those inventing such technologies. Innovations thusly financed would be considered “public goods”, free from intellectual property obstacles, and legal and contractual restrictions. Clearly, the realization and implementation of such initiative would require negotiating a binding global instrument for R&D and innovation for health.

Unfortunately, such a system has been unobtainable so far, as it has been hampered by the United States, which is under pressure by large pharmaceutical companies and has been supported by Japan, Switzerland, and some countries in the European Union. They do not support the creation of a new innovative model, even if it does not replace but complements the current one, because they believe it would take away research resources from the industry, thereby affecting growth. They are aware that the current model ignores health needs of the developing world, but for them, their industry’s interests prevail over the well-being of 80% of humankind.<sup>17</sup>

It is up to civil society in all countries, both developed and developing, to make every effort to convince governments of the urgent need to unite around the binding global instrument proposed by the WHA.

In the opinion of Stiglitz, “the WHO’s recommendations represent a once-in-a-generation opportunity to remedy a long-standing and egregious inequity in health care, and, more broadly, to set a model for governance of global public goods befitting an era of globalization. We cannot afford to let this opportunity pass us by”.<sup>18</sup>

## **LACK OF ACCESS TO EXISTING MEDICAL TECHNOLOGIES**

The second cause for the shortage of medicines in the developing world is the lack of access to existing medical technologies. This may be attributed to two important factors: (1) The high price of pioneer medicines and (2) the war against generic drugs – that is, the set of intellectual property rules and practices of large multinational pharmaceutical companies and their governments aimed at blocking the sale of generic medicines; the only drugs to which many health systems have access without affecting the provision of other basic services and the only ones the majority of people living in low- or middle-income countries can get.

Justification for the high prices is founded on pharmaceutical patents and on the exclusive protection of the data that is filed with the health agency to obtain marketing authorization for the drug, which, by granting the manufacturers a commercial monopoly over the pioneer product for a specified number of years, allows them to set a price much higher than would normally occur in a competitive market, with the apparent purpose of recuperating the investment made in the research and development stage of production and of making a reasonable profit.<sup>19</sup>

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<sup>17</sup> Holguin, G. Op. cit, p 105 and next.

<sup>18</sup> Stiglitz, JE. A breakthrough opportunity for global health. [On line]. 2012 May 18. Available at: URL:<https://www.project-syndicate.org/commentary/a-breakthrough-opportunity-for-global-health>

<sup>19</sup> Lu Y, Hernandez P, Abegunde D, Edejer T. The World Medicines Situation 2011 Medicine Expenditures, 3<sup>rd</sup> ed [On line] Geneva: World Health Organization: 2011. WHO/EMP/MIE/2011,2.6. Available at: URL:[http://www.who.int/health-accounts/documentation/world\\_medicine\\_situation.pdf](http://www.who.int/health-accounts/documentation/world_medicine_situation.pdf)

The troubling thing is that those who receive government-granted monopoly protections do not exercise it responsibly. Rather than taking into account production cost structures and a reasonable profit margin, which normally occurs with industrial products, they employ an eminently speculative approach based on what the consumer is willing to pay in the marketplace. This practice begets outrageous prices that are unaffordable for health systems and for consumers who must pay for the drugs out of their pockets, which is common in developing countries.

Regarding cancer, for example, the journal, *Blood*, has revealed that “of the 12 treatments approved in 2012 by the FDA, 11 cost around \$100,000 dollars annually in the United States”,<sup>20</sup> making them inaccessible for most patients. This treatment cost is morally unjustified according to oncologists that were consulted by the journal, “as those medicines that patients depend upon to preserve their lives should not be submitted to the laws of the market”.<sup>21</sup>

Sofosbuvir (Sovaldi®, from Gilead Sciences), used in combination with other antivirals to treat chronic hepatitis C, costs at present \$1000 dollars daily. Against this backdrop, twelve weeks of treatment costs \$84,000 dollars, and that which lasts for 24 weeks, required for patients affected by certain variety of the virus, runs \$168,000 dollars.<sup>22</sup>

The situation is even more alarming in the case of biotechnological medicines, used to treat severe illnesses such as certain types of cancer, rheumatoid arthritis and diabetes, among others, whose cost ranges on average between \$50,000 and \$250,000 per year per patient.

The outrageous price of medicines not only blocks access to these essential goods but also represents a prime factor in the financial crisis of health systems, which is characterized by the difficulty in providing patients with the services and products that satisfy their needs.

As a consequence of the irrational setting of these prices, they may vary widely among countries. A symbolic example is that of ciprofloxacin, an antibiotic used in the treatment of various common infections. As shown in the following graph, a summary of a “global instant” taken on November 30<sup>th</sup>, 2009 of the pioneer product (Cipro®), treatment prices range from 42 cents in India to \$131 dollars in Colombia, a difference of 311 times! All the other countries (91), including developed countries that were investigated, fall somewhere between these two extremes. A shocking difference.<sup>23</sup>

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<sup>20</sup> Blood Magazine. Cited by: AFP. Oncólogos denuncian los precios excesivos de los medicamentos anticancerígenos. [On line] 2013 Apr. 26 Available at: [URL:https://es-us.noticias.yahoo.com/onc%C3%B3logos-denuncian-precios-excesivos-medicamentos-anticancer%C3%ADgenos-182310770.html](https://es-us.noticias.yahoo.com/onc%C3%B3logos-denuncian-precios-excesivos-medicamentos-anticancer%C3%ADgenos-182310770.html)

<sup>21</sup> Ibid.

<sup>22</sup> Hepatitis C Online [Internet] Washington: University of Washington. Available at URL: <http://www.hepatitisc.uw.edu/page/treatment/drugs/sofosbuvir-drug>

<sup>23</sup> Hai Global. Global pill price “snapshot” reveals large differences in the price of ciprofloxacin. [On line] Hai Global 2009 Nov 30. Available at: URL:<http://www.haiweb.org/medicineprices/05012010/PressRelease.pdf>

### Originator Brand Product (dollars)



Irrational price fixing also translates into disproportionate and occasionally exorbitant profits. A study carried out by Dr. Hubbert Schellekens from the Department of Pharmaceutical Sciences at the University of Utrecht, in reference to biotechnological medicines, shows that the cost/price relation of eight products analyzed ranges between 0.7% and 4.4%, for an average of only 2.3%.<sup>24</sup> Of course to the 97.7% margin, research and development costs must be added, but as high as these may be – and they are never as high as the multinationals claim they are – an excessive profit will be made by the manufacturer.

<sup>24</sup> Schellekens H. Biosimilars: a regulatory update. Conference given at the training seminar on biotechnological medicines; 2102 Oct. 23-25; Bogotá, Colombia.

The corresponding relation for each product may be observed in the following chart:

Product	Price	price/g	Manufacturing Cost Assuming 2 g/L yield (\$/gr)*	Cost / Price*
Avastin	\$687.5/ 100mg	\$6,875	\$188	2.7%
Enbrel	\$243 / 25mg	\$9,706	\$428	4.4%
Remicade	\$784 / 100mg	\$7,839	\$188	2.4%
Humira	\$1,816 / 40mg	\$45,400	\$308	0.7%
Rituxan	\$675 / 100mg	\$6,751	\$188	2.8%
Herceptin	\$3,331 / 440mg	\$7,570	\$126	1.7%
Erbitux	\$600 / 100mg	\$6,000	\$188	3.1%
Soliris	\$5122 / 300mg	\$17,073	\$135	0.8%
<b>Average</b>	<b>1657.3125</b>	<b>\$12,877</b>	<b>\$231</b>	<b>2.3%</b>

Falling barriers and increasing profits attract competition

Source: Bernstein analysis, market data; note: IP licensing is excluded from cost calculation; objective of analysis is to show the market from perspective of subsequent entrant

Given the disproportionate increase in the cost of medicines and health expenses, many countries, beginning with members of the Organization for Economic Co-operation and Development (OECD), have been forced to design and implement strategies to control said costs and to improve accessibility to these necessary goods. They are aware that if limits are not placed on the greediness of these large corporations, national health systems will collapse, and will be forced to lower the quality of their services to the detriment of the population. The strategy which has been most effective is that of stimulating competition with generic drugs.

Regarding the war against generic medicines – the second explanatory factor in relation to the lack of access to existing medical technologies – ironically, the reason for the conflict lies in the two essential attributes of these products: their high quality, which is attested to by important studies carried out in the United States and other countries,<sup>25</sup> and their affordable prices. With regard to the latter, on the international scene, generic drugs cost on the average between half and one third of the pioneer drugs and in some cases fifty times less.

These qualities have opened pharmaceutical market doors for generics, with the consequent public health benefits, but at the same time have triggered strategies devised

<sup>25</sup> Studies cited in Holguin, G. Op. cit., p.117 and next.

by the beneficiaries of monopolies to block them. From the standpoint of certain producers of pioneer drugs, it is legitimate to defend their economic interests by all the means they have at their disposal, independently of the harm that this may cause to the health of countries.

The following quote by a senior executive from a pharmaceutical multinational aptly sums up this attitude: "We are not in the business to save lives, but to make money. Saving lives is not our business".<sup>26</sup>

Being consistent with this principle, certain laboratories that produce pioneer medicines draw on all available "weapons" at their disposal, both legal and illegal, to preserve and strengthen their monopoly, since they well know that by doing so they ensure their enormous profits and the positioning of their shares on the main stock markets the world over. The war against generic drugs is the compendium of these "weapons".

Among the legal weapons used, the pharmaceutical patents and the exclusive protection of the information submitted to obtain the marketing authorization are what most stand out. The former provides nominal monopolies for 20 years and effective ones for between 10 and 15 years while the latter affords effective monopolies between 5 and 12,5 years depending on the legal system in force in the country in question. During these periods, generic versions of the pioneer drug may not enter the marketplace and hence, the majority of the population have little prospect of obtaining these essential goods for preventing, alleviating and curing illnesses.

It is worth noting that patents for pharmaceutical products have not always existed, as many believe. Rather, they were invented only a short time ago by pharmaceutical multinationals with the support of their governments in order to protect their commercial interests. In England, Germany, Switzerland, Italy, and Spain they were only established between 1949 and 1986.

In developing countries they were only enacted 20 years ago through the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994. Having accomplished this, periodically, these countries are forced to strengthen their patent systems further through various coercing mechanisms, mainly free trade agreements (FTAs) which usually contain a chapter related to intellectual property rights that includes new pharmaceutical patent arrangements (regarding products, processes, new uses, minor changes in known substances, etc.) and an increase in their applicable term.

Developing countries should have never agreed to grant pharmaceutical patents and should take the necessary steps to abolish them, since medicines need to be public goods, available to all, just as are the air, streets, squares, bridges and roads and should therefore not be subject to patent protection. Having coerced developing countries to

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<sup>26</sup> Clark, J. Pharmaceutical Maker Roche: "Saving Lives Is Not Our Business". [On line] 2008. Available at: URL:<http://money.howstuffworks.com/10-great-moments-corporate-malfeasance1.htm>

accept pharmaceutical patents, having committed to grant them and maintaining them constitute serious violations of the right to health, susceptible to be denounced using established mechanisms set up to protect human rights at the national, regional and global levels.

Another important aspect of the war against generic medicines is the pressure that is brought against developing nations for them to abstain from exercising the right to use the safeguards established by international regulations, such as compulsory licenses, parallel importations, the Bolar exception, and prior consent, to protect public health from the harmful effects of pharmaceutical patents. These safeguards are not at all liked by those engaged in the war against generics because they stimulate competition, low medicines prices and reduce their participation in the marketplace. Both coercion from large multinational pharmaceutical companies and their allies aimed to prevent developing nations from exercising these rights and the inaction on the part of developing nations with respect to utilizing these rights also constitute a serious violation of the right to health, which should be denounced using the mechanisms set up to defend it.

Regarding illegal “arms” used to block the use of generic drugs, among the most common are attempts by companies to discredit these medicines and incentive payments made to some doctors which encourage them to discredit generic drugs and to prescribe certain pioneer products of equal quality to the generics but much more expensive, even for uses that are not approved by the medicines regulatory agency.

With respect to discrediting campaigns, these are carried out through different means, the most important of which include visits to medical practitioners, advertisements, and articles by and interviews with persons sponsored by the industry who pretend to be independent scientists.

An example of this type of advertisement, the publication of which should never have been authorized, is shown below. The advertisement<sup>27</sup> shows Tomás, a 45 year old man, who, after claiming to be hypertensive, warns that should his medicine fail, he will suffer a stroke. And then he states: “I’m not taking any chances, I use only original drugs. They are the ones that are backed up by studies which corroborate their quality, safety and efficacy”.

The message is clear: If you suffer from hypertension, treat your disorder with the original, trademarked drug, not a generic one. Should you use the generic medicine, “you could suffer a stroke”! Nothing less than a stroke! And the advertisement rests on an implied falsehood: that generic drugs are of poor quality and are not supported by scientific evidence which demonstrates their safety and efficacy.<sup>28</sup>

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<sup>27</sup> Prensa Libre. Guatemala. 2006 Jul 27.

<sup>28</sup> Holguin, G. Op. cit., p.141

The greatest problem with such campaigns is that patients may be left untreated: not using generics because they have been convinced that generics are of poor quality and harmful to their health, and not using the pioneer drugs because they cannot afford them.

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PRENSA LIBRE : Guatemala, jueves 27 de julio de 2006

**"Soy *hipertenso*,  
si mi medicamento falla,  
podría sufrir un *derrame*."**

**YO NO ME LA JUEGO**  
uso sólo **ORIGINALES.**

Los medicamentos originales  
cuentan con estudios que respaldan su calidad, eficacia y seguridad

EXIJA CALIDAD  
PREFERA EL ORIGINAL

Respete la receta médica. Pregunte a su médico o regente farmacéutico cuál es el medicamento original.

ABBOTT AstraZeneca Bristol-Myers Squibb Boehringer Ingelheim GlaxoSmithKline JANSSEN-CILAG Lilly  
MENARINI MERCK SHARP & DOHME Pfizer Roche sanofi aventis SCHERING Schering-Plough Wyeth  
Laboratorios asociados a Fedefarma

Regarding incentive payments and bribes made to doctors, a study cited by the New York Times (NYT) disclosed that in the United States, one out of four doctors receives money from large pharmaceutical companies for prescribing their medicines, even for therapies and in prescribed doses that have not been approved.<sup>29</sup>

The book this summary comprises describes 12 cases of large pharmaceutical companies that within the last 6 years have accepted to pay fines of 14 billion dollars to the United States government for promoting some of its products for unauthorized uses and for increasing its sales through payment of commissions and other illegal privileges to doctors and other health professionals.<sup>30</sup>

Other illegal "arms" include, among others, (1) seizure in European ports and airports of legally produced Indian generic products bound for developing countries, (2) technical

<sup>29</sup> Ibid, p 246.

<sup>30</sup> Ibid, p 246 and next.

barriers intended to block the manufacturing and commercialization of bio-generics, and (3) agreements among manufacturers to delay entrance of generic drugs into the market.

It is clear then that lack of access to existing medicines is not a misfortune due to inevitable and irremediable factors, like an earthquake, but is the result of policies and strategies conceived, coordinated and implemented deliberately by certain multinational pharmaceutical companies, with support from their governments, in order to protect their economic interests.

The problem is that the consequent effects are not solely economical in nature, but, as has been seen, jeopardize the health and the lives of millions of human beings in the developing world.

### **PROPOSALS TO SUPPRESS THE WAR AGAINST GENERIC DRUGS**

Without claiming to have a magical formula for suppressing the war against generic drugs, the book this summary details proposes three fundamental measures that need to be taken:

- i. Abolition of pharmaceutical patents for essential medicines in the developing world;
- ii. Full and systematic use by civil society of right to health protection mechanisms established at the global, regional and national levels whenever there are acts or omissions that block access to essential medicines, and
- iii. The war against generic drugs, to the extent that it produces illness, suffering, disability, and loss of human life, be declared a crime against humanity from the legal standpoint and be adjudged by the International Criminal Court.

### **ABOLITION OF ESSENTIAL DRUG PATENTS IN THE DEVELOPING WORLD**

Patents on medications have caused immense damage in developing countries since they were imposed 20 years ago: they have concentrated pharmaceutical innovation on “business medicines”, stimulated inefficiency in the international pharmaceutical industry and increased the lack of access to existing treatments, putting into jeopardy the quality of life and life itself. Thus, it would appear that the time has come to abolish medical patents in developing countries, at least with respect to essential medicines.

It is undeniable that such a measure would necessitate a new international agreement modifying the TRIPS agreement, which, as previously explained, imposed on the developing world the obligation to acknowledge this privilege in the first place.

I am fully aware that this is an extreme measure, just as was at the time the extension of this intellectual property rights category to the developing world, but I am also aware that without it, there is no possibility of ending the war against generic affordable drugs. While there exist instruments encouraging pharmaceutical monopolies, high prices and huge

profits, those who benefit from such systems will strive by every means possible to continue doing so, whatever the economic, social and humanitarian consequences of such actions may be, because they are simply not willing to lose their patent privileges.

Apart from that, the abolition of pharmaceutical patents would not be an extravagant measure. Rather it would mark a return to the model that existed before developing countries agreed to join TRIPS with pharmaceutical patents included.

To be able to do so is by no means utopic, but rather a thorny dream that could be achievable, just as other actions initially considered impossible, such as the demise of the Free Trade Area of the Americas Agreement (FTAA) and the Asian Free Trade Area (AFTA), the failure of the Multilateral Agreement on Investment, the sinking of the Anti-counterfeiting Trade Agreement due to its disapproval by the European Parliament (2012) and the adoption of: the fourth ministerial Conference held in Doha (Qatar) in 2001 (the Doha Declaration), the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008), and the report of the Consultative Expert Working Group (CEWG) by the WHA (2012).

In this vein, a recent document of the Global Commission on HIV from the United Nations Development Programme (UNDP) acknowledges that TRIPS seeks “maximal profits for pharmaceutical monopolies rather than the unmet health needs of millions”, which “endangers the health of millions of people.” The report further notes the need to design “a new intellectual property regime for pharmaceutical products” and asserts that while this is being accomplished, “the WTO Members must suspend TRIPS as it relates to essential pharmaceutical products for low- and middle-income countries.”<sup>31</sup> That is, it may be concluded that pharmaceutical products patents should be suspended in low- and middle-income countries.

MSF,<sup>32</sup> the Permanent People’s Tribunal (PPT), the academic community, important NGOs that defend human rights and numerous developing countries have expressed themselves in similar terms. Indeed, the aforementioned commission of the UNDP has recommended that, “The UN and its member states must mobilise adequate resources to support LDCs to retain this policy latitude”.<sup>33</sup>

The World Health Organization (WHO), after recording that “benefits and costs of patents are unevenly distributed across countries, according to their level of development and

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<sup>31</sup> UNDP – Secretariat, Global Commission on HIV and the law. Risks, Rights and Health. [On line] New York: UNDP; July, 2012 Available at [URL:http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf](http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf) p 86 Recommendations 6.1

<sup>32</sup> Doctors Without Borders. Campaña para el Acceso a Medicamentos Esenciales. Patentes de Medicamentos en el punto de mira: Compartiendo Conocimientos Prácticos sobre las Patentes Farmacéuticas. [On line] MSF 2003 May. Available at: [URL:http://www.femeba.org.ar/fundacion/quienessomos/Novedades/patentesinformemsf.pdf](http://www.femeba.org.ar/fundacion/quienessomos/Novedades/patentesinformemsf.pdf)

<sup>33</sup> UNDP – Secretariat, Global Commission on HIV and the law. Risks, Rights and Health. Op. cit. p. 87 Recommendation 6.4.

scientific and technological capacity”,<sup>34</sup> acknowledges that developing countries have the right to “devise their patent systems to seek the best balance, in their own circumstances, between benefits and costs”,<sup>35</sup> and recommends that the countries, “reduce regulatory barriers to the market entry of generic equivalents”.<sup>36</sup> This is a recommendation that opens the doors to the abolishment of patents, the major barrier against said medicines.

Of equal scope would be the invitation to the states by the United Nations Special Rapporteur on the right to health, “to do all they reasonably can to make sure that existing medicines are available in sufficient quantities in their jurisdictions... (and that medicines are) economically accessible (i.e. affordable) to all, including those living in poverty”.<sup>37</sup> It is obvious that among the measures developing nations could take to ensure the availability and the accessibility of existing medicines is the abolition of pharmaceutical patents.

Professor Carlos Correa reminds us that Thomas Jefferson, a fervent defender of patent systems, wrote in a famous letter to an inventor in 1813, that patents are not a “*natural*” right of an inventor but a privilege that the society is free to grant or not grant without anyone opposing them. Developing countries have every right not to grant them, because the right to health and life, which must prevail over intellectual property rights and commercial interests, so demands it. As Dr. Bernard Pécoul, director of Drugs for Neglected Diseases Initiative (DNDi), has wisely stated, “Patents are not divine rights. They are tools designed to benefit society as a whole and not so that a handful of pharmaceutical companies may fill their pockets”.<sup>38</sup>

As may be seen, there are obvious signs within the international community that are conducive to abolition of pharmaceutical patents in developing countries. Those bodies that are responsible for global development within the framework of respect for human rights, governments and civil society organizations, little by little, have become aware of the fact that medicines are a public good and, as such, should not be subject to monopolies, which transform these public goods into source of wealth and luxuries for a minority and a source of blood and misery for the majority.

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<sup>34</sup> Commission on intellectual property rights, innovation and public health. Op. cit.

<sup>35</sup> Ibid.

<sup>36</sup> Cameron A, Ewen M., Auton M., Abegunde D., The World Medicine Situation 2011: Medicines Prices, Availability and Affordability. [On line] Geneva: World Health Organization. 2011 WHO/EMP/MIE/2011.2.1. Available at: [URL:http://www.who.int/medicines/areas/policy/world\\_medicines\\_situation/WMS\\_ch6\\_wPricing\\_v6.pdf](http://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf)

<sup>37</sup> Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’s Report. Presented to the General Assembly. 61<sup>st</sup> period of sessions. September 13, 2006. A/61/338. [On line]. Available at: URL: [http://www.who.int/medicines/areas/human\\_rights/A61\\_338.pdf](http://www.who.int/medicines/areas/human_rights/A61_338.pdf)

<sup>38</sup> Interview with Bernard Pécoul, Director of Drugs for Neglected Diseases Initiative (DNDi) in: López A, Nos hacen falta 400 millones para 12 nuevos tratamientos. [On line] El Mundo June 19, 2013. Available at: URL: <http://www.elmundo.es/elmundosalud/2013/06/18/biociencia/1371581277.html>

In the meantime, while the objective of abolition is accomplished, governments of developing countries should strive to implement all measures necessary to reduce the damaging effects of patents by utilizing the legal mechanisms available. This course of action emanates from the obligation to *respect, protect* and *fulfill* the fundamental right to health. Some of the most important measures are:

- i. Strict enforcement of patentability requirements (novelty, inventive step, and industrial application).
- ii. Rejection of new intellectual property barriers or attempts to strengthen existing ones through international trade agreements and other mechanisms.
- iii. Full exercise of the right to issue compulsory licenses and other public health safeguards established in international law.

It is often argued that the abolition of pharmaceutical patents is objectionable because large multinational pharmaceuticals need the high prices that pharmaceutical patents create to recuperate the resources they invest in researching and developing products capable of curing illnesses and saving lives. This contention forms part of what could be called “the myth of the pharmaceutical world”, a product of the imagination of those who wage the war. The truth is:

i. The cost of developing a molecule and putting it on the market is not \$1,300 million dollars, as the large pharmaceutical companies claim, but much less: \$43.3 million according to a recent study published by the London School of Economics.<sup>39</sup>

ii. This cost burden is not entirely shouldered by pharmaceutical companies, but rather mostly by governments (85% in the case of the 5 bestselling medicines in the United States in recent years).<sup>40</sup>

iii. Research and development (R&D) does not result in drugs that are necessarily better than those already on the market. Various studies have revealed that as of the 80’s, when pharmaceutical patents emerged, only between 14 and 16 percent of new drugs approved were considered to be innovative. The rest were “me too” drugs, that is, trivial modifications to known molecules that possess therapeutic indices that are similar to their existing reference products. However, these “me-too” drugs are sold at much higher prices than their known comparator products. In other words, rather than providing incentives for innovation, patents are in fact reducing them.

iv. Relieving developing countries of the economic burden inherent to pharmaceutical patents would hardly affect the earnings of large multinational pharmaceuticals given that their combined markets hardly represent 20% of the total global pharmaceutical market.

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<sup>39</sup> Light DW, Warburton R. Demythologizing the high costs of pharmaceutical research. The London School of Economics and Political Science. Biosocieties [Serial online] 2011 Feb. 7:34-50. Available at:URL: <http://www.palgrave-journals.com/biosoc/journal/v6/n1/abs/biosoc201040a.html>

<sup>40</sup> Public Citizen: [On line] Available at: [URL:http://www.citizen.org/Page.aspx?pid=183](http://www.citizen.org/Page.aspx?pid=183)

In short, the monopolies granted by patents have not been historically a *sine qua non* condition for industrial and technological development in the pharmaceutical business. On the contrary, their absence or flexibility has promoted innovation, investment and growth of the pharmaceutical industry.<sup>41</sup>

The initiative to conceive, orient and implement the process of abolishing patent systems in developing countries must be assumed by the governments of these countries, in adherence to the fundamental right to health, which they are obliged to respect, protect and fulfill.<sup>42</sup>

Those countries where multinational pharmaceuticals have their headquarters, for their part, must support this process, in compliance with the international cooperation obligation, emanating from the fundamental right to health, which demands taking actions to meet the full realization of this right in all countries.<sup>43</sup>

The goal is to achieve a new world order in which the concept of unity or *community* and the preeminence of life takes precedence over the appropriation of goods on the part of only a few; a new mindset in which the right to health is the core of health policy in all corners of the planet instead of intellectual property rights, commerce and “the wild pursuit of money”. Let there be no illnesses for which diagnostic tests, vaccines and effective treatments are unaffordable; no patients who are deprived of existing health goods: A world where health equity prevails.

As was proclaimed by Pope Francisco in his *Apostolic Exhortation Evangelii Gaudium* (The Joy of the Gospel), “As long as the problems of the poor are not radically resolved by rejecting the absolute autonomy of markets and financial speculation and by attacking the structural causes of inequality, no solution will be found for the world’s problems or, for that matter, to any problems. Inequality is the root of social ills.”<sup>44</sup>

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<sup>41</sup> Lobo, F. La evolución de las patentes sobre medicamentos en los países desarrollados. Departamento de Economía, Universidad de Oviedo. [Conference]. 1988.

<sup>42</sup> General Comment No. 14. The right to the highest attainable standard of health (Committee on Economic, Social and Cultural Rights of the United Nations (CESCR) Available at: URL: [http://tbinternet.ohchr.org/\\_layouts/treatybodyexternal/Download.aspx?symbolno=E%2fC.12%2f2000%2f4&Lang=en](http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=E%2fC.12%2f2000%2f4&Lang=en)

<sup>43</sup> Ibid.

<sup>44</sup> Pope Francisco I. Apostolic Exhortation Evangelii Gaudium on the Proclamation of the Gospel in Today’s World. Given at the closing session of the year of Faith. [On line] 2013 Nov. 24; Rome. Point 202. Available at:URL: [http://w2.vatican.va/content/francesco/en/apost\\_exhortations/documents/papa-francesco\\_esortazione-ap\\_20131124\\_evangelii-gaudium.html#The\\_economy\\_and\\_the\\_distribution\\_of\\_income](http://w2.vatican.va/content/francesco/en/apost_exhortations/documents/papa-francesco_esortazione-ap_20131124_evangelii-gaudium.html#The_economy_and_the_distribution_of_income)

## **CIVIL SOCIETY'S USE OF ESTABLISHED INSTRUMENTS FOR DEFENDING THE RIGHT TO HEALTH WHENEVER CONDUCTS INHERENT TO THE WAR AGAINST GENERIC DRUGS ARE PRESENT.**

The aim of this proposal is to induce civil society organizations from developing countries, supported by their counterparts in industrialized countries, to organize, through new or existing Right to Health Observatories or other specialized bodies, such that they may appeal to existing instruments for defending right to health at the global, regional and national levels, whenever conducts aimed at blocking generics are present, even those that claim to be upheld by intellectual property rights, which are precarious and subordinate to fundamental human rights.

Choice of the instrument to be employed depends on whether the plaintiff's aspiration is that of obtaining a mandatory compliance sentence or simply that of a symbolic ruling by the competent body with declarations and recommendations to the state found to be responsible.

Should it be the former, there are three alternative ways of filing suit: globally, with the International Court of Justice; regionally in the Americas, with The Inter-American Court of Human Rights; and nationally, with those bodies indicated in the domestic legal system.

Should it be difficult to put together a strong legal case, the next best option is to seek a ruling from a competent body with pronouncements and recommendations to the state found to be responsible. If this path is taken, there are four available bodies that might take up this cause, of which the first three derive from the United Nations and the fourth from the Inter-American system: the UN special Rapporteur on the Right to Health, The United Nations Human Rights Council (UNHRC), the Committee on Economic, Social and Cultural Rights of the United Nations (CESCR) and the Inter-American Commission on Human Rights.

It is lamentable that only occasionally are these channels used to investigate and sanction conducts aimed at blocking the use of generics, despite the severe impact this has on public health. We take no action as if nothing were happening, as if we were not protagonists in this disconsolate history that should not be perpetuated. It is indeed sad and deplorable; a symptom that we are losing our souls.

We cannot settle for simply being spectators to what is happening around us. We must react. "Fight against the war and against what man does against man".<sup>45</sup> We must make a strong commitment to reality. Denounce. Not doing so makes us accomplices, since our unresponsiveness gives carte blanche to the intellectual and material perpetrators of the war.

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<sup>45</sup> Guayasamin. Cited by PabaloCuvi, La Capilla del Hombre. Santillana, 2013.

## **THE WAR AGAINST GENERIC DRUGS CONSIDERED LEGALLY AS A CRIME AGAINST HUMANITY**

The book which is the focus of this summary puts forward the working hypothesis that the war against generic drugs can be judged from a legal standpoint as a crime against humanity prosecutable by the International Criminal Court (ICC), specifically as a crime of “other inhumane acts” which are described by the subparagraph k of article 7.1 of the Rome Statute of the International Court

The hypothesis is founded on the fact that, in the opinion of the author and based on the reasons presented in the book, it is a behavior that in the first place meets the four essential requirements of these crimes: i. An attack against any civilian population; ii. A widespread or systematic attack; iii. Perpetrated pursuant to a state policy or the policies of an organization of committing such acts; iv. With the intent to cause harm. And, in the second place, it is a conduct that fits into criminal acts as defined by the aforementioned subparagraph k of article 7.1 of the Rome Statute.<sup>46</sup>

What I propose by formulating this working hypothesis is that the issue be submitted to a serious and objective international debate. The mere fact that this issue could become the object of reflection and deliberation in independent scenarios of recognized ethical and moral character, would contribute to highlighting the drama that it entails, would open the doors for its incorporation into the United Nations political agenda and also that of the Inter-American Human Rights System, and would most certainly trigger a process of searching for and coming up with formulas for solving the problem.

If the conclusion of such a debate were to favor the hypothesis, the following step would be that of putting together a blockage case with a detailed exposition of the facts and the resulting damage, and to bring it before the International Criminal Court (ICC) under the sponsorship of some State willing to support it, with a view to compensating the victims, reestablishing the right to health which has been abused, and for those responsible individuals applying exemplary punishments which would serve to dissuade other actors from committing the same acts or omissions.

If the conclusion to such an international debate was contrary to the hypothesis, a path would still remain open: negotiating an amendment to the Rome Statute of the International Criminal Court expressly typifying the blockage of essential affordable medicines as a crime against humanity. Article 123.1 of the Statute clears the way for such an endeavor as it states that the Statute is subject to review at any time and that the revision may cover the list of crimes within the competence of the court.

Meanwhile, the theory that blockage of generic drugs is a crime against humanity committed in defense of commercial interests, shall remain in place, condemning the

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<sup>46</sup> The Statute of Rome holds that those who act intentionally in relation to a consequence (For example blockage of access to medicines that save lives) “is aware that it will be produced in the normal course of the events”

practice of putting the “idolatry of money” before the dignity of human beings, of subordinating the fundamental right to health and to life to intellectual property rights and of placing commercial interests before human rights.

In the words of Pope Francisco, “Just as the commandment ‘*thou shalt not kill*’ sets a clear limit in order to safeguard the value of human life, today we also have to say ‘*thou shalt not*’ to an economy of exclusion and inequality. Such an economy kills”.<sup>47</sup>

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I am fully aware that implementing these three proposals will be a long and difficult battle, not only because of the difficulty for developing countries to join together in their support and to resist the pressures that the industrialized countries will surely apply to break the unity, but because, as Martin Luther King stated from the jail in Birmingham, “History is the long account of how privileged groups rarely give up their privileges voluntarily”.<sup>48</sup> But we must give battle if we wish to guarantee universal access to existing medicines, and we must do so with the decision and the courage that noble causes engender. We, as civil society are not force to win this battle; we are forced to give it, but “we must win for the poor of the world”.

The day that pharmaceutical patents and the protection of exclusive data regarding essential medicines are eliminated, that the mechanisms aimed at defending the right to health against those who would block such drugs are fully utilized, and that the authors of this conduct are brought before the International Criminal Court to be accused, judged and condemned, along with their accomplices, concealers, and collaborators in these criminal demeanors, others will think twice before engaging in the same behavior. That day will mark the beginning of the end to the war against generic drugs; a *war* that kills.

I foresee such a day on the horizon. Let us conquer it. Just as in 1969, we were able to conquer the moon to prove that it is possible to live beyond Earth, clearly we shall be able to “conquer” the universal consciousness to demonstrate that it is possible to live on it. “The earth is our common home and we are all brothers”.<sup>49</sup>

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<sup>47</sup> Pope Francisco I. Op. Cit., point 53.

<sup>48</sup> Cited by Velasquez G. A treaty to Reorient the Pharmaceutical Industry \_ Research without Patents. Le Monde Diplomatique 2013 Abr.

<sup>49</sup> Pope Francisco I. Op. Cit., point 183.