# *Inaugural address as Doctor "Honoris Causa" of the*

# *Excmo. Sr. Germán Velásquez Arango*

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Honorable Dean, Honorable Representative of the Government of Colombia, University authorities, Professors, my family here present: Christine and Saskia and my sons who could not be present due to university commitments, Bastian, Nicolas and Emmanuel, students and friends.

Many years ago I met a doctor in Vietnam who spent the war building bridges ... I, as an economist, have found myself in the position of issuing prescriptions and recommendations regarding drugs ... and no bridge has collapsed despite the bombings.

I wish, first of all, to express my profound gratitude for the distinction granted me today by the Complutense University of Madrid, one of the oldest universities in the world, which has, for centuries, contributed to the progress of science, politics and the arts.

This distinction is for me both **a great personal honor** and **a responsibility**. An **Honor** for which I thank the University and in particular Professor Luis Montiel and his students involved in this struggle for access to health and medicines which has been the great challenge of my entire career. But this distinction is above all a **responsibility** conferred upon me today by the University to continue working on the same topics, with the knowledge that the Complutense University shares this challenge of access to medicines. Today, more than ever, it is necessary to continue with the efforts in research and develop new models and paths. The debate on access to medicines can advance only insofar as the university and the academy are fully involved.

This Honoris Causa Doctorate is also a recognition of all who have fought and continue to fight for access to medicines.

The thought processes and works on policies for access to medicines were initiated by the World Health Organization at the Conference of Alma Ata in 1978. In the following years, WHO developed drug policies that would allow access to all citizens, in particular the unprotected, sometimes forgotten or ignored persons in the countries of the South.

WHO, where I have had the privilege of working for 20 years, was certainly a pioneer in the defense of access to medicines and led this issue from the start. In recent years, as we shall see later, this agency has been experiencing a severe crisis and its multilateral and public character is in danger. In the future, will WHO have the capacity and independence to continue leading this topic? **Who will lead, coordinate and point the way forward in the field of access to medicines in the coming decades? This is the challenge we face today.**

There are three closely interrelated points which I would like to develop in this reflection: 1) a quick diagnosis of the current situation of the World Health Organization whose mission it was, in principle, to foster and lead the access to medicines, 2) The problems the current pharmaceutical product research and development model is facing today and 3) How the solutions and new models on access to medicines being currently debated can at the same time be a solution for the future of WHO.

As I recently expressed in an article published by Le Monde Diplomatique, WHO, the United Nations specialized agency for health: "is slowly dying, in the eyes of the international community which is divided among promoters, accomplices and observers of the disaster."[1]

**The analyses of WHO are not always clear, nor are its epidemiological predictions sufficiently science-based, and its recommendations can lead to unnecessary waste. Let us take a look at two examples:**

- In 2005, the H5N1 avian flu: In August 2005, the chief of staff of the Director-General of WHO announced in a press release that 150 million people could die from this global epidemic. Five years later, WHO reports as total deaths from the H5N1 avian flu: 331 people, concentrated mainly in Indonesia and Vietnam.[2] Between 150 million or 331 deaths, the least that can be observed is the lack of rigor in the epidemiological predictions. Safety stocks of Oseltamivir (known by the brand name of "Tamiflu") were constituted. Never, in the history of medicine, had stocks been constituted for a medicine whose effectiveness was unknown, to treat a disease that had not yet arrived and that never did come. Stocks for 25% of the population in Canada, 25% in the USA, 25% in the UK, 50% in France and other European countries, 23% in Japan.[3]

[1] Velásquez, G. "WHO: An Organization Adrift - in the May 2015 issue of Le Monde Diplomatique.
[2] Velasquez, G. « The management of A(H1N1) pandemic: an alternative view. Journal of health law Vol. 13 No. 2, Oct. Sau Paulo, 2012, p. 108 - 122
[3] Idem, p. 125.

- In 2009-2011, with the outbreak of the H1N1 flu, WHO launched a new alarm, and contrary to the opinion of recognized international experts, WHO declared the highest phase of global pandemic. This disease, whose transmission is extremely fast, nevertheless caused fairly low mortality. While roughly 500,000 people die each year from the normal seasonal flu, WHO reported only 18,449 deaths from the H1N1 flu over a period of two years.

  The declaration of the highest phase of pandemic by WHO allowed the vast majority of industrialized countries to buy several million vaccines, 90% of which had to be incinerated because they were not used. France, for example, with a population of 66 million people, bought 94 million doses, of which only 6 million were used. The same volume of squandering as in France occurred in the USA, Germany, Belgium, Spain, Italy, Holland and Switzerland… with the purchase of vaccines and, once again, with the constitution of stocks of Oseltamivir.

  **In the last few years, WHO states that the socio-economic determinants of Health occupy an important position in the emergence of diseases and epidemics. However, these social and economic determinants are not always taken into account. The analyses of the causes are not in-depth, and answers are slow. This is the case of the current EBOLA epidemic.**

- In the management of Ebola (2014-2015), the outbreak was announced by MSF in March of 2014 and WHO started acting only in July/ August of the same year… a delay of 4 months. Ebola is a type of hemorrhagic fever that appeared for the first time in Zaire in 1976, nearly 40 years ago. In the previous periodic outbreaks, an average of 300 deaths per year had been reported.

  On 25 January 2015, WHO had reported 20,689 cases and roughly 8,626 deaths, mainly in Sierra Leone, Liberia and Guinea.

  Why this significant leap in the number of cases? In all the documents produced by WHO in recent months, none is asking questions as to the causes of the disease, nor as to the dramatic increase in the number of cases… Some ongoing studies [4] seem to suggest that one of the main causes could be massive deforestation for farming and mining **which could have changed the balance between the jungle animals and man.** The causes and roots of the problem have not been addressed. Causes that are probably

[4] David Sanders & Amit Sengupta, "Ebola Virus Disease: What's the primary pathology? Presentation at the "Prince Mahidol Award Conference, Bangkok, January 2015.

associated with environmental damage due to massive exploitation of minerals by foreign companies.

According to data from the International Monetary Fund, in the case of Sierra Leone, the rapid expansion of the mineral extraction industry led to an economic growth of 20 percent last year. This is one of the highest economic growth rates in the world.

This exceptional economic growth does not seem to be benefiting the national economy. Tax evasion is one of the major causes of loss of income, especially in the mining sector in Sierra Leone. In 2010, the country's mining industry contributed almost 60% of exports, but only 8% of the government's income. Of the five major mining companies in Sierra Leone, only one is currently paying taxes.[5]
Had the country benefited from this "economic boon", some health infrastructures could have been built to address this epidemic. These are not the social and economic determinants of health WHO speaks of… The resolution on Ebola, adopted by the World Health Assembly in May 2015, does not mention these aspects.

**Loss of public and multilateral control of WHO which leads to the inability to set priorities**

In parallel with the repeatitive malfunction in the management of health problems on a worldwide scale, and led by some of the industrialized countries, with the complicity or the silence of the Secretariat of WHO and some developing countries, a gradual privatization of the agency, which in 8 years has gone from having a budget of 50% of public funds constituted by the mandatory contributions from member countries, to only 18 %, is taking place. The agency is currently in the hands (approximately 82% of its budget) of philanthropic foundations such as the Bill and Melinda Gates Foundation, a small number of industrialized countries that offer some voluntary contributions and the big pharmaceutical industry…

The dizzying loss of control of the budget leads to an inability to set priorities ... the member states, with their slow rhetoric, try to set priorities ... but funds are coming from the private sector for specific topics, set by private and public donors, the new owners of the organization.

[5] David Sanders & Amit Sengupta, "Ebola Virus Disease: What's the primary pathology? Presentation at the "Prince Mahidol Award Conference, Bangkok, January 2015.

**Problems of governance, both in the line of power between headquarters, regional and country offices, as well as in the increasingly less effective operation of the governing bodies.**

As demonstrated by the case of Ebola, in WHO there is today a breakdown in the hierarchical line of power between the headquarters in Geneva and the six totally autonomous regional offices which do not report to the Director or the Director-General. Power relations between headquarters, the regional offices and the operational arm, which are the roughly 150 country offices, are unclear, leading to an institution without a central command ... unable to respond timely and
ffectively to problems such as the avian flu or H1N1 or the Ebola pandemic currently being experienced.

The operating mode of the governing bodies of WHO (Executive Council composed of representatives from 34 countries and the World Health Assembly -WHA- composed of the ministers of Health and their delegations from the 194 member countries) is archaic and dysfunctional; delegates spend three annual meetings (two Executive Councils and WHA) discussing details and resolution wording that ultimately are agreed to in complicated diplomatic arrangements, decisions which are voluntary in nature ... WHO does not have, or rather does not use[6] the mechanisms for mandatory application of decisions that are taken based on technical evidence.

**Summing up this diagnosis of WHO, we see how the progressive loss of the public nature of the institution creates serious problems of governance, that answers are slow in coming, that analyses and recommendations are not always clear and that mechanisms for the implementation of policies, strategies and action plans are almost non-existent.**

This Agency, which we have just described, is the one which is supposed to keep leading the **debate on access to medicines at a time when a third of the world's population, living in the developing countries, lacks regular access** to medicines and also at a time when health systems in industrialized countries are finding it increasingly difficult to continue ensuring its citizens access to drugs.

Patents for pharmaceutical products has been one of most-debated topics on access to essential medicines since the creation of the World Trade Organization (WTO) in 1995 and the signing of the Trade-Related Aspects of Intellectual Property Rights (TRIPS).

[6] . In 65 years, article 19 of the WHO Constitution, which gives it the power to negotiate treaties or agreements that are binding in nature, has been used only once, in the Convention against the tobacco… with the effectiveness that we already know.

The current model of research and development - R&D - for drugs based on the scheme: research - patent –monopoly – high price – restricted access… does not allow today the result of R&D to be immediately accessible to all those who need it.

The failure of the incentive systems of the current Research and Development model, based on intellectual property, requires thought on the alternatives for the future. There is a need for new mechanisms that simultaneously and efficiently promote innovation and access to medicines.

Patents grant a monopoly on the drug to the owner of the patent who has the freedom to set prices. This freedom to fix the prices of patented products has led to a large number of medicines not being accessible to the vast majority of the world's population living in developing countries because business logic prevails over the right of access to health care.

**Four major problems can be identified in the current patent system applied to drugs:**

1. **The philosophy of the R & D model**

For historical reasons, and perhaps due to lack of vision of the public sector, R&D for pharmaceutical products was developed since the mid-twentieth century as a business within a public service. In the past 20 years, the pharmaceutical industry has been characterized by a speculative financial capitalism with a high and immediate performance of not less than 15 %.[7].

As of the 90s, the pharmaceutical industry of the USA and Europe turned into an export industry, key in financial terms. The main objective is financial profitability, far beyond that of the number of people treated and cured. However, until the end of 2014, industrialized countries manage to afford this model. The South suffers dramatically from the lack of access to medicines, particularly from the lack of access to the very expensive medicines against HIV-AIDS; but the North organizes charitable channels such as the Global Fund, PEPFAR or UNITAID. Most recently, industrialized countries have started finding it difficult to pay their pharmaceutical bills, and in international negotiations taking place, especially in WHO, consensus is reached that the current model of R&D has reached a structural and irreversible crisis. The business model fails to meet the needs of the public service. The philosophy of the model is what is being questioned.

2. **Reduction of pharmaceutical innovation**

Pharmaceutical innovation is not up to par with what seemed to suggest the rapid advances in molecular biology, genetics or bioinformatics over the last 10 years.

[7] See P. Even, B Debré "Guide des 4000 médicaments utiles, inutiles ou dandereux (*Guide of the 4,000 useful, useless or dangerous drugs)*, Ed. Cherche midi, Paris 2012.

A recent study by the journal Prescrire[8] analyzed the drugs that were introduced in the French market from 2006 to 2011 (six years), concluding that the number of molecules that provided significant therapeutic advance dropped dramatically: from 22, in 2006 to 15, 10, 7 and 4 in the following years until 2011 when the study states that only 1 (one) drug of major therapeutic interest was put on the market (5). In the case of France, one of the largest pharmaceutical markets in the world, where, in addition, the State pays the bill for drugs, supposedly the vast majority of drugs that came out in the world between 2006 and 2011 were introduced in the French market. In other words, the decline in innovation observed in France is already an indicator of the global situation.

### 3. High prices

The case of hepatitis C is an alarm signal of what is happening and could occur in the future. Hepatitis C, which the World Health Organization estimates 150 million people suffer from in the world, was until now being treated with pegylated Interferon, an expensive, complex to use drug with serious side effects. The new oral drugs, Sofosbuvir and Simeprevir, known as direct-acting antivirals (DAAS), newcomers to the market in the last 10 / 12 months, could revolutionize the treatment of hepatitis C. Studies show cure rates of over 90% for some genotypes of the disease. (Four of the six known ones). Unfortunately the sales price of the treatment is exorbitant. In the United States, a standard 12-week treatment costs US $ 84,000 equivalent to US $ 1,000 per tablet. Experts from the University of Liverpool estimate that the cost of production is within a range of US $ 68-136 per treatment. [9]

The striking difference in price is often justified with the argument that the development of novel drugs is very expensive. However, in this case, the product was developed by a small company that was acquired by Gilead Sciences, the North American laboratory, proprietor of the patent of the product, that did not perform the research on the product and only bought the laboratory that conducted the research.

Countries such as Spain and France have managed to negotiate with the manufacturer, up to 25,000 and 42,000 euro respectively per treatment, figures

[8] Cited by Even P, Debre B. Guide des 4000 médicaments utiles, inutiles ou dangereux. Paris: Cherche Midi; 2012.

[9] Santi P. Hépatite C: le nouveau hold-up des labos (*Hepatitis C: the new holdup by the laboratories)*. Le Monde [Internet]. 8 July 2014 [cited 10 July 2014]. Available at: http://www.lemonde.fr/sciences/article/2014/07/08/nouveaux-traitements-de-l-hepatite-c-le-hold-up-des-labos_4452689_1650684.html

that, with the volume of potential patients in these countries, would bankrupt social security systems.

## 4. The costs of R&D

Since the fifties, some references on the costs of R&D for pharmaceutical products can be found. According to some sources, these figures could have increased from 1 million to 2.5 billion US dollars for the development of a single product. As long as there is no clarity and transparency in this field, the problem that can cause the high prices of drugs will remain unsolved.

Granting patents on the basis that the inventor must recover the cost of his investment when the actual costs are not clear, is something that States and society in general should be questioning. For example, the duration of patents for a period of 20 years, arbitrarily required by the TRIPS Agreement, should be based on the actual R&D costs of the products.

An article in the scientific journal BioSocieties,[10] published by the London School of Economics, argues that the real cost of R&D is, in fact, a fraction of the commonly cited estimates. According to the authors, Donald Light and Rebecca Warburton, the average cost of R&D to develop a drug, would be $ 43.4 million for the R&D for each new drug.

The Drugs for Neglected Diseases Initiative (DNDi), founded by the NGO Medecins Sans Frontieres (MSF) in 2004, recently published their research costs after 10 years of experience[11]. Their figures are as follows: 100 to 150 million euro for R&D for a new chemical entity.[12]

As the true costs of R&D are not known, prices are set simply based on the maximum of what each market can take on or pay.

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[10] Light D, Warburton R. Demythologizing the high costs of pharmaceutical research. BioSocieties. 2011;6(1):34-50.

[11] DNDi. An innovative approach to R&D for neglected patients: Ten years of experience and lessons learned by DNDi [Internet]. Geneva: DNDi; 2013 [cited 10 July 2014]. Available at: http://www.dndi.org/images/stories/pdf_aboutDNDi/DNDiModel/DNDi_Modelpaper_2013.pdf

[12] figures that have been readjusted in the usual manner for pharmaceutical R&D for infectious diseases to cover the risks of failure.

**The future of WHO: Binding resolutions?**

In May 2012, a resolution adopted by the World Health Assembly in Geneva[13] represented a first step towards a change in the dominant model of pharmaceutical research today.

This resolution follows up on the report of the "Consultative Expert Working Group on Research and Development: Financing and Coordination" -known under the acronym of CEWG-, which recommended **starting negotiations on a binding international convention to promote research and development on drugs.**

Relying on a binding global treaty or convention, negotiated in WHO, could allow sustainable financing of the research and development of useful and safe drugs at affordable prices for the population and the public social security system to be ensured. The adoption of a convention of this sort, within the framework of the WHO, based on article 19 of its constitution[14], would also allow global health governance to be rethought. The negotiation of "global and binding instruments in health issues of global concern" is perhaps the most promising clue of the role WHO could take on in the future.

The dilemma for the member countries of WHO is clear, they will have to choose between: an Office to manage projects financed by the private and philanthropic sector, or rebuild a public and independent International Agency to watch over public health. The University and the Academy should play a central role to persuade the States that recommending or legislating is the dilemma of WHO, of public health and access to medicines.

Thank you

[13] 65th WORLD HEALTH ASSEMBLY WHA65.22 "Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination", 26 May 2012.
[14] Article of the WHO Constitution which grants the organization the possibility of adopting binding international conventions or treaties. This article was used only once since WHO exists with the adoption of the convention on tobacco control adopted in 2003.