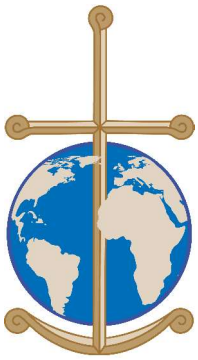
THE CARITAS IN VERITATE FOUNDATION WORKING PAPERS
"The City of God in the Palace of Nations"

Universal Access to Medicines

Ethical Reflections on Ending Pediatric HIV



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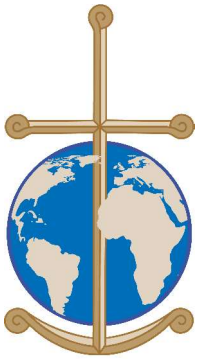

With a selection of recent documents from the
Church's engagement on Universal Access to Medecines

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LIST OF ACRONYMS

4Children	Coordinating Comprehensive Care for Children
ACT	Accelerating Children's HIV/AIDS Treatment
ADB	Asian Development Bank
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
AR/ARV	Antiretroviral
ART	Antiretroviral Treatment
AZT	Zidovudine
BITs	Bilateral Investment Treaties
CEO	Chief Executive Officer
CHAI	Clinton Health Access Initiative
CI	Caritas Internationalils
CIFF	Children's Investment Fund Foundation
CIPHER	Collaborative Initiative for Paediatric HIV Education and Research
CRS	Catholic Relief Service
CST	Catholic Social Teaching
DBS	Dried Blood Spot
DFID	Department for International Development
DNDi	Drugs for Neglected Diseases Initiative
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment Short course
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe
DTG	Dolutegravir
EAA	Ecumenical Advocacy Alliance
EDARP	Eastern Deanery Aids and Relief Program
EGPAF	Elizabeth Glaser Pediatric Aids Foundation
EID	Early Infant Diagnosis
EMA	European Medicine Agency
EOI	Expression Of Interest
EpiC 3-90	Epidemic Control 90-90-90
ESA	East and South Africa
FAO	Food and Agriculture Organization
FBO	Faith-Based Organizations
FDA	Food and Drug Administration
FTAs	Free Trade Agreements
GAP-f	Global Accelerator for Pediatric Formulations
GCSF	Global Community Service Foundation
GID	Global Infectious Disease
GNP+	Global Network of People Living with HIV

GRAIL Project	Galvanizing Religious Leaders for Accelerated Identification and Linkage to Pediatric ART
HIV	Human Immunodeficiency Virus
HLD	High-Level Dialogue
HRH	Human resources for health
HTS	HIV testing services
IAS	International AIDS Society
ICAP	international centre for Aids care and treatment Program
ICCPR	International Covenant on Civil and Political Right
ICESCR	International Covenant on Economic, Social and Cultural Rights
ILO	International Labour Organization
IMPAACT	International Maternal Pediatric Adolescent AIDS Clinical Trials
INERELA+	International network of religious leaders (?)
IPRs	Intellectual Property Rights
LDCs	Least Developed Countries
LMICs	Low and Middle Income Countries
MFN	Most Favored Nation
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NACA	National Agency for the Control of AIDS
NGO	Non-Governmental Organizations
NRA	National Regulatory Authorities
OVC	Orphans and Vulnerable Children
PACF	Positive Action for Children Fund
PADO	Paediatric Antiretroviral Drug Optimization
PAWG	Paediatric ARV. Working Group
PCR	Polymerase Chain Reaction
PENTA	Paediatric European Network for Treatment of AIDS
PEPFAR	President's Emergency Plan for AIDS Relief
PHTI	Paediatric HIV Treatment Initiative
PIP	Pediatric Investigation Plan
PLHIV	People Living with HIV
PMTCT	Prevention of Mother-To-Child Transmission
POC	Point-Of-Care
PSP	Pediatric Study Plan
R&D	Research and Development
RAL	Raltegravir
RTAs	Regional Trade Agreements
SDGs	Sustainable Development Goals
SGSSS	Spanish acronym for Colombia general social health system
STI	Sexually Transmitted Infections
SRA	Stringent Regulatory Authorities
TB	Tuberculosis
TRIPs	The Agreement on Trade Related Aspects of Intellectual Property Rights

UN	United Nations
UNAIDS	United Nations Emergency Plan for AIDS
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNICEF	United Nations International Children's Emergency Fund
UN-MPP	United Nations Medicines Patent Pool
USAID	United States Agency for International Development
USFDA	US Food and Drug Administration
VACS	Violence Against Children Surveys
WASH	Water, Sanitation and Hygiene
WCA	West and Central Africa
WCC	World Council of Churches
WCC-EAA	World Council of Churches- Ecumenical Advocacy Alliance
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organizations

EDITORIAL: ACCESS TO MEDICINES - A CATHOLIC PERSPECTIVE

CARDINAL PETER KODWO APPIAH TURKSON
Prefect of the Vatican Dicastery for Promoting Integral Human Development

1. Introduction

The Catholic Church recognizes the right to health as a fundamental human right, intrinsically linked to the right to life, insofar medical care is necessary for the proper development of human beings.[1]

This fundamental human right is also codified in several instruments of international law, such as article 25 of the Universal Declaration on Human Rights, whose customary nature is widely acknowledged.

Moreover, through the adoption of the Sustainable Development Goals, the family of Nations has undertaken to "achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all".[2] Ensuring the success of this target, including an end to the epidemics of AIDS, tuberculosis, malaria, neglected tropical diseases and combat hepatitis, water-borne and other communicable diseases, will require global solidarity and partnership, especially in times of diverse and demanding global challenges.

2. State of Play

Despite formal recognition of the right to health, its full enjoyment remains, for millions of people around the world, an elusive goal, due to, *inter alia*, obstacles in access to high quality, accessible, affordable, and acceptable medicines.

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It is worth noting that through both private and public investment, we witness significant scientific advancement in the understanding and use of biological resources. The application of this advancement holds great social value and potential to improve the lives of people, particularly in the medical and pharmaceutical fields.

While justice requires that the fruits of scientific progress serve the entire human family equally and not only the sectors with the greatest purchasing potential, we often observe that they are unfairly distributed.

Let us recall only one example. Today, millions of people continue to be newly infected with HIV. Those already living with this virus are at risk of developing the life-threatening illnesses associated with AIDS, and among them are many children. In July 2018, the Joint United Nations Programme on HIV/AIDS (UNAIDS) reported that 21.7 million people were accessing ART out of an estimated 36.9 million people living with HIV.[3] In the past years, there has been much progress with the development of ARV medicines for adults and in making them available to many people in need of such treatment throughout the world. Regrettably, children living with HIV have not been accorded priority attention in this field. Even at the present time, more efforts are needed to provide optimal, affordable, accessible and acceptable formulations of such medicines and of medication to prevent transmission from mothers to babies, to develop more options for diagnosing HIV among children at community levels and at the point of care. Thus, we continue to face many challenges in effort to implement goals of early infant diagnosis and treatment of HIV. In fact, less than half (43 percent) of infants born with HIV receive such services within the first two months of their lives. Without access to early diagnosis and ART, more than one-third of children living with HIV die before their first birthday, and one-half die before their second birthday.

In the face of such situations, the Social Teaching of the Church offers some guiding principles that could hopefully inspire public policies.

3. Some guiding principles

Among the relevant principles of the Social Teaching of the Church, it is worth recalling that of the common good, that is the good of all people and of the whole person.[4] When applied to the field of medical and pharmaceutical research, this principle requires that the resulting achievements effectively benefit all mankind.

Another pertinent principle that should be mentioned is that of the universal destination of earthly goods. According to the Catholic Church, "God destined the earth and all it contains for all men and all peoples so that all created things would be shared fairly by all mankind under the guidance of justice tempered by charity".[5]

New technologies and knowledge constitute a particular form of property that is no less important than land or capital. These resources, like all goods, have a universal destination, in the sense that they are originally meant for all.

New technologies and knowledge constitute a particular form of property that is no less important than land or capital. These resources, like all goods, have a universal destination, in the sense that they are originally meant for all.[6] They must then "be placed in a context of legal norms and social rules designed to guarantee that they will be used according to the criteria of justice, equity and respect of human rights. The new discoveries and technologies, thanks to their enormous potential, can make a decisive contribution to the promotion of social progress. However, if they remain

concentrated in the wealthier countries, or in the hands of a small number of powerful groups, they risk becoming sources of unemployment and increasing the gap between developed and underdeveloped areas".[7]

While acknowledging the validity and also the necessity of the right to private property, the Catholic Church considers that this right does not nullify the validity of the principle of the universal destination of goods and the necessity to prioritize the common good. As St. John Paul II put it, private property "is under a 'social mortgage', which means that it has an intrinsically social function, based upon and justified precisely by the principle of the universal destination of goods".[8]

This reasoning also applies to intellectual property rights. These rights need to be adequately recognized, insofar they do compensate investments in time and capital, and they do encourage promising research. Furthermore, they promote the common good by accelerating the search for solutions to the modern world. For example, in the pursuit of new medical treatments, special protections are needed to ensure that producers are able to recover their massive expenditures on research—these include just wages for scientists and researchers, as well as compliance with regulations that ensure product safety. In this regard, intellectual property rights protection enables the search for solutions to problems in the world.

It is noteworthy that intellectual property rights are not an end in themselves but a mean to an end. They are, then, subordinated to the requirements of the common good, which demands that control mechanisms monitor the logic of the market. As St John Paul II affirmed, the "law of profit alone cannot be applied to that which is essential for the fight against hunger, disease, and poverty".[9] These words continue to ring true.

Policies and laws should maintain a perspective focused on the respect and the promotion of human dignity, in a spirit of solidarity within and among nations. This means that while recognizing the value of intellectual property rights protection, we should focus on the purpose of such rights and the negative consequences of the current system. When, for example, high-income countries excessively protect knowledge based on a rigid assertion of intellectual property rights, this leads to an imbalance that must be addressed. Let us not forget that the right to health should be prioritized over private interest and, therefore, access to medicine should be guaranteed in accordance with the principle of non-discrimination and in a spirit of equity transparency, participation and accountability.

Policies and laws should maintain a perspective focused on the respect and the promotion of human dignity, in a spirit of solidarity within and among nations. This means that while recognizing the value of intellectual property rights protection, we should focus on the purpose of such rights and the negative consequences of the current system.

As stated by Pope Francis, "what is needed is sincere and open dialogue, with responsible cooperation on the part of all: political authorities, the scientific community, the business world and civil society".[10]

In order to promote positive dialogue that results in positive action, the three principles of solidarity, subsidiarity, and concern for the common good are needed. Solidarity would have us care about the concerns of others as much as our own; and subsidiarity would have us accept others as equals.

They speak for themselves, we listen, and we help them to participate, if they need such help.[11]

4. Conclusion

Notwithstanding all the positive initiatives implemented over the last decade, for example for ending the HIV/AIDS epidemic, there is still much to be done to reach the goal of fair access to medicine.

Among the challenges experienced by many countries, there is a predominant emphasis on profitability of medicines and diagnostic tools, resulting in prohibitive price structures. Furthermore, insufficient attention has been given to research and development of "child friendly" medications and diagnostic tools to be used for children living in low-income and low technology settings.

"Now is the time for courageous actions and strategies, aimed at implementing a 'culture of care' and 'an integrated approach to combating poverty, restoring dignity to the excluded, and at the same time protecting nature'.

"Now is the time for courageous actions and strategies, aimed at implementing a 'culture of care' and 'an integrated approach to combating poverty, restoring dignity to the excluded, and at the same time protecting nature'. 'We have the freedom needed to limit and direct technology'; 'to devise intelligent ways of […] developing and limiting our power'; and to put technology 'at the service of another type of progress, one which is healthier, more human, more social, more integral'".[12]

Without timely, effective and cooperative actions, diseases such as HIV will continue to claim the lives of too many persons, including children and adolescents.

As a conclusion, I would like to spare a special thought to all the children who lose their lives because they have no access to medicines. Let us keep in mind that these children are part of our future; they experience much suffering during their brief lives. Their premature deaths deprive the human family of their talents and potential contributions to the wellbeing of their families, local communities, and society-at-large.

Notes

1. Pope John XXIII, Encyclical Letter *Pacem in Terris*, para. 11.
2. United Nations Sustainable Development Goals, SDG n. 3.8; Available at: https://sustainabledevelopment.un.org/SDG3 [Accessed 21 November 2018].
3. UNAIDS Report, Miles to Go: Closing Gaps, Breaking Barriers, Righting Injustices, Geneva, 2018.
4. Pontifical Council for Justice and Peace, Compendium of the Social Doctrine of the Church, 2004, n. 165.
5. Second Vatican Ecumenical Council, Pastoral Constitution *Gaudium et Spes*, 69: AAS58 (1966), 1090.
6. Pope John Paul II, Encyclical Letter *Solicitudo Rei Socialis*, para. 42.
7. Pontifical Council for Justice and Peace, Compendium of the Social Doctrine of the Church, 2004, para. 283.
8. Pope John Paul II, Encyclical Letter *Solicitudo Rei Socialis*, para. 42.
9. Pope John Paul II, Address to 'Jubilee 2000 Debt Campaign', 23 September 1999.
10. Pope Francis, Address to the United Nations Office at Nairobi, Apostolic Journey to Kenya, Uganda and the Central African Republic, 26 November 2015.
11. Cardinal Peter K.A. Turkson, Address to German-African Healthcare Symposium, 13 October 2016.
12. Pope Francis, Address to the Joint Session of the United States Congress, 24 September 2015.

SECTION ONE:

ETHICAL REFLECTIONS ON ENDING PEDIATRIC HIV

UNIVERSAL ACCESS TO MEDICINES, TRIPS AND THE PATENT SYSTEM

A *Caritas in Veritate* Foundation Report by

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1. Introduction

Over the last few decades, medical innovation has noticeably improved the lives of millions of people across the globe. Vaccines have significantly reduced the incidence and prevalence of diseases. ARV medicines have greatly improved the lives of PLHIV. Despite this significant progress, however, millions of people continue to suffer and die from treatable conditions because they lack access to health technologies. Indeed, current investment in R&D of health technologies is not adequately addressing a number of important health needs. For some conditions and diseases, this is due to inadequate resources for R&D when the market does not provide sufficient return on investment.

Despite this significant progress, however, millions of people continue to suffer and die from treatable conditions because they lack access to health technologies.

Achieving universal health coverage requires access to safe, effective, quality and affordable essential medicines and vaccines, as also foreseen in the targets of the UN SDGs.[1] Thus, proper access to health care is a global concern, especially in view of the following factors: the rising prices of new medicines that place increasing pressure on the ability of all health systems to provide full and affordable access to health care; persisting problems of shortages and insufficient stock of essential medicines, especially for non-communicable diseases and vaccines; and the increasing number of substandard and falsified medical products that pose an unacceptable risk to public health.

This article will cover the technical barriers to access of medicines and to the full realization of the right to health, through an analysis of the work carried out in the multilateral environment, such as the WTO and WIPO. As it will be outlined in the subsequent publication, millions of children living with HIV still lack this fundamental human right.

2. The right to health in international law

The right to health is recognized as a fundamental right in customary international law, as well as in treaty law. Article 25 of UDHR includes the right to health and medical care within the more general rubric of the right to "enjoy an adequate standard of living"[2]. In its Article 12.1, the ICESCR, which is part of the International Bill of Human Rights, along with the UDHR and the ICCPR, directly recognizes the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health".[3] Additionally, the bylaws of the WHO Constitution[4] further specify the content of that right.

Under Article 12 of the ICESCR, States are further obliged to (1) ensure the care of mothers and children, (2) provide vaccines against the most serious infections that affect the community, (3) take measures to prevent, treat and control epidemics, (4) sensitize the public about health issues, and (5) provide training to health personnel.[5] In addition to identifying other international instruments for the protection of health, the ICESCR General Comment No. 14[6] offers further interpretation of its own Article 12, re-affirming that its core obligation is to ensure, at minimum, the essential standards of each right guaranteed by the same Covenant. General Comment No. 14 also identifies the following minimum requirements which States must ensure: (1) the access to health care in a non-discriminatory way, (2) access to basic nutritional level, (3) access to housing, basic sanitation and a sufficient supply of drinking water, (4) the supply of essential drugs, as identified by WHO in the WHO Action Program on Essential Drugs, (5) an equitable distribution of benefits and health services, and (6) adoption of national strategies to prevent and combat epidemics. In addition to these obligations, States have a duty to encourage medical research, as defined in the Report of the High Commissioner for Human Rights on the TRIPs Agreement.[7] Regardless of whether a fundamental right to health should be recognized, the legal question seems to be settled. Moreover, the above-mentioned General Comment No. 14 serves as a useful tool to define the legal content of that right.

3. Patent protection and right to health

A question arises: is it still valid to affirm the traditional understanding that patent protection poses no conflict to the enjoyment of the right to health?

Given the above legal framework, a question arises: is it still valid to affirm the traditional understanding that patent protection poses no conflict to the enjoyment of the right to health? In this regard, from a general and theoretical perspective, as well as from the framework of the current system of patents for intellectual property, we are, perhaps, obliged to offer a negative response.

The modern patent system, based on the objective assessment of inventions, was introduced by the Venetian Republic in 1474.[8] The two

requirements indicated by the Venetian Republic – the usefulness and the novelty of an invention – still are in force today in all States. As in a Faustian bargain, the inventor and the government undertake a long-term pact: the inventor commits to disclose all information of his/her invention, and the government guarantees that it will provide legal protection to give exclusive rights on the economic returns of the invention. IPRs have evolved substantially over the centuries, but the Faustian bargain remains unchanged.[9]

The need for clarity regarding intellectual property and public interest was clearly outlined by Lord Thomas Macaulay in his statement opposing an 1841 bill to increase the term of copyrights at a debate in the British House of Commons. In that historic case, the bill's supporters argued that the Parliament should grant the additional period of protection, simply because it was "right and just" to do so. Lord Macaulay, on the other hand, emphasized that Parliament should grant the additional rights only if it was determined empirically that doing so would benefit the public, since copyright protection had been created, ultimately, for the public good and not for the private benefit of authors. In defining the principle of copyright law, he stated: "It is a tax on readers for the purpose of giving a bounty to writers. The tax is an exceedingly bad one; it is a tax on one of the most innocent and most salutary of human pleasures; and never let us forget, that a tax on innocent pleasures is a premium on vicious pleasures. I admit, however, the necessity of giving a bounty to genius and learning. In order to give such a bounty, I willingly submit even to this severe and burdensome tax. […] It is good that authors should be remunerated; and the least exceptionable way of remunerating them is by a monopoly. Yet monopoly is an evil. For the sake of the good we must submit to the evil; but the evil ought not to last a day longer than is necessary for the purpose of securing the good".[10] The approach adopted by Lord Macaulay was to view copyright as a right that exists only by government decree, created for the public good, and which must be regulated by the government to ensure that the public purpose is fulfilled. As even recalled by William Patry, former Senior Copyright Counsel at Google, the final part of Lord Macaulays's speech is not an attack on the entire copyright system but an acknowledgment that there is not an automatic benefit to IPR protection.[11] If, as in Macaulay's situation, increasing the cost of books would increase the number of books written, and thereby increase learning, we would gladly pay the higher rate.

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All the *Sturm und Drang* about IPRs that took place during the last decades served to pit developed countries against developing ones and civil society and NGOs against the private sector (particularly the pharmaceutical sector); beneath it all is a basic fact that must be noted: the global system of intellectual property protection has profoundly changed over the last 20 years. At the beginning of the 21st century, anyone who thought that

the implementation of the TRIPs Agreement would settle international debates on the wisdom of increasing global IPRs was sorely mistaken. In 2015, The Economist published an article on patents, aptly titled "A Question of Utility", which outlined how arguments about IPRs have become contentious and forceful, largely due to strong economic interests on both sides of the issue.[12]

A. Patent-related barriers to access medicines

The current system of IPR protection interferes in two ways with the right to health. First of all, people from LDCs cannot generally afford the high cost of patented drugs, which is often due to the patent owner's monopoly on production of such medications. As demonstrated in the Report of the Commissioner for Human Rights of the Council of Europe, and following the current economic crisis and the austerity measures adopted in Greece, there were "shortages of certain medications in public hospitals, thus obliging doctors to change treatment protocols".[13] Moreover, in both developing and developed countries, the high cost of patented drugs exceeds the budgets earmarked for public expenditure on health care, in general.

The second obstacle is related to R&D and the fact that patent protection does not operate as an incentive to research on so-called "no market" treatments, including those for malaria and TB. In other words, the market (although large) has proven to be too poor to ensure a return on R&D investments made by pharmaceutical companies for certain drugs. For this reason, we are witnessing a diversion of pharmaceutical research from strategic areas to those of less importance, such as for weight-loss treatments or remedies for impotence, which have greater market potential in wealthier industrialized countries. Does this commercially determined "question of utility" indicate a failure of the patent system to serve as an incentive for medical research? Is it sufficient to delegate medical research to the private sector alone? Can the State withdraw from this discussion or refuse to take any role in defining research priorities? Does juridical science have an obligation to answer these questions, or should the matter be left only to politics? As is a concern for most of these questions, the conflict between IPRs and enjoyment of the right to health is greatly related to the access to medicines, which must be closely examined.

Does this commercially determined "question of utility" indicate a failure of the patent system to serve as an incentive for medical research? Is it sufficient to delegate medical research to the private sector alone? Can the State withdraw from this discussion or refuse to take any role in defining research priorities? Does juridical science have an obligation to answer these questions, or should the matter be left only to politics?

B. International development of IPRs

Before the Agreement on TRIPs in 1994, developing countries enjoyed practically unlimited power to pursue public health objectives. Moreover, any potential conflict or interference with IPRs was insignificant. Developing countries inherited this prerogative from the processes of decolonization outlined in the Paris Convention of 1883.[14] However, the basic patent principle of the Convention was limited

to the so called "Unionist Priorities"[15] and in respect to the principle of "national treatment".[16] In this regard, the Paris Convention left States free to develop their own system of patents and to deny stipulation or restriction for patented pharmaceutical products. Thus, the ability of the developing and of the least developed countries to provide essential medicines was subject to such variables as methods of procurement and local production capacity. In relation to this issue, other key factors included the reverse engineering capacity of the generic drug producers, their pricing policies and the availability of chemical substances on the world market.

Behind these legal scenarios and repercussions, one also must take into account the capacity of some developing countries to produce generic drugs at low cost, irrespective of whether or not these drugs had been patented in Europe or in the United States. After the TRIPs Agreement of 1994 entered into force, the developing countries were forced to strengthen and, in some cases, create their own pharmaceutical patent laws from scratch.

C. The impact of compulsory license for pharmaceutical products in the TRIPs Agreement

Article 31 of the TRIPs Agreement[17] outlined standards for granting compulsory licenses for situational use of patented intellectual property; however, it also required (among several conditions) that patent owners still be fairly compensated and that the use of such licenses would primarily be restricted to supplying the domestic market of the applicant State.[18] From 1 January 2005 onwards, all countries in the developing world, except LDCs, were forced to implement all provisions of TRIPs. This shift had the potential for dramatic repercussions, since the availability of lifesaving drugs now would be left to the pricing policies of large pharmaceutical patent holders. Developing countries that already were producing generic drugs at low cost – India for example – could no longer benefit from the immense *reservoir* of allowances which had previously enabled the country to face the most serious health crisis in the world. The spread of HIV in Africa posed not only a challenge of significant social and ethical proportions, but it was also a main trigger for subsequent events. The latter explains the WTO's adoption of the Doha Ministerial Declaration of "TRIPs and Public Health 2001",[19] as well as other subsequent WTO developments in the field, all of which led to an amendment of TRIPs, which is currently subject to ratification by States.

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D. The way leading to the Doha Declaration

The adoption of the Ministerial Declaration of "TRIPs and Public Health 2001", held in Doha by the WTO Ministerial Conference on "TRIPs and Public Health", marked a turning point in the WTO policies. The developing countries, sharing common goals and adopting a unified strategy, made their voices heard. The essence

of the Declaration is contained in paragraph 4: "We agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".

The Declaration found its raison d'être directly from issues discussed in the "Uruguay Round" negotiations in 198620 (which eventually led to the creation of the WTO), during which countries such as Brazil and India expressed their concern about the shift of IPRs within trade law. Those concerns were mainly related to the incompatibility between IPRs and fundamental rights, such as access to health and food.

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Concerns emerged in a public controversy that arose when the then-South African president, Nelson Mandela, and 39 pharmaceutical companies faced a disagreement on the 1997 Medical Act. Due to this law, the South African government had the capacity to obtain compulsory licenses for certain medicines, especially for HIV treatment, in exchange of the payment of royalties to patent holders; all of which was in line with the abovementioned Article 31 of TRIPs. The South African Association of Pharmaceutical Industries and the 39 multi-national drug companies, however, attempted to block the legislative initiative by presenting a case before the Pretoria High Court which alleged a breach of Article 28[22] of TRIPs. The dispute continued until 2001, when the multinational drug companies decided to withdraw the appeal. Although these companies initially were supported by the U.S. government, the public reaction to the legal developments was so strong that the companies were forced to withdraw their complaint and suffered significant reputational damages. The intention of the drug companies to intimidate the South African government was quite clear, and their strategy cost the government a four-year delay in the production of generic ARV drugs, together with incalculable human suffering and loss.

Similarly, the United States used the WTO Dispute Settlement to challenge the law on compulsory licenses in Brazil in 2001. Brazil, however, had just embarked on a program to combat HIV, and such a move appeared, in the eyes of international public opinion, to negatively target the treatment program just started by the Brazilian government. To avoid diplomatic complications, the U.S. abandoned the dispute.

These legal battles have certainly fueled public and political debate on patent protection of pharmaceuticals. On the one hand, pharmaceutical manufacturers and industrialized countries argue that the high prices of medicines are justified by their respective investment in long-term scientific research. On the other hand, developing and least developed countries deem long-term planning a second priority when facing a humanitarian emergency of enormous proportions like that of HIV/AIDS. There was also a widespread belief that the availability of generic drugs, combined with the stimulus of competition in the market, would play a decisive role in reducing the prices of medicines. A WHO report, issued in 2001, showed that certain drugs—cough syrups and other types, including acetylsalicylic acid—were produced under conditions of near-perfect competition (number of manufacturers, products with low differentiation, minimal asymmetric information, low barriers to input); yet for others in which the market was characterized by a low degree of competitiveness, such as ARV medications, the prices were far higher than the marginal costs of production.

The Doha Declaration broadened the flexibilities through amendments of TRIPs – the so-called Doha Waiver - and restored the exercise of powers allocated to each State under Article 31 of the TRIPs Agreement, which previously went ignored by a narrow interpretation of the provision that reached far beyond the literal interpretation. The Declaration, however, left open questions. Indeed, the wording of paragraph 6 of the Declaration refers back to the WTO General Council to solve the problematic use of compulsory licenses by LDCs. These countries, in fact, do not possess the technology and infrastructure for local production of drugs: compulsory licensing would, therefore, be proven useless without granting the ability to import less expensive drugs from countries with sufficient manufacturing capacity and without interference from the pharmaceutical patent holders. The real problem is that, since 2005, two major suppliers, India and Brazil, have been obliged to implement their legislation in accord with the TRIPSs Agreement and thus to grant patent protection to the medications discussed above.

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From the standpoint of the United States and Europe, the interest was to reasonably limit the use of the compulsory licensing system. There were many proposals from others, however, and at the end of the negotiations, the U.S. played a successful weapon of *quid pro quo*: in exchange for a surrender on the issue scope of diseases, the Doha Waiver substantially limited the mechanism of compulsory licensing to the poorest countries of Africa. The Doha Waiver automatically gives to less developed countries the *status* of "eligible importing members", on the presumption that such countries do not have sufficient manufacturing capacity in the pharmaceutical sector. With regard to other countries, the situation is more complex. More than 40 countries (mainly industrialized) said they did not

want to use the compulsory licensing system or wanted to use the system only in cases of national emergency or circumstances of extreme urgency. In order to use the compulsory licensing systems, an importing country is required to notify the TRIPs Council of its intention to use the system in a whole or restricted manner. Such notification may be sent at any time and is not subject to the approval of any body of the WTO. When a country indicates its intention to participate in this system, it must declare that it has insufficient manufacturing capacity in the pharmaceutical sector for the product in question and communicate this statement to the TRIPs Council. If, with time, the *status* of incapacity to produce the drug no longer applies, the State exits from the system. The system is not based on the generic manufacturing capacity of the State, but on its practical ability to develop a particular drug. Therefore, the manufacturing incapacity *status* cannot be based on the lack of infrastructure alone; it also must be based on a lack of technology in reference to a specific pharmaceutical product.

The Doha Waiver of 2003 has been subject to harsh criticism on several fronts. According to most NGOs, it imposes unnecessary obstacles, mainly of a procedural and bureaucratic nature, to the effective use of compulsory license by countries with insufficient manufacturing capacity. The same criticisms have been raised in institutional settings, such as the European Parliament.

Ordinarily, States have not paid sufficient attention to concerns about the ability of non-WTO member countries to export medicines under compulsory licensing system. The Doha Waiver of 2003 has been subject to harsh criticism on several fronts. According to most NGOs, it imposes unnecessary obstacles, mainly of a procedural and bureaucratic nature, to the effective use of compulsory license by countries with insufficient manufacturing capacity. The same criticisms have been raised in institutional settings, such as the European Parliament. These criticisms are not only of an ideological nature but also propose specific remedies. There has also been occasion to dwell on the complexity of the notification system, and the difficulties of matching supply and demand due to the impossibility for producers to engage in any type of industrial planning. Many elements present obstacles to employing this system, such as the need to specify the amount of drugs required by the importing country. Even though the projected quantity can be changed over time, the fear of trade sanctions resulting from an incorrect use of the system presents a strong deterrence to its employment. Indeed, before July 2007, no country had used this licensing system.

The first country to notify the TRIPs Council of its desire to employ the mechanism of compulsory licensing was Rwanda in 2007. Since this country was included in the list of LDCs, it was not obliged to present such a notification and could have used the system without complying with any such formality. In any case, despite some pressure to the contrary, Rwanda expressed its intention to import 260,000 packs of TriAvir, a drug manufactured in Canada by Apotex, within a two-year period. Within the document, Rwanda reserved the option to change, over time, the projected amount of drugs subject to import. On October 4, 2007, Canada notified the TRIPs Council of its intention to issue a compulsory license for the production of TriAvir, in the same amount requested by Rwanda. However,

this pioneering choice made by Rwanda and Canada remained an isolated one on the world stage.

E. The post – Doha agenda: the "alphabet soup"

The strengthening of IPRs has led States, international organizations, NGOs and academia to express their concerns in an increasing number of international *fora*. The intellectual property issues have been high on the agenda of WHO and FAO, and are currently discussed by bodies such as the Conference of the Parties to the Convention on Biological Diversity of 1992. Moreover, they are of interest to political actors, such as the UN Council on Human Rights. States, and other actors in the International Community, are advancing negotiations in areas outside those related to intellectual property, including those of fundamental rights or of biodiversity. These subjects are much closer to the interests of developing countries, and they call into question positive regulations already established in international conventions while successfully creating new principles and standards for intellectual property protection. Since the TRIPs Agreement came into effect, bilateral and regional FTAs concluded by several governments have progressively expanded and deepened patent and test data protections on health technologies. Such provisions further exacerbate policy incoherence by narrowing the options provided by the TRIPs Agreement and the Doha Declaration for governments to ensure that intellectual property protection and enforcement does not undermine their human rights obligations and public health priorities. Several provisions found in bilateral and regional FTAs exceed the minimum standards for intellectual property protection and enforcement required by the TRIPs Agreement. These clear and higher standards of protection made through bilateral treaties are called TRIPs *Plus*. In some cases, such as the FTA between Europe and Mexico, these standards are clearly enumerated in a list and open to any subsequent instrument of intellectual property protection; in other cases, they generally refer to the new standards generated through bilateral investment treaties (BIT), which set the rules for the entry and exit of investments. Here used, the term "investments" provides for intellectual property and licensing of patents or trademarks, as well.[23] The contracting parties generally are required to open their borders to investments and to adopt the highest international standards of protection of such investments. However, the BIT and the possible application of the principle of Most-Favored-Nation (MFN)[24] does not have a direct impact on standards of protection of intellectual property. For this reason, "prospective BIT partners are generally expected, at the time the BIT is signed, to make a commitment to implement [...] TRIPs Agreement obligations within a reasonable time". A BIT always is followed by another agreement related to intellectual property. The main users of these instruments are Europe and the United States, which conclude these agreements in order to ensure

States, and other actors in the International Community, are advancing negotiations in areas outside those related to intellectual property, including those of fundamental rights or of biodiversity. These subjects are much closer to the interests of developing countries, and they call into question positive regulations already established in international conventions while successfully creating new principles and standards for intellectual property protection.

the quickest possible accession of the countries in developing the existing multilateral conventions on intellectual property regimes. The *status* of MFN is a bilateral arrangement providing TRIPs *Plus* requirements, and according to the application of Article 4 of TRIPs, the arrangement obliges the developing country to extend this treatment to all WTO members. In this way, the principle of MFN operates almost exclusively in favour of the United States and Europe. Faced with these observations, it seems natural to ask: what is pushing both the developing and least developed countries to conclude these bilateral agreements?

As rightly pointed out by Professor Okediji, the developing countries are still participating in these bilateral negotiations for the same reasons that they took part in them during the '60s and' 70s: the strong conviction that foreign aid and investment are vital to the promotion of economic development. At the same time, however, these countries show a certain myopia in not seeing the negative effects that can be caused by too high standards of intellectual property protection, especially for those that need "softer" regimes for a more open access to information and technology—or any modern economic development.[25]

The inadequacy of the TRIPs Agreement to set standards of intellectual property protection seems clear. The continuous pressure the United States and Europe put on other countries to sign bilateral treaties has led to an unprecedented expansion of international trade rules—rules which are inextricably intertwined with other international institutions such as those linked to human rights.

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Counter-multilateralism, such as bilateral or plurilateral agreements, is an umbrella term used to describe a set of strategies pursued by States, multilateral institutions, and non-State actors. Multilateralism is not necessarily cooperative, and it is characterized by integrative rules. Multilateral institutions continuously are challenged through the use of other multilateral institutions, either without resort to unilateralism or bilateralism or in conjunction with it.

Dissatisfied Intergovernmental Organizations, civil society, and less developed States are not likely to be able to counter the policies of established multilateral institutions, and, for many of them, multilateralism is the only way to effectively contest such policies in the first place. However, the strategy of developing countries is not limited to this approach. The shifting system can also function as a strategy that allows developing countries to create the necessary political platform for intellectual property changes in the WTO and WIPO, generating new dynamics of legislative output, standard-setting and composition dispute.

The phenomenon of counter-multilateralism represents a significant and difficult process, but it is a tool for institutional change. When there is a substantial link between different institutions and power—shared by many and not in the hands of only a few—multilateral institutions become a

strong tool for States and non-State actors. This term represents a more effective way to understand the persistence of contemporary multilateralism and the major changes at play in this sector.[26]

As a consequence of the Doha Round negotiation stalemate, we have observed a proliferation of bilateral and plurilateral agreements on intellectual property occurring outside the WTO framework. The great increase of bi-laterals and pluri-laterals led some authors to ironically define the multiplying acronyms as "alphabet soup". For example, the following agreements have all been concluded or negotiated in the last six years: SECURE (Standards to Be Employed by Customs for Uniform Rights Enforcement), ACTA (Anti-Counterfeiting Trade Agreement), TPP (Trans-Pacific Partnership Agreement), COICA (Combating Online Infringement and Counterfeits Act), PIPA (Protect IP Act), SOPA (Stop Online Piracy Act), and OPEN (Online Protection and Enforcement of Digital Trade Act), the Transatlantic Trade and Investment Partnership (TTIP).[27]

Such developments are consistent with what this article has repeatedly outlined: the TRIPs Agreement should not be seen as the endpoint in the development of the international intellectual property regime. The so-called new bilateralism is more consistent with developed countries' historic approach in foreign relations; this is particularly true of the general framework of international law in its dealings with developing countries since the independence era.

However, the Director General of WIPO, Francis Gurry, has expressed concern that by negotiating ACTA, in particular, countries have "taken matters into their own hands to seek solutions outside of the multilateral system to the detriment of inclusiveness of the present system". Michael Geist, a law professor at the University of Ottawa, also noted that "some might wonder whether ACTA is ultimately designed to replace WIPO as the primary source of international IP law and policy making".[28]

4. Conclusion: Balancing intellectual property protection with the human right to health

Today's IPR system is built on long-standing and traditional concepts of protection, and it is designed for an era before the technological revolution such as e-commerce or open-research networks. Classic copyright laws virtually are impossible to sustain today in the digital world, and the one-size-fits-all approach of patent law is no longer sustainable for the cross-industry complications accompanying the new technological development.[29]

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The tendency to further enlarge bilateral and plurilateral agreements in order to form megaregional agreements—such as the Transatlantic Trade and Investment Partnership or the Trans-Pacific Partnership—has been identified as one way forward. Certainly, the enlargement of RTAs

is a step towards further trade liberalization, but we have to bear in mind that these agreements inevitably threaten the desirability of reaching an agreement on a truly multi-lateral basis. In fact, by entering into a regional trade agreement, a country reduces the incentives to extend its efforts on trade liberalization at a multi-lateral level. Most importantly, we know that only the multi-lateral system is a clear, equitable system which provides effective guarantees for small and poor countries that tend to be penalized in an asymmetric RTA. Among the most damaging concessions that developing countries make in regional and bilateral agreements, there are, on the one hand, those concessions which enhance the monopolies on life-saving medicines[30] —only reducing access and affordability—and, on the other hand, those which provide excessive legal rights to foreign investors, limiting the policy space for nations to promote sustainable and inclusive development.[31]

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As happens with many deals, however, this one is rarely fully implemented, and the inventor often tries to hide as much as possible about his invention, while the government is not often in a position to assure full appropriation of the returns of the invention. The fundamental problem with intellectual property as an ethical category is that it is purely individualistic. It focuses on the inventor and ignores the social role of the creator and of the work itself, thus overlooking their significantly ethical relationship to the rest of society.

To remedy the current imbalance, both Pope Benedict XVI[32] and Pope Francis[33] stressed the impelling need to overcome the "excessive zeal for protecting knowledge through an unduly rigid assertion of the right to intellectual property, especially in the field of health care" by the application of the principles of solidarity with all humanity and of service for the common good.

The patent *status* of an essential medicine can represent one of the barriers to achieving a system of affordable pricing and to the fulfillment of a government obligation to assure the right to essential medicines for its respective population.

Among the challenges experienced by many countries, there is a predominant emphasis on profitability of medicines and diagnostic tools, resulting in a prohibitive price structure.

The success of the WTO TRIPs Council to facilitate a waiver extension in November 2015, and thus to ensure maximum flexibility in the patenting of pharmaceutical products until at least 2033 for use in LDCs, represents a solid foundation for positive future actions. Access to medicine is intrinsically linked to the principle of equity and non-discrimination, transparency, participation, and accountability. The right to health and the access to essential medicines should always be prioritized over private interest.

Without timely, effective and cooperative actions, HIV will continue to claim the lives of too many children and adolescents. There is an urgent need to implement attainable and measurable milestones in the efforts to end HIV among children by 2020; one necessary step is to make available early diagnosis and treatment in order to "leave no child living with HIV behind". These milestones also will require constant monitoring and reporting in order to achieve the goals already articulated by the Internationally Community in this regard.

Again, if paying higher prices for medicine would aid the research in other sectors that are usually invisible to the market, we would be ready to do so. However, neither copyright taxes nor patents lead to the creation of new jobs, and, in some cases, they lead to the suppression of innovation. The solution to the current international framework is not to throw out the system entirely; instead, we must reform it while inspired by a relevant question: will the proposal actually serve the common good by promoting access to medicine?

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Notes

1. SDG target 3.8 calls for the achievement of "universal health coverage, including financial risk protection, access to quality essential health- care services and access to safe, effective, quality and affordable essential medicines and vaccines for all". Available at http://indicators.report/targets/3-8/ [Accessed 19 November 2018]

2. Article 25 UDHR: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control". Available at http://www.claiminghumanrights.org/udhr_article_25.html#at27 [Accessed 19 November 2018]

3. Article 12.1 ICESCR: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health". Available at https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx [Accessed 19 November 2018]

4. Constitution of WHO (1946) preamble: "The States Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples: health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition". Available at http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1 [Accessed 19 November 2018]

5. More information available at https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx [Accessed 21 November]

6. The ICESCR General Comment No. 14 is available at http://www.refworld.org/pdfid/4538838d0.pdf [Accessed 19 November 2018]

7. Full report is available at https://documents-dds-ny.un.org/doc/UNDOC/GEN/G04/113/90/PDF/G0411390.pdf?OpenElement [Accessed 21 November 2018]

8. Archivio di Stato di Venezia, Senato terra, registro 7, carta 32:"*L'andarà parte che per auctorità de questo Conseio, chadaun che farà in questa Cità algun nuovo et ingegnoso artificio, non facto per avanti nel dominio nostro, reducto chel sarà a perfection, siche el se possi usar, et exercitar, sia tegnudo darlo in nota al officio di nostri provveditori de Comun. Siando prohibito a chadaun altro in alguna terra e luogo nostro, far algun altro artificio, ad immagine et similitudine di quello, senza consentimento et licentia del auctor, fino ad anni X"*.

9. D. Archibugi and A. Filippetti, The globalisation of intellectual property rights: four learned lessons and four theses, Paper No. 21930, posted 9 July 2010, Available at http://mpra.ub.uni-muenchen.de/21930/ MPRA [Accessed 21 November 2018]

10. The full statement is available at http://yarchive.net/macaulay/copyright.html [Accessed 21 November 2018]

11. W. Patry, Moral Panics and the copyright wars, Oxford University Press, 2009

12. *Cfr*. The Economist, A question of utility, 8 August 2015, available at http://www.economist.com/node/21660559 [Accessed 19 November 2018]: Gene Quinn, What 'The Economist' Doesn't Get About Patents, 13 August 2015, available at http://www.ipwatchdog.com/2015/08/13/what-the-economist-doesnt-get-about-patents/id=60626/ [Accessed 21 November 2018]

13. Report of the Commissioner for Human Rights of the Council of Europe available at https://rm.coe.int/report-on-the-visit-to-greece-from-25-to-29-june-2018-by-dunja-mijatov/16808ea5bd [Accessed 19 November 2018]

14. The Convention is available at http://www.wipo.int/edocs/lexdocs/treaties/en/paris/trt_paris_001en.pdf [Accessed 21 November 2018]

15. The Paris Convention foresees the right of priority in the case of patents, marks and industrial designs. This right means that, on the basis of a regular first application filed in one of the Contracting States of the Convention, the applicant may, within a certain period of time (12 months for patents and utility models; 6 months for industrial designs and marks), apply for protection in any of the other Contracting States. These subsequent applications will be regarded as if they had been filed on the same day as the first application. In other words, they will have priority (hence the expression "right of priority") over applications filed by others during the said period of time for the same invention, utility model, mark or industrial design. Moreover, these subsequent applications, being based on the first application, will not be affected by any event that takes place in the interval, such as the publication of an invention or the sale of articles bearing a mark or incorporating an industrial design. One of the great practical advantages of this provision is that applicants seeking protection in several countries are not required to present all of their applications at the same time but have 6 or 12 months to decide in which countries they wish to seek protection, and to organize with due care the steps necessary for securing protection.

16. The substantive provisions of the Paris Convention on national treatment, provide that, as regards the protection of industrial property, each Contracting State must grant the same protection to nationals of other Contracting States that it grants to its own nationals. Nationals of non-Contracting States are also entitled to national treatment under the Convention if they are domiciled or have a real and effective industrial or commercial establishment in a Contracting State.

17. The full text is available at https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm [Accessed 21 November 2018]

18. Please refer to the abovementioned Article 31 of the TRIPs Agreement

19. The full Declaration is available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [Accessed 21 November 2018]

20. More information available at https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm [Accessed 21 November 2018]

21. Resolution n. WHA49.14 - Revised Drug Strategy (1996). The Resolution requested the Director-General to prepare a study on the implications of the TRIPS agreement. This study was entrusted to the Programme of Action on Essential Medicines (PAME). In November 1997, PAME published the study "Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement," commonly known in the WHO as the "red book" on the TRIPS Agreement. Available at http://www.who.int/phi/WHA49.14.pdf [Accessed 19 November 2018]

22. Article 28 TRIPs Agreement: " Rights Conferred: 1. A patent shall confer on its owner the following exclusive rights:(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts." Available at https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm [Accessed 21 November 2018]

23. P. Drahos, BITs and BIPs: Bilateralism in Intellectual Property (2002), Journal of World Intellectual Property, 4

24. The MFN principle is mentioned, among others, in the Article 4 of the TRIPs Agreement

25. R. L. Okediji, Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection, University of Ottawa Law & Technology Journal, vol. 1, 2003, pp. 127 – 145

26. J. C. Morse -R. O. Keohane Contested Multilateralism in Review of International Organization, (2014). Available at http://www.princeton.edu/~rkeohane/publications/PublishedCM.pdf [Accessed 19 November 2018]

27. Peter K. Yu, The Alphabet soup of Transborder Intellectual Property Enforcement (2012), in Intellectual Property Law Drake University Law School. Available at: http://www.law.drake.edu/clinicsCenters/ip/docs/ipResearch-op7.pdf [Accessed 19 November 2018]

28. M. Geist, Toward an ACTA super-structure: How ACTA may replace WIPO (2010) available at: http://www.michaelgeist.ca/content/view/4910/125/ [Accessed 19 November 2018]

29. Keith E. Maskus, Private Rights and public problems, Peterson Institute for International Economics (2012)

30. R. Malpani, All costs, no benefits: How TRIPS-*plus* intellectual property rules in the US-Jordan FTA affect access to medicines, Oxfam Briefing Paper No. 102, 2007, available at http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf. [Accessed 18 November 2018]

31. See, among others, UNCTAD, "Towards a New Generation of International Investment Policies: UNCTAD's Fresh Approach to Multilateral Investment Policy-Making," IIA Issues Note No. 5, July 2013, available at http://unctad.org/en/PublicationsLibrary/webdiaepcb2013d6_en.pdf [Accessed 21 November 2018]

32. Pope Benedict XVI, Encyclical Letter *Caritas in Veritate* (2009)

33. Pope Francis, Apostolic Exhortation *Evangelii Gaudium* (2013)

Ending Pediatric HIV as a Case in Point

FAITH-BASED ORGANIZATIONS: ESSENTIAL PARTNERS IN ENDING PEDIATRIC HIV

A *Caritas in Veritate* Foundation Report by

MICHEL SIDIBÉ
Executive Director, UNAIDS

FBOs have been our steadfast partners from the earliest days of the AIDS epidemic. They share with UNAIDS a common foundation of values rooted in justice, dignity, compassion and human rights. Together, we have created a powerful platform to advance social justice, human development and health reform agendas.

FBOs have a long tradition of caring for people living with and affected by HIV. And although some faith leaders and communities have been less supportive than others, I know of many who adopt frank and pragmatic approaches to end a disease rooted in the historically charged issues of sexuality, stigma, marginalized populations and politics.

I am proud to stand together today with faith leaders and FBO partners who are working at the front lines of the HIV response while at the same time pushing the boundaries within their own faith communities. This is the way we shift the drivers of stigma and discrimination.

FBOs are integral to UNAIDS' unique, cosponsored structure. As a Joint Programme of the United Nations, UNAIDS brings together 11 UN entities to multiply the impact of leadership, investments and results, uniting countries and partners to achieve lifesaving outcomes.

We are guided by our Programme Coordinating Board, comprising representatives of 22 governments from all geographic regions, the 11 UNAIDS co-sponsors,[1] and a rotating delegation of NGOs that include civil society, faith-based and other groups, including associations of people living with HIV.

FBOs are pillars that support UNAIDS' platform for engaging top political leadership, gathering the best evidence, deploying world-class technical expertise, overcoming barriers to HIV services and enhancing coordination so that resources have the greatest possible impact.

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1. Principles, strategies and priorities for partnering with civil society and FBOs

UNAIDS' partnerships with civil society and FBOs focus on specific strategic priority areas:[2]

- Together, we engage PLHIV and other marginalized and vulnerable groups in ways that strengthen community voices. This creates a path to advancing policy development, strategic planning, monitoring and evaluation, resource allocation, service delivery, human rights protection and capacity building at local, regional and global levels;
- We support civil society to be "watchdogs" of national AIDS responses and to hold governments to account on their commitments;
- We provide services to PLHIV, other marginalized and vulnerable populations, local communities and affected groups and constituencies on HIV prevention, treatment, care and support;
- We leverage the HIV movement's passion and experience to generate a new, integrated movement that situates the AIDS response within the broader context of health, development, human rights and gender equality; and
- We engage civil society and affected communities in advocacy to promote and protect human rights.

UNAIDS, together with its FBO partners, developed a Strategic Framework for FBO partnerships in 2009 to guide our joint work.

UNAIDS, together with its FBO partners, developed a "Strategic Framework" for FBO partnerships in 2009 to guide our joint work.[3] It encourages global and national religious leaders to take positive public action in the AIDS response in 10 areas.[4] This Framework enables UNAIDS to efficiently create new partnerships and support existing partnerships with established FBOs working on HIV and related issues.

UNAIDS-FBO partnerships are established and growing. One of our oldest is with *Caritas Internationalis*, a longstanding collaborator in the AIDS response with huge reach into communities. Since 1999, CI and UNAIDS have maintained a Memorandum of Understanding[5] (renewed in 2003) that sets the parameters for productive cooperation between the two organizations, supporting exchanges of information and experiences and pursuing progress against HIV together.

One example of what this partnership delivers is a series of dialogues held in 2016 and 2017 at the Vatican with pharmaceutical and diagnostic companies, multilateral partners, FBOs and PLHIV to scale up access to pediatric HIV medication. Under the leadership of its President, Cardinal Peter Kodwo Appiah Turkson, the then Pontifical Council for Justice and Peace convened these dialogues in partnership with *Caritas Internationalis*, UNAIDS, PEPFAR and other partners, many of whom are also contributing

to this publication. This high-level advocacy was influential in strengthening the language and targets for the treatment of children living with HIV in the 2016 United Nations Political Declaration on HIV and AIDS[6] and in the adoption of an Action Plan for the targets.[7]

Another recent example is UNAIDS' partnership with the "We Will Speak Out" Coalition, which I launched in 2011 with the then-Archbishop of Canterbury, Rowan Williams. This global coalition of Christian-based NGOs, churches and organizations is working to end sexual violence across communities around the world. UNAIDS is currently exploring possibilities to integrate efforts with other faith partners, including Islamic Relief, to address sexual violence in conflict zones.

The "Strategic Framework" for FBO partnerships also aims to strengthen links at the country level to ensure strong FBO connections to national AIDS responses. This year, under the auspices of the PEPFAR/UNAIDS Faith Initiative,[8] four country consultations have taken place (in the Democratic Republic of the Congo, Nigeria, Tanzania and Zimbabwe) to develop "Faith in the Fast-Track" action plans to support national AIDS responses.

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2. HIV today: progress and challenges

Today, the AIDS movement has clear reasons to hope. Activism, community engagement, political leadership, science and innovation have enabled amazing progress and delivered important results for people.

Globally, 21.7 million people are accessing lifesaving treatment, and four out of five (81 percent) are virally suppressed.[9] At last, we have more people receiving treatment than waiting for it.

Just remember how far we have come. In 2000, South Africa had just 90 people receiving treatment in public health centres. Nowadays, 4.4 million people receive treatment, making it the largest treatment program in the world.[10] Globally, new HIV infections have fallen by 1 million since 2000.[11]

High- and low-income countries alike are closing in on the Fast-Track targets of 90-90-90 (90 percent of people living with HIV know their *status*, 90 percent of those individuals are receiving treatment and 90 percent of those have achieved viral suppression). In just four years, we have achieved 75-79-81 globally.[12]

3. Children still left behind

The AIDS response has achieved treatment and prevention coverage across most of the global adult population. But tragically, children and adolescents are being left behind. Just 52 percent of children under 14 had access to treatment in 2017.[13]

The world is on the Fast-Track to eliminating new HIV infections among children and ensuring that their mothers are alive and healthy, but we need to do more to ensure that all children living with HIV have access to treatment immediately.

We know what works. When we launched the Global Plan, we were told our goals were too ambitious. But over the course of six years, we brought down new HIV infections among children by 35 percent, from 270,000 to 180,000 in 2017, and a decrease of 58 percent (420,000) since 2000.

At the heart of this progress are strong partnerships that bring together technical agencies, bilateral donors, private and philanthropic sectors, civil society and—critically—FBOs, who were a part of shaping and implementing the Global Plan from the outset.

When we launched the Global Plan, we were told our goals were too ambitious. But over the course of six years, we brought down new HIV infections among children by 35 percent, from 270,000 to 180,000 in 2017, and a decrease of 58 percent (420,000) since 2000.

Today, the "Start Free, Stay Free, AIDS Free" Framework builds on the successes of the Global Plan and brings additional focus to the HIV prevention and treatment needs of children and adolescents to accelerate the end of the AIDS epidemic among this population by 2020.

"Start Free, Stay Free, AIDS Free" embraces the goals of the 2016 Political Declaration on Ending AIDS. Countries pledged to take a life-cycle approach to reach young children, adolescents and young women from age 0 to 24 to prevent new infections, ensure treatment and promote good health for those living with HIV.

Start Free targets

- Reduce new HIV infections among children to 40,000 by 2018.
- Reach and sustain 95 percent of pregnant women living with HIV with lifelong HIV treatment by 2018.

Stay Free targets

- Reduce the number of new HIV infections among adolescents and young women to less than 100,000 by 2020.
- Provide voluntary medical male circumcision for HIV prevention to 25 million additional men by 2020 globally, with a focus on young men aged 10 to 29 years.

AIDS Free targets

- Ensure that 1.6 million children under 14 and 1.2 million adolescents aged 15 to 19 living with HIV have access to ART by 2018.

In the call to action, faith leaders made their own pledge: to take significant and sustained action during the next five years in four particular areas: reducing stigma and discrimination, increasing access to HIV services, defending human rights, and ensuring treatment for children. They called on all faith leaders to join them.

In its one-year progress report, "Start Free, Stay Free, AIDS Free" acknowledged the challenges that contribute to the slow growth of access to treatment for children, including poor testing rates. In 2016, only 9 of the initiative's 23 priority countries had been able to test and diagnose at least half of children exposed to HIV.[14]

The rates of early infant diagnosis in the first two months of life, when it is most important to test, are particularly low. Without access to testing and treatment, half of all children living with HIV will die before their second birthday.

FBOs have been a part of the "Start Free, Stay Free, AIDS Free" Initiative since its beginning, implementing and driving forward the Action Plan. The challenge now is to expand the number of FBO partners working in the focus countries.

The rates of early infant diagnosis in the first two months of life, when it is most important to test, are particularly low. Without access to testing and treatment, half of all children living with HIV will die before their second birthday.

4. Faithful partners

Every child has the right to grow up free from preventable, treatable diseases like HIV. The right to health is the right to life.

We have the science to end the AIDS epidemic as a public health threat. What we need now are the political will and leadership at the national level, adequate funds to finish the job, and social mobilization to address HIV-related stigma, create demand for testing, retain people in treatment and reach those left behind.

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Faith communities can be our strongest ally in achieving these objectives. Its leaders are opinion leaders with both political and ethical influence. We cannot understand national politics unless we truly understand the religious lives of people and the function their faith leaders play as conduits between the community and the powers of government.

These faith leaders shape national and local opinion and policy. They can usher in tolerance, compassion and social justice—which is of tremendous support to this advocacy—and can have great and lasting effects. They reach into and change the lives and attitudes of whole communities. And we have seen across the history of the AIDS response that communities deliver results.

FBOs are better positioned than ever to play a transformative role. They are highly innovative and structured these days, bringing strategic entry points to address the epidemic. Through their communities, they have the reach to identify children in need and support parents in seeking HIV testing and treatment without fear. In addition, pastoral services can keep whole families in care and support.

FBOs shape public opinion and can model new ways of responding to people living with HIV to dispel stigma and discrimination. For example, the World Council of Churches Campaign for Religious Leaders, Leading by Example,[15] reached 1,500 religious leaders, each of whom have taken an HIV test while encouraging their constituencies to do the same.

As deliverers of health care, FBOs can drive demand for HIV services, referrals and retention in care. Throughout more than three decades of the AIDS response, FBOs have provided care and treatment through

their networks of health service providers. And they remain an important resource that countries must engage to achieve national coverage.

In Tanzania and Kenya, FBOs provide more than 40 percent and 60 percent of health services, respectively. Additionally, faith-based supply chain organizations serve 40 percent of the population in both of these countries.[16] This market penetration demonstrates how FBO health services complement national responses.

Beyond being a delivery partner, FBOs have strategic leverage with governments to provide the leadership needed to end the epidemic. Their ethical imperative is a powerful motivator to advocate with governments to provide adequate funds and to reach those left behind.

The linkages between health facilities and the structures of faith communities, which go down to village level in many communities, are of critical importance. These community-level structures are where much of the work to create demand, keep people on treatment and address stigma and discrimination take place.

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5. Bright horizon

FBOs recently were called to help achieve the ambitious and above-mentioned 90-90-90 targets with a $4-million grant from PEPFAR and UNAIDS that will strengthen the capacity of faith-based leaders and organizations to advocate for and deliver a sustainable HIV response.[17]

The Initiative will strengthen partnerships with FBOs in PEPFAR and UNAIDS partner countries with five focus areas:

- Collect, analyse and disseminate data on health services provided by FBOs;
- Address stigma and discrimination in communities and health care settings;
- Build capacity for joint action between communities of faith and people living with HIV to increase demand for HIV services and retain people in care;
- Strengthen networks of faith-based health service providers—Christian, Islamic and others—to reach the most marginalized and at-risk populations; and
- Strengthen FBO leadership and advocacy for the Fast-Track Approach and a sustained AIDS response to end the global AIDS epidemic by 2030.

Results from the first phase of this Initiative are promising, and country plans have been developed for the second phase.

We have come together in new ways through these initiatives. There is evidence that the combination of social and community mobilization,

high-level advocacy, political commitment, strengthened service delivery and increased investment has made a difference. But we are not there yet.

We have come so far but we have miles to go. We will not stop or slow down. We cannot end the HIV epidemic in children or adults without the faith-based partners. We need to do this together, to close the gaps, break the barriers, right injustices and finish the job we started together 30 years ago.

We will not stop or slow down. We cannot end the HIV epidemic in children or adults without the faith-based partners. We need to do this together, to close the gaps, break the barriers, right injustices and finish the job we started together 30 years ago.

Notes

1. UNAIDS Co-sponsoring organizations: UNHCR, UNICEF, WFP, UNDP, UNFPA, UNODC, UN Women, ILO, UNESCO, WHO and the World Bank Available at : (http://www.unaids.org/).

2. UNAIDS Working Paper: UNAIDS engagement with civil society. April 2013. Available at : http://files.unaids.org/en/media/unaids/contentassets/documents/document/2013/ubraf/20130624_UNAIDS_WorkingPaper_CSengagement.pdf. [Accessed 22 July 2018]

3. UNAIDS. Partnership with Faith-Based Organizations: UNAIDS Strategic Framework. Geneva. December 2009. Available at : www.unaids.org/sites/default/files/media_asset/20100326_jc1786_partnership_fbo_en_0.pdf. [Accessed 22 July 2018]

4. Strategic Framework 10 action areas: HIV prevention; treatment; care and support; youth; children and orphans; people living with HIV; gender; key populations; stigma and discrimination; human rights, dignity and justice.

5. Memorandum of Understanding between UNAIDS and *Caritas Internationalis*. Available at : www.caritas.org/wordpress/wp-content/uploads/2017/06/MemorandumUNAIDSCI.pdf. [Accessed 22 July 2018]

6. Political Declaration on HIV and AIDS: On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030. July 2016. Available at : www.unaids.org/en/resources/documents/2016/2016-political-declaration-HIV-AIDS. [Accessed 22 July 2018]

7. The full version of the Action Plan can be read in the second section of this publication (Page 135).

8. Fact Sheet: PEPFAR-UNAIDS Faith Initiative: Strengthening Faith Community Partnerships for Fast Track. PEPFAR. Washington, D.C. 20 January 2018. Available at: www.pepfar.gov/press/265876.htm. [Accessed 22 July 2018]

9. UNAIDS Fact Sheet: Latest statistics on the *status* of the AIDS epidemic. July 2018. Available at: http://www.unaids.org/en/resources/fact-sheet. [Accessed 22 July 2018]

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12. *Ibid.*

13. *Ibid.*

14. Start Free, Stay Free, AIDS Free: 2017 Progress Report. UNAIDS. Geneva. 27 April 2018. Available at : www.unaids.org/en/resources/documents/2018/start-free-stay-free-aids-free-2017-progress-report [Accessed 22 July 2018]

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17. Fact Sheet: PEPFAR-UNAIDS Faith Initiative: Strengthening Faith Community Partnerships for Fast Track. PEPFAR. Washington, D.C. 20 January 2018. Available at: www.pepfar.gov/press/265876.htm [Accessed 22 July 2018]

THE PEPFAR/UNAIDS FAITH INITIATIVE: ADVANCING THE DIAGNOSIS AND TREATMENT OF CHILDREN LIVING WITH HIV THROUGH PARTNERSHIPS IN FAITH

A *Caritas in Veritate* Foundation Report by

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> "We understand the challenges we must face together to reach our goals for pediatric treatment by 2020. The urgency to reach children in need of HIV testing before they get sick is critical to getting them tested and ensuring them safe, effective, and affordable treatment."
> Ambassador Deborah L. Birx, MD

1. Introduction

The global response to the HIV pandemic is unprecedented. Since the discovery of the disease and the development of treatment, billions of dollars and millions of manhours have been dedicated to saving lives and to controlling the spread of the disease. Since its establishment in 2003, PEPFAR has supported lifesaving ART for more than 14 million people globally, including about one million children and youth, has enabled more than 2.2 million babies to be born HIV free, and supports more than 6.4 million orphans, vulnerable children, and their caregivers.[1] For the first time in modern history, we have the opportunity to control this epidemic – even without an available vaccine or cure.

Since the discovery of the disease and the development of treatment, billions of dollars and millions of manhours have been dedicated to saving lives and to controlling the spread of the disease.

Together, we have achieved remarkable success – but it isn't enough. The potential to control the pandemic exists in the tools we have for HIV prevention and treatment services; however, achieving control is completely dependent on successful implementation at full scale these critical interventions. In order to change the course of the pandemic, the highest level of political and community leadership is fundamental. One of our essential priorities is ensuring that children are protected from HIV and that those already infected are found and treated. This means a substantive change in how we view the disease and increase access to critical services. We cannot afford to wait until people are ill and their immune systems are destroyed – we need to reach and test people, including children, before they become ill, so they can thrive, and we must ensure that all HIV negative children remain negative.

The potential to control the pandemic exists in the tools we have for HIV prevention and treatment services; however, achieving control is completely dependent on successful implementation at full scale these critical interventions.

Children are our future, and we have a moral imperative to do all we can to make sure that they not only survive to reach adulthood, but also become healthy and thriving adults who contribute to their communities. The communities of faith are essential to our work both as implementing partners of PEPFAR and as community leaders to ensure there are no barriers to accessing any and all HIV prevention and treatment services. Saving the lives of children with HIV is not only the right thing to do, it's the smart thing to do. Healthy, thriving children will, in adulthood, grow economies, create jobs, and strengthen their communities for decades to come.

Children are our future, and we have a moral imperative to do all we can to make sure that they not only survive to reach adulthood, but also become healthy and thriving adults who contribute to their communities.

PEPFAR is the world's largest supporter of children living with and affected by HIV/AIDS. PEPFAR continues to spend nearly half a billion dollars annually on expanding the diagnosis and treatment of children living with HIV. In addition, PEPFAR dedicates 10 percent of its annual program funds to mitigate the physical, emotional, and economic impact of the disease on this priority population. By the end of 2017, PEPFAR was supporting more than 6.4 million OVC and their caregivers, as well as nearly one million children living with HIV on lifesaving treatment; yet while we have had great success, we know that we must do more. PEPFAR has also led the world in providing effective prevention services to boys through voluntary medical male circumcision and to girls and young women through its DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) Public-Private Partnership.

PEPFAR, along with the Bill & Melinda Gates Foundation, Girl Effect, Johnson & Johnson, Gilead Sciences, and ViiV Healthcare, implements DREAMS. Through its implementation in 10 African countries, PEPFAR has driven down new HIV diagnoses among adolescent girls and young women by 25 to 40 percent in nearly two-thirds of the communities with the highest HIV burden in just 13 months of full program implementation.

PEPFAR takes a developmental approach to HIV prevention, with differentiated primary focuses for those aged 9 to14, 15 to 19, and 20

to 24. The Violence Against Children Surveys (VACS) have shown that most of those aged 9 to 14 have not yet had sex, or if they have had sex, it was often forced or coerced. This puts these children on a trajectory for negative health outcomes, especially the risk of HIV infection. Therefore, PEPFAR has significantly expanded its efforts to support youth aged 9 to 14 through primary prevention (preventing risk before it ever occurs) – the main emphasis being on preventing these children from experiencing sexual violence, as well as on giving them the information and skills they will need throughout their lives to make healthy decisions. PEPFAR is also helping communities and families surrounding these youth by giving support and education, and all these activities are grounded in evidence-based prevention programming. PEPFAR is actively leveraging FBOs and traditional authorities to further the reach and impact of this programming.

The scaling-up of successful universal ART for pregnant women has dramatically reduced the number of new infant infections in recent years, which has led to increasing proportions of HIV-positive children aged 5 and older (as shown below) and the need to refocus our case-finding and treatment efforts on school-age children and adolescents.

The scaling-up of successful universal ART for pregnant women has dramatically reduced the number of new infant infections in recent years, which has led to increasing proportions of HIV-positive children aged 5 and older and the need to refocus our case-finding and treatment efforts on school-age children and adolescents.

Figure 1: Global number of children living with HIV by age band from 2000-2017[2]

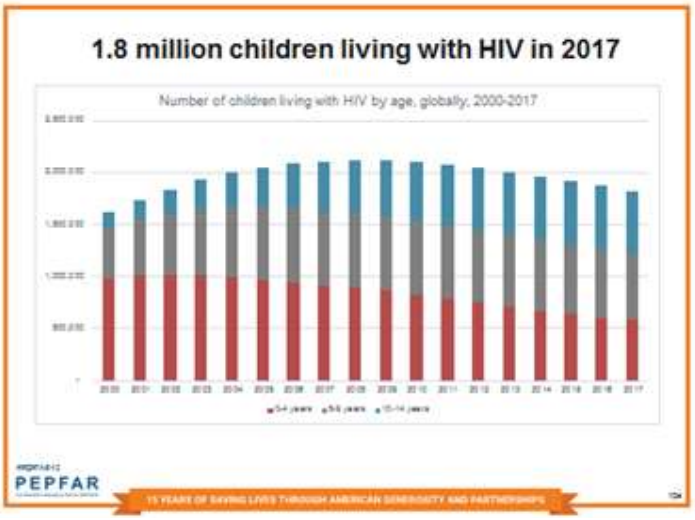
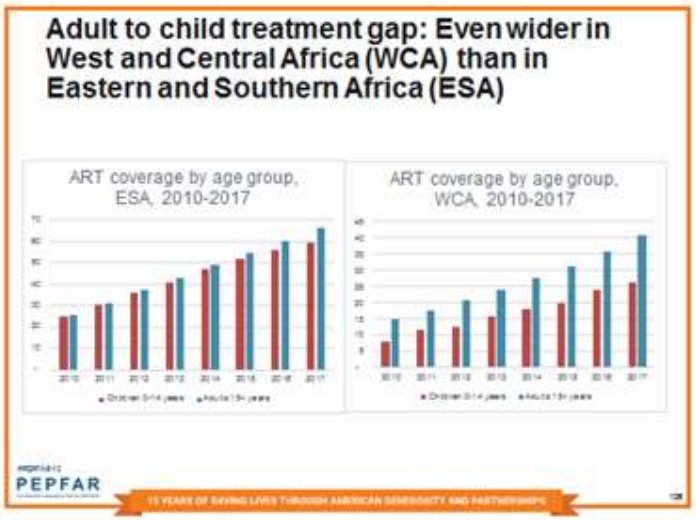


Figure 2: ART coverage for children in East and Southern Africa (ESA) lags behind that of adults; this gap is even wider between children and adults in West and Central Africa (WCA)[3]



In 2017, with only 52 percent of children under fifteen with HIV having access to treatment, treatment coverage for children continues to lag behind that for adults (59 percent in 2017).

It is troubling that one new pediatric infection continues to occur approximately every three minutes, because without treatment, children with HIV/AIDS are at high risk of death. In 2017, with only 52 percent of children under fifteen with HIV having access to treatment, treatment coverage for children continues to lag behind that for adults (59 percent in 2017). Pediatric ART coverage in countries of West and Central Africa are particularly concerning at only 26 percent - these numbers must change.[4] PEPFAR, along with other global stakeholders, have committed to several ambitious goals around pediatric treatment – namely, ending the epidemic in children, adolescents, and young women by 2020. The window of opportunity to reach these populations is much narrower, but if we can succeed there, we can change the trajectory of the epidemic.

At its core, PEPFAR is an expression of the compassion and generosity of the American people, which connects at a fundamental level to the mission of our faith-based partners: caring for the least fortunate among us. In the countries where PEPFAR works, FBOs have been on the ground from before the beginning of the HIV epidemic, providing care and treatment to their communities. In this context, FBOs were among the first programs to respond to the particular needs of children infected with, affected by, and orphaned by HIV/AIDS. Even as the global response has expanded since the earliest days of the epidemic, faith-based partners continue to be among the largest providers of HIV testing, treatment, care and support services.

2. PEFPAR and FBOs

The provision of health services by FBOs has been a cornerstone of the global response to HIV from the earliest days of the epidemic, as well as a foundation of PEPFAR's work over the last fifteen years. In many countries where we work, FBOs are the largest local, non-governmental service providers, and just as importantly, they offer crucial physical, emotional, and economic support to those impacted by the disease.

Our faith-based partners are key stakeholders in the HIV/AIDS response, and their role needs to be better recognized, understood, and supported. Religion plays an important role in many of the countries facing the brunt of the epidemic, not only for spiritual support but also as a source of information and inspiration.

At PEPFAR, we know that the tremendous successes of the past fifteen years would not have been possible without the crucial contributions of our faith-based partners, and we also know that we will not be able to reach our ambitious targets without building upon these relationships. The continued commitment of FBOs and faith leaders to service, non-judgmental support, and universal access functions as an example to all funders as we engage in care and treatment.

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In September 2017, PEPFAR's Guiding Strategy for Accelerating HIV/AIDS Epidemic Control included a necessary pillar: renewed engagement with FBOs [...] to accelerate and improve efforts toward epidemic control. This inclusion not only acknowledges the role played by faith-based partners in the response thus far, but it also refocuses attention on the role of these important partners in helping countries achieve epidemic control and sustaining that achievement into the future. For the past few years, one of the prime areas of coordination with FBOs has been the PEPFAR-UNAIDS Faith Initiative - "Strengthening Faith Community Partnerships for Fast-Track."

3. The PEPFAR/UNAIDS Faith Initiative - "Strengthening Faith Community Partnerships for Fast-Track"

In September 2015, PEPFAR and UNAIDS launched a $4 million, multi-year initiative designed to strengthen the capacity of African faith-based leaders and organizations to advocate for and deliver a sustainable, successful HIV response. History demonstrates that community and faith responses are key to ensuring that no one in need of treatment is left behind. This Initiative has engaged large umbrella organizations, networks and consortia, like *Caritas Internationalis* and WCC-EAA, as primary partners to provide local capacity building and technical assistance.

The first phase of the Initiative, conducted in five PEPFAR/UNAIDS partner countries, had five focus areas:

- Collect, analyse, and disseminate data on health care services provided by FBOs;
- Address stigma and discrimination in communities and health care settings;
- Create demand for service uptake and retention in care by building the capacity for joint action between communities of people living with HIV and
- Strengthen HIV-related service provision by strengthening networks of faith-based health service providers – Christian, Islamic, and others – to reach the most marginalized and at-risk populations with comprehensive, equitable HIV testing, prevention, and treatment services through strengthened national partnerships, improved data collection, and careful monitoring and evaluation;
- Strengthen FBO leadership and advocacy for the Fast-Track Approach and a sustained HIV response to end the global AIDS epidemic by 2030.

These focus areas were developed in consultation with faith-based partners and other stakeholders. With the ability to quickly respond to updated data and program realignment, the work of the participants will have a greater impact.

In June 2017, *Caritas Internationalis*, with PEPFAR support, convened a regional multi-stakeholder consultation in Abuja, Nigeria, focused on the early diagnosis of and treatment for children living with HIV (an entire case study is dedicated to the work *Caritas Internationalis* is doing in Nigeria – see case study by Fr. E. Bassey, Page 99). Outputs of this meeting included plans to strengthen collaborative national partnership and national action plans and highlight opportunities for cross-country exchange of lessons learned and replicable models. The discussions at the Nigeria Consultation informed Phase II programming in partner countries.

Outputs of this meeting included plans to strengthen collaborative national partnership and national action plans and highlight opportunities for cross-country exchange of lessons learned and replicable models.

Adjacent to the September 2017 United Nations General Assembly Meeting, and with PEPFAR support, WCC-EAA hosted its Annual High-Level Interfaith Prayer Breakfast: Fostering Partnerships for Fast-Tracking Access to Testing and Treatment for Infants, Children, and Adolescents. This event brought together leaders from all major church traditions, government, private sector, and other NGOs, and served as an opportunity for all stakeholders to recommit to our shared goals. Immediately following the successful conclusion of Phase I, on-the-ground Phase II activities began in four countries: Democratic Republic of the Congo, Nigeria, Tanzania, and Zimbabwe. Outcomes from the work in these countries include:

- Development and implementation of action plans for strengthened engagement of FBO service providers;
- Creation of online data and monitoring and evaluation platforms to strengthen the integration of health and community services;
- Completion of country case studies to document effective models of HIV health service delivery, including innovative service delivery models, and to identify common challenges and best practices to address them;
- Development of strategic guidance and advocacy/training initiatives on reducing stigma and discrimination in faith communities and in health care settings;
- Finalization and promotion of guidance around accurate faith healing messages in the HIV context.

On the global advocacy front, stakeholders sponsored a pre-conference at the 2018 International AIDS Society Meeting, "Faith Building Bridges", which provided a prime opportunity for networking, sharing, and building bridges for a stronger and more visible faith response to HIV. Participants from a wide cross section of faith traditions shared best practices and engaged in thoughtful dialogue about challenges and opportunities in reaching those most vulnerable to HIV.[5]

Following the completion of current year programming, UNAIDS and PEPFAR will complete a Phase III in line with the September 2017 Strategy, which expands faith-based engagement to additional countries with three key focus areas for collaboration:

- Partnering to reach men and boys;
- Partnering to reduce risk among young people, especially adolescent girls (9-14 years old), and to eliminate sexual violence;
- Partnering to increase access to treatment for children and adolescents living with HIV.

4. Challenges and opportunities for action

For the first time since the start of the epidemic, we have the opportunity to control the spread of HIV.

For the first time since the start of the epidemic, we have the opportunity to control the spread of HIV; however, we are aware that there are gaps. Children under 15 years of age have inadequate access to HIV diagnosis and treatment, and while there has been a dramatic decline in new pediatric infections, there are still millions of children that are in critical need of lifesaving treatment.

Children under 15 years of age have inadequate access to HIV diagnosis and treatment, and while there has been a dramatic decline in new pediatric infections, there are still millions of children that are in critical need of lifesaving treatment.

In November 2017, PEPFAR, along with the Vatican Dicastery for Promoting Integral Human Development, UNAIDS, *Caritas Internationalis*, WCC-EAA, the WHO, and EGPAF, convened a High-Level Dialogue on Scaling Up Early Diagnosis and Treatment of Children and Adolescents.

This Dialogue, which included leaders of major pharmaceutical and medical technology companies, multilateral organizations, donors, governments, faith-based partners, and other key stakeholders, focused on ways to expedite the research, development, approval, introduction, and uptake of optional treatments for infants, children, and adolescents.

Following the meeting and building on earlier meetings held in 2016 and 2017, a new Action Plan for Scaling Up Early Diagnosis and Treatment of Children and Adolescents was drafted and released.[6] PEPFAR is fully supportive of the new Action Plan, and we are taking positive steps to fulfil our shared commitments. The progress by PEPFAR and all partners in completing each of their commitments is publicly tracked and updated online.[7]

At the conclusion of the Vatican High-Level Dialogue, Pope Francis released the following statement: "Health care strategies aimed at pursuing justice and the common good 'must be economically and ethically sustainable. Indeed, while they must safeguard the sustainability both of research and of healthcare systems, at the same time they ought to make available essential drugs in adequate quantities, in usable forms of guaranteed quality, along with correct information, and at costs that are affordable by individuals and communities.'[8]."[9] This is in line with PEPFAR's goals and with the global commitment to end pediatric HIV.

If we have learned one thing in the past 37 years, it is that no single actor can control and ultimately end the HIV epidemic.

If we have learned one thing in the past 37 years, it is that no single actor can control and ultimately end the HIV epidemic. It will take concerted effort by all sectors of society, and one of PEPFAR's most important partners will continue to be faith-based parties. We need all those impacted to work together – on financing, on demonstrating advocacy and political will, on delivering essential services – to bring about the end of HIV.

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Notes

1. https://www.pepfar.gov/documents/organization/278118.pdf [Accessed 8 November 2018]
2. Figure 1: Global number of children living with HIV by age band from 2000-2017, available at UNAIDS, 2018
3. Figure 2: *ibid.*
4. *Ibid.*
5. http://www.iacfaith.org [Accessed 8 November 2018]
6. The full version of the "Action Plan" is included in this publication (see Page 135)
7. https://www.paediatrichivactionplan.org/updates [Accessed 8 November 2018]
8. The New Charter for Health Care Workers, 2017, English edition
9. Pope Francis, Message to the Participants in the 32nd International Conference on the theme: "Addressing Global Health Inequalities," Vatican City, 16-18 November 2018, available at https://w2.vatican.va/content/francesco/en/messages/pont-messages/2017/documents/papa-francesco_20171118_conferenza-disparita-salute.html [Accessed 8 November 2018]

How Pharmaceutical and Diagnosis Industries can Contribute to Scaling Up Access to Life-saving Diagnosis and Treatment of Children and Adolescents Living with HIV

FROM DIALOGUE TO ENGAGEMENT

A *Caritas in Veritate* Foundation Report by

DR. GOTTFRIED HIRNSCHALL

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Despite significant progress in scaling up HIV services for children, a treatment gap for pediatric HIV continues to persist. In 2017, only 52 percent of children living with HIV received ART, and of those only half received an optimal regimen. WHO guidelines[1] have recently introduced more potent and tolerable regimens for treatment of infants and children, but optimal formulations to deliver those regimens across the age spectrum are still lacking.

The delay in availability of new and optimal pediatric formulations is a result of a traditionally meagre R&D pipeline and slow adaptation of adult ARV regimens dosing to pediatric equivalence – a delay often attributed to a small and inconsistent market for these drugs. Recently, considerable progress has been made to better coordinate global efforts around pediatric ARVs and to leverage innovative solutions to these problems. Advances include joint commitments from a wide group of relevant stakeholders: policy makers, research networks, regulatory agencies, procurement agencies, funding organizations, civil society and manufacturers, to engage in both high-level dialogue and to synergize efforts between the public and private sectors to close the R&D and regulatory gaps, and to move from dialogue to concrete engagement.

This dialogue began in earnest in 2013, when WHO and partners began to more systematically adapt and apply the principles of drug optimization to pediatric ART. It has evolved over time and now provides key opportunities to identify challenges and design potential solutions to deliver better medicines for children living with HIV. Key moments in this transformation from dialogue to engagement are marked by the conferences on PADO. The first conference was held in Senegal and spearheaded a process of critically reviewing pediatric treatment needs and drawing a clear line of action to support and target the most optimal ARVs for study and development. What resulted was the first PADO priority list which continues to be the primary reference of priority pediatric ARV products to be developed and introduced in low and middle income countries.

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In 2014, UNITAID, DNDi and MPP, launched the Pediatric HIV Treatment Initiative (PHTI), to develop and deliver specific pediatric formulations; CHAI and EGPAF joined the PHTI later. In 2014, partners came together to advance the pediatric HIV agenda under the umbrella of the Global Pediatric Antiretroviral Commitment-to-Action (CTA). Several broad consultations held in 2016 explored mechanisms to advance pediatric formulation development and introduction. In parallel, two meetings organized under the leadership of the Holy See generated high-level support to facilitate closer collaboration between the private sector and relevant stakeholders. These efforts to support pediatric formulation development and uptake were and remain essential elements of the AIDS Free Agenda of the "Start Free, Stay Free, AIDS Free" Super-Fast-Track Framework for ending AIDS in children, adolescents and young women by 2020, launched by UNAIDS and PEPFAR in 2016.

A critical milestone of the journey from dialogue to engagement in support of better ARVs for children was the Third High Level Dialogue convened by the Holy See in 2017. This consultation provided a powerful and unique political platform to elevate the technical work in optimizing ARV formulations by creating a bridge to sustainable engagement through a list of commitments agreed upon by all stakeholders – including pharmaceutical companies.

A critical milestone of the journey from dialogue to engagement in support of better ARVs for children was the Third High Level Dialogue convened by the Holy See in 2017. This consultation provided a powerful and unique political platform to elevate the technical work in optimizing ARV formulations by creating a bridge to sustainable engagement through a list of commitments agreed upon by all stakeholders – including pharmaceutical companies. The major output - The "Rome Action Plan" - creates and maintains joint partner focus, acceleration and collaboration (The full length of the "Rome Action Plan" is included in this publication – Page 135). While many of the activities undertaken since 2017 represent the continuation of previous implementation efforts, the "Rome Action Plan" leapfrogged processes and provides the opportunity to strengthen and expedite action, as well as, to spur complementary steps that would not have otherwise been taken.

What remains weak in this equation is an innovative mechanism to further accelerate the development of the most needed pediatric ARVs in appropriate formulations. Faster progress is needed to develop and test optimized drugs for children, accelerate the process from R&D to regulatory approval, and explore how best to facilitate subsequent introduction and uptake of optimal products in national formularies - all while ensuring sustainable and reliable procurement and supply. Key stakeholders involved with R&D, manufacturing, regulatory matters, funding, advocacy, program and policy decision-making are now promoting an innovative solution through GAP-f. The latter is designed as a flexible framework to accelerate research, development, regulatory filing, introduction and uptake of key pediatric ARVs in age-appropriate formulations by 2020 and beyond. The GAP-f solution can also be applied to other diseases of public health importance, including TB and viral hepatitis. The GAP-f, led by WHO in close collaboration with CHAI and with key stakeholders including, PEPFAR, IAS, CHAI, MPP, UNITAID, ICAP, EGPAF, PENTAid, UNICEF, DNDi

and the Global Fund, was officially launched in July 2018 and is now recognized as an essential component of the AIDS Free Agenda.[2]

The pediatric HIV community has demonstrated that it is able to step up and join forces. The technical dialogue and political engagement have led to a well-developed vision for action with the GAP-f Framework as one element to catalyze action. Sustaining this commitment, ensuring continued dialogue and deepened engagement at country level will enable progress towards our shared vision and goal of providing children with the best possible treatment to ultimately ensure an "AIDS FREE Generation".

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WORLD HEALTH ORGANIZATION GLOBAL ACCELERATOR FOR PEDIATRIC FORMULATIONS (GAP-F)

A *Caritas in Veritate* Foundation Report by

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1. Background

Tremendous progress has been made in the past decade in the scale-up of ARV medicines in LMICs. However, an estimated 5 million children have died of HIV-related causes as a result of late diagnosis and limited treatment options since the start of the epidemic. Despite remarkable decline in the number of new pediatric infections, there remain around 1.8 million children living with HIV globally, predominantly in Africa.[1] Only 51 percent of all children in need received treatment in 2018, and virological suppression continues to be poor[2] as too many children in LMICs are still being treated with suboptimal regimens and formulations.[3]

The development and introduction of optimal ARVs for infants and children lags behind that of adults, and the global treatment targets for children will not be met without access to new appropriate drugs and formulations. Challenges persist with the development of formulations that can be administered to children of different ages, particularly in neonates and young infants. Solutions such as taste masking of unpalatable drugs can be difficult and expensive which further disincentivize manufacturers to invest in pediatric formulations. In addition, the lack of ARVs produced in flexible dosage forms can limit the number of doses or tablets available; this fragmentation results in a market that is difficult to sustain, with frequent supply insecurities and stock outages at health facilities.

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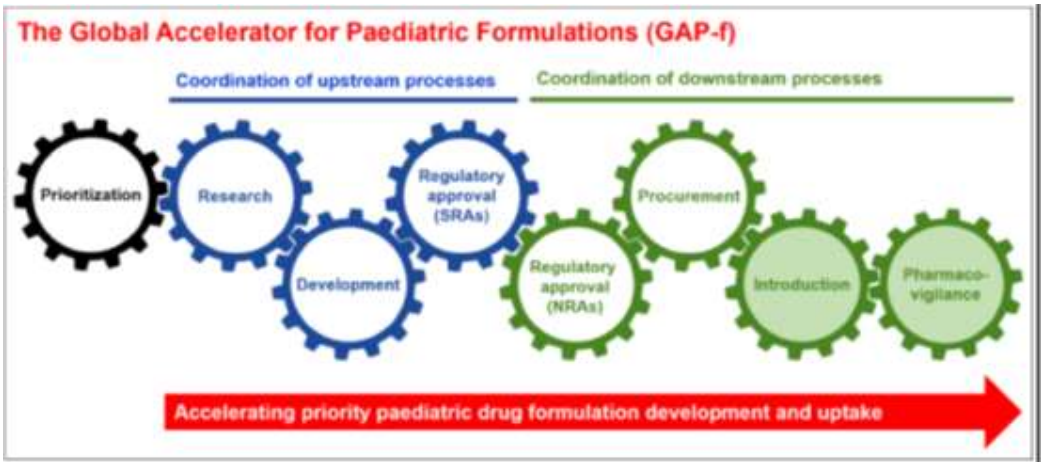
To address these market concerns, global partners have come together to incubate innovative ideas and collaboratively coordinate global efforts to assure access to pediatric ARVs in the appropriate dosage and formulations across the age bands. These efforts have led to the development of the collaborative platform called the Pediatric GAP-f, which is tasked to accelerate R&D, regulatory filing, and the introduction and uptake of key pediatric

ARVs in age-appropriate formulations by 2020. GAP-f was born out of the need to consolidate existing work streams into a comprehensive, streamlined platform. The GAP-f will focus on four key areas: accelerating the prioritization and evaluation of priority products, supporting more rapid development, introduction and uptake of optimal formulations, and ensuring strategic and sustainable financing in the upstream pathway from R&D to the downstream introduction of new products. The principles of GAP- f are currently being applied to the development of pediatric ARVs, but it has the flexibility to address other orphaned products for children with TB, hepatitis, malaria and other diseases (Figure 1).

Figure 1



2. Accelerating prioritization and evaluation of priority pediatric drug formulations

Since 2013 the WHO-led PADO group has established a set of mid- and long-term priorities for drug development to accelerate access to optimal formulations in the context of fragmented markets for ARV. Since its first edition in 2013, the PADO list has provided an evidence-based priority list and a clear and consistent message to guide the industry and interested stakeholders on the most needed formulations to be developed. This list has reduced the number of unnecessary formulations and serves to focus efforts and resources on GAP- f priority products.

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The PADO priority list provides visibility on the anticipated direction that treatment guidelines will take, and subsequent iterations of this list have been fairly consistent over time, with products prioritized in the long-term graduating into mid-term priorities, and with drugs like raltegravir (RAL) and DTG being incorporated into recent treatment guidelines.[4] It is also vital that timely updates and dissemination of PADO recommendations and priorities take place within industry and regulatory bodies who have typically placed more confidence in WHO guidelines (leading to

delays before initiation of development plans). GAP-f will play a role in encouraging national regulators in countries where ARVs are produced and/or submitted for regulatory approval - for example, Drug Controller General of India (DCGI) or Medicines Control Council of South Africa (MCC) - to recognize and act on PADO priorities by facilitating and accelerating approval, registration, and introduction of those specific drugs and formulations.

Experts of the PADO group have also identified potential ways to optimize the clinical research required to enable approval and optimal use of better drugs and formulations. These solutions are the core principles of GAP- f that promotes a more strategic design of pediatric drug studies to be started earlier in the drug-development process. A significant outcome of the GAP-f consultations has been that both the EMA and the US FDA have signalled an overall endorsement of these principles for acceleration. The GAP-f will play a key role in promoting and implementing these required changes; collaboration among all key stakeholders across the drug development spectrum will be critical in order to harmonize and align manufacturers, researchers, and regulators on these elements. For this reason, the GAP-f has developed a research toolkit to support strategic research design to inform the development and optimal use of a given drug or formulation.[5]

With the current average time for completing a pediatric plan taking 8 to 10 years, the process for submission and modification of PIPs and PSPs at US FDA, a process which must be made more efficient to facilitate more timely high-quality development plans, is another area requiring work. GAP- f will work through and with experts of the PAWG to provide advice to innovative companies when designing their PIPs/PSPs and promote alignment of regulatory bodies on decisions regarding those.

3. Supporting more rapid development, introduction and uptake of optimal formulations

An important role for the GAP-f will be to explore and assess options for fast-tracking the development of optimal formulations of drugs that have already been approved. Improving the dialogue between originators and generic manufacturers, as well as between industries and stakeholders interested in pediatric drug optimization is of critical importance. GAP-f will facilitate early collaboration between generic and originator manufacturers by enabling a more transparent and rapid transfer of technology from originator companies to generic companies early in the drug development stage, with the goal of accelerating development and approval of pediatric formulations. Such timely coordination could also allow generic manufacturers to develop pediatric formulations from promising adult ARVs all while the adult development is being completed.

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This would leapfrog over the more typical approach of originator companies which are starting pediatric formulation development only after adult efficacy is established.

The GAP-f will also play an important part in providing incentives through innovative financing mechanism, ensuring greater transparency around the expected market life of key products, and enabling more realistic planning of development and production timelines. The GAP-f will scrutinize future markets and assist key stakeholders to improve quantification, forecasting, and ARV demand, to better inform manufacturing plans and to be nimble enough to respond to time-limited markets related to changing and updated global treatment guidelines.

4. Ensuring strategic and sustainable financing

A strategic and sustainable financing framework is needed to fund faster pediatric ARV development for both upstream interventions (e.g., financing clinical trials and development steps such as taste-masking) and downstream interventions on the demand side (e.g., facilitating in-country registration, advanced market commitments, and mitigation of financial risk for generic manufacturers). Funding for formulation development may be more important for certain products, such as those with an inherent bitter taste that is difficult to mask and FDCs that draw on products from more than one originator. Importantly, enabling manufacturers to share costs with GAP-f financing, and therefore sharing risks, will send a strong stability signal to decision-makers in companies.

For downstream interventions, the small and complex pediatric ARV market for generic manufacturers, could be buoyed by the GAP-f by expediting in-country registrations. This will facilitate more rapid country programme uptake of new optimal pediatric products. In addition, the GAP-f could be used to mitigate financial risk if a PADO-prioritized product is not in demand and uptake is lower than expected, thus ensuring that the appropriate number of generic manufacturers are committed and adequately supported to get a viable return on their investment in development and manufacturing. Activities in this area will depend on the development of reliable information on market size and target pricing, evaluation of the need to provide and standardize of incentives, and support for generating demand in large-volume countries to ensure commercialisation of these products.

5. Conclusion

The current momentum in pediatric drug development and scale-up represents an important window of opportunity to generate the change needed at both global and national levels in order to ensure that child-friendly formulations of optimal ARVs and other life-saving drugs are developed for children. However, this will require commitment and a willingness to challenge the *status quo* from a large variety of stakeholders: regulators, innovator and generic drug manufacturers, research networks, implementers, UN agencies and civil society. Speeding up the drug development process and mitigating the risk for a broader array of private industry partners to enter the market will require a coordinated mechanism and sustainable financing; this gap must be filled. Years of collaborative work across sectors in pediatric HIV have led to a proposal for such a mechanism: the GAP-f. The innovative solutions in GAP-f are applicable across disease areas and promise added value beyond HIV, particularly for TB and viral hepatitis. Now is the time to bring greater visibility to the problem of inadequate pediatric treatment options globally and to ensure that key players commit to a common goal of change so that children can have access to age-appropriate, life-saving treatments.

The current momentum in pediatric drug development and scale-up represents an important window of opportunity to generate the change needed at both global and national levels in order to ensure that child-friendly formulations of optimal ARVs and other life-saving drugs are developed for children.

Acknowledgements

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HIV AND THE RESPONSE OF THE PHARMACEUTICAL INDUSTRY

A *Caritas in Veritate* Foundation Report by

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1. Overview

The combination of ViiV Healthcare's mission to leave no PLHIV behind and the potency of our core medicine, dolutegravir, could help to transform the landscape of HIV treatment across the world. PLHIV are now able to have a fully productive and active life. Within five years of approval, more than half a million people worldwide now take dolutegravir-based regimens to treat HIV, and it has been incorporated into global guidelines for treatment. Globally, physicians trust dolutegravir as a core first-line agent for part of treatment regimens in adults and hope that it could offer similar benefits to children, which highlights the need for improved access for them.

There are considerably fewer optimized treatment options available for children, especially for those under the age of two. The many different reasons therefore, include a lack of appropriate formulations, long and complicated studies, and limited financial incentives for generic manufacturers to supply due to uncertain volumes and a fragmented marketplace. The majority of children living and growing up with HIV are in sub-Saharan Africa; this is also where the majority of new infections of children continue to occur. Models of supply rely upon generic manufacturers and often global agencies for funding. Groups such as the DNDi have identified pediatric HIV as a neglected disease.

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In 2009, when ViiV Healthcare was first formed, the leadership team established a multidisciplinary team focused on ensuring pediatric access to dolutegravir. Further to this, in 2014, a team led by the WHO called the PADO stated that the development of dolutegravir for children had become a priority.

ViiV Healthcare's progressive access policies, which cover the entire marketed portfolio, enable people living in the world's poorest countries (where the greatest burden of the epidemic lies) to have access to the same optimized medicines as those fortunate enough to live in wealthier countries.

At ViiV Healthcare, we embrace the recent impetus provided by the global health community to find new solutions to enable more children to have the benefit of optimal treatment with a dolutegravir-based regimen. Last November, we proudly stood shoulder to shoulder with many partners at the Vatican to formulate an Action Plan to improve access to HIV medicines for children in resource-poor settings. Quite simply, it is the right thing to do. We do not have all the answers, but we will absolutely play our part and work with others to find them.

2. HIV and the response of the pharmaceutical industry

ViiV Healthcare is one of just a few companies that continues to invest in research for new and innovative medicines for HIV. Our company generates revenue by selling medicines to health systems in countries that have the ability to pay for them, which in turn enables us to put funding into R&D. It is this cycle which continues to result in the development of new optimized and much-needed treatments for people living and ageing with HIV.

For those countries that cannot afford to pay, ViiV Healthcare has developed a different model to enable every PLHIV to access our medicines. As part of our access to medicines policy, we grant voluntary licenses for our medicines both directly and through the UN–MPP, which enables generic manufacturers to make and supply generic versions of our medicines in the licensing territory.

For those countries that cannot afford to pay, ViiV Healthcare has developed a different model to enable every PLHIV to access our medicines. As part of our access to medicines policy, we grant voluntary licenses for our medicines both directly and through the UN–MPP, which enables generic manufacturers to make and supply generic versions of our medicines in the licensing territory. Our most recent license, for dolutegravir, includes all LDCs, low-income, LMICs, and all sub-Saharan countries for adults, plus many middle-income countries for children. When announced, we believe this covered 94 percent of adults and 99 percent of children living with HIV in the developing world.

At the turn of the millennium, substantial progress had been made in the testing and treatment of PLHIV in developed Western markets. But the picture in sub-Saharan Africa was bleak. At the time, only one in a thousand PLHIV in sub-Saharan Africa had access to HIV treatment. ARV drugs were largely available only from the originator companies that owned the patents and came with an average price tag of more than US$10,000 per patient, per year. Perhaps most significantly, the multilateral programs funding the fight against HIV, as we know them today, did not exist. Many donors—including national governments—had not provided a single dollar toward ART in resource-limited countries.

However, over the last 18 years, the picture of the AIDS epidemic has been completely turned around. This is due to a combination of unprecedented commitment, funding, and multilevel stakeholder collaboration amongst global partners; a dramatic reduction in ARV prices coupled with the upscaling of pharmaceutical access programs pioneered by companies such as ViiV Healthcare; and rapid medical innovation. By June 2017,

20.9 million PLHIV were receiving lifesaving ART. In September 2017, ViiV Healthcare played an enabling role in ensuring the availability of the first affordable, generic, single-pill HIV treatment regimen containing dolutegravir for people living in low- and LMICs. This breakthrough pricing agreement enabled public sector purchasers in these countries to purchase the fixed-dose combination of tenofovir/lamivudine/dolutegravir at around $75 per person, per year—more than a hundred-fold decrease from therapies available in 2000. The agreement was announced by the governments of South Africa and Kenya and represents an incredible collaborative effort from many parties, including UNAIDS, CHAI, the Bill & Melinda Gates Foundation, Unitaid, the United Kingdom's DFID, PEPFAR, USAID, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Mylan Laboratories and Aurobindo Pharma.

3. Unlocking progress for pediatrics

ViiV Healthcare believes that all infants, children, and adolescents living with HIV should have access to both suitable lifesaving therapies and the social support they need. Fundamentally, the key to unlocking effective and inclusive HIV healthcare for affected infants, children, and adolescents is access to currently available effective medicines coupled with ongoing research to develop age-appropriate formulations and new therapies. We believe there are five strategic elements that are critical to improving outcomes in children living with HIV globally:

Fundamentally, the key to unlocking effective and inclusive HIV healthcare for affected infants, children, and adolescents is access to currently available effective medicines coupled with ongoing research to develop age-appropriate formulations and new therapies.

- Expedite R&D efforts to generate necessary data for pediatrics;
- Develop age-appropriate formulations of ARVs;
- Ensure access to medicines globally through partnerships and effective regulatory strategy;
- Focused and collaborative approaches to improve diagnosis and treatment strategies in HIV-positive children and adolescents, particularly in the developing world;
- Support families, caregivers, and communities affected by HIV.

A. Expedite R&D efforts to generate necessary data for pediatrics

Clinical data is currently being generated for dolutegravir both to support product registration and to inform treatment strategy for global health settings in partnership with the two largest pediatric networks: IMPAACT and PENTA. The aim of this data is to provide a comprehensive data package (from the age of 4 weeks to 18 years) for registration, as well as information for international guideline committees and generic partners. There is also a need for more options for neonates, and ViiV Healthcare is actively exploring this with IMPAACT. It is our absolute goal to follow

the science, which will enable children living with HIV to be treated with dolutegravir from infancy and, ideally, birth.

B. Development of age-appropriate formulations of ARVs

ViiV Healthcare is developing age-appropriate formulations of ARVs for infants, children, and adolescents and is focused on sustainable partnerships aimed at expanding access via royalty-free licensing agreements.

One of the major challenges in treating infants, children, and adolescents living with HIV is the availability of formulations that are easy for children to take and their care providers to support. The formulations also need to be simple enough for non-specialist providers to prescribe to children of different weights and ages.

Infants who are too young to swallow tablets need ARVs that are more age-appropriate and preferably in a dispersible form, but these are currently not widely available and supply is inconsistent.

However, as announced in the last few months, ViiV Healthcare, Unitaid, and CHAI have started a new and significant project focusing on expediting the development and provision of more affordable generic pediatric formulations of dolutegravir for resource-poor settings. The intent of the project is to ensure availability of optimized pediatric products from generic manufacturers on an affordable yet sustainable basis, as quickly as possible after ViiV Healthcare's dispersible tablet formulation of dolutegravir has been approved by a stringent regulatory authority. In the first phase of the project, ViiV Healthcare is providing technology transfer for its dispersible tablet and supporting formulation development by two voluntary license holders: Mylan Laboratories Limited and Macleods Pharmaceuticals Limited. CHAI, via Unitaid, will provide financial incentives to the agreed generic partners to support development and registration of their products. In addition, CHAI will support demand generation and market uptake activities in key Unitaid countries in sub-Saharan Africa to enable rapid adoption in national programs once approved.

The intent of the project is to ensure availability of optimized pediatric products from generic manufacturers on an affordable yet sustainable basis, as quickly as possible after ViiV Healthcare's dispersible tablet formulation of dolutegravir has been approved by a stringent regulatory authority.

C. Ensuring access to medicines globally through partnerships and effective regulatory strategy

As well as CHAI, ViiV Healthcare works with many partners who are committed to making a difference, including EGPAF, the Bill & Melinda Gates Foundation, USAID, and PEPFAR to name a few. ViiV Healthcare also nurtures a host of invaluable relationships with academic and community groups.

ViiV Healthcare places great importance on its working relationships with regulators and external partners delivering our registration programs. The processes with regulators are formal and clear and should absolutely remain so; however, we continue to engage with them to ensure that the data package produced can meet their needs as well as those of appropriate

guideline bodies and generic partners. We are also committed to supporting continuous improvement through R&D to make sure that dosing and formulations are as optimal and simple as possible for children, their caregivers, and the programs that serve them. In addition, we continue to explore potential alternative registration approaches that might speed up access in key affected countries. These include regional harmonized regulatory review, the WHO collaborative registration procedure, and the WHO prequalification program to name a few.

We are also committed to supporting continuous improvement through R&D to make sure that dosing and formulations are as optimal and simple as possible for children, their caregivers, and the programs that serve them.

D. Focused and collaborative approach to improve treatment strategies in HIV-positive children and adolescents particularly in the developing world

In addition to the lack of low-cost medicines that are palatable and acceptable for use by children, there are still knowledge gaps in the care and treatment of pediatric HIV. For example, access to virologic testing for infants and rapid antibody testing in children over 18 months of age remains poor in many countries, creating a bottleneck for the scale-up of diagnosis and treatment of children.

In addition to the lack of low-cost medicines that are palatable and acceptable for use by children, there are still knowledge gaps in the care and treatment of pediatric HIV. For example, access to virologic testing for infants and rapid antibody testing in children over 18 months of age remains poor in many countries, creating a bottleneck for the scale-up of diagnosis and treatment of children.

As referenced earlier, ViiV Healthcare works with PENTA and IMPAACT to carry out research that will help clinicians make decisions about the best treatment regimens for their pediatric patients. PENTA is part of an international research collaboration in pediatric HIV, involving 26 academic institutions across four continents called the EPIICAL Consortium. Its goal is to establish a predictive platform to inform treatment strategies for children living with HIV, aiming toward ART-free remission.

Enabling collaboration remains pivotal to driving success, as evidenced by examples such as the IAS and CIPHER, whose research fellowship program is aimed at answering outstanding clinical and operational research questions needed to optimize clinical management and delivery of HIV services for infants, children, and adolescents. It also focuses on building the capacity and expertise of the next generation of pediatric HIV researchers and clinicians in resource-limited settings. ViiV Healthcare also has a partnership with EGPAF to increase early detection and access to ART for HIV-positive infants and young children in Malawi and to strengthen leadership and policies around pediatric HIV/AIDS.

E. Supporting families, caregivers, and communities affected by HIV

ViiV Healthcare has a broad and deep commitment to supporting those that represent PLHIV, and we have specific programs aimed at children. Our Positive action Programs are fully aligned to the priorities of the HIV community, supporting more than 300 programs that address the needs of PLHIV.

The Positive Action for Children Fund (PACF) is an integral part of ViiV Healthcare's commitment to communities affected by HIV and AIDS.

PACF's efforts align to UNAIDS' Global Plan and the PMTCT strategy, both of which aim to eliminate new HIV infections among neonates and infants while keeping their mothers alive.

In 2009, ViiV Healthcare committed to invest £50 million in PACF over ten years; in the first five years, ViiV Healthcare has invested £19.8 million in more than 150 partnerships.

PACF supports organizations across four continents, with special attention given to countries with the most need of PMTCT interventions: Nigeria, the Democratic Republic of Congo, Uganda, Ethiopia, Cameroon, Mozambique, Zimbabwe, Zambia, Malawi, Angola, Burundi, Chad, Tanzania, Kenya, and India.

The Positive Action for Girls Fund was established in 2015 and has committed £2 million per year to reducing HIV risk and building aspiration through advocacy, opportunity, and gender equality.

Positive Action for Adolescents was also established in 2015. This program has been focused on supporting and evaluating the impact of new behavioral and service delivery tools and interventions that may address key gaps in adolescent HIV prevention, testing, and care. It also enables improved service provision and treatment outcomes for adolescents through to adulthood.

4. Commitment to increase our collaborative efforts more broadly

ViiV Healthcare remains willing to increase its collaborative efforts and resources to work with external partners and to collectively drive progress in resolving structural barriers that are slowing down access to pediatric formulations of ARVs—as articulated by the WHO-led GAP-f Initiative.

ViiV Healthcare remains willing to increase its collaborative efforts and resources to work with external partners and to collectively drive progress in resolving structural barriers that are slowing down access to pediatric formulations of ARVs—as articulated by the WHO-led GAP-f Initiative. To date, ViiV Healthcare has played a role in supporting the development of GAP-f within working groups and speaking on behalf of the originator industry at global key stakeholder meetings.

To deliver on our commitments, we call upon our partners and public health experts to:

- Continue to work with the WHO team to ensure that all dolutegravir formulations are included in the WHO prequalification EOI early and even temporarily if it will serve to meet a short-term need to enable supply and access to children, whilst dosing continues to be optimized;
- Advocate actively for the rights and needs of children living with HIV globally, including efforts to tackle stigma;
- Formalize the PAWG consultation mechanism to efficiently include this in the pediatric product development planning process;
- Maintain momentum to make pediatric volumes more certain and predictable for manufacturers so they can sustainably meet demand.

At ViiV Healthcare, we believe the outlook for PLHIV and for pediatrics in particular is becoming one of hope and optimism. The development of ARVs is surely one of the greatest triumphs of the pharmaceutical industry, transforming HIV from a death sentence to a manageable chronic illness in less than 20 years. In pediatrics, the situation is undoubtedly more complex and nuanced, but with recent successes and improvements around PMTCT, complacency remains our greatest enemy.

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The solution is focus and partnerships. We must remain focused on the following: developing innovative, well-tolerated, and efficacious new medicines for adults and children living with HIV; pursuing effective prevention strategies for those at risk of infection; increasing access to medicines in the countries most in need of ART; and tackling the still-rife issue of stigma and discrimination associated with HIV.

Partnerships are at the core of the ViiV Healthcare operating model (PLHIV and their supporting organizations, advocates, health care providers, research institutions, and governments) to achieve the ultimate goal of putting an end to the epidemic and deliver on our mission to leave no person living with HIV behind.

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The Role of Faith-Based Organizations and Good Practices in the Diagnosis, Care and Treatment of Children and Adolescents Living with HIV

IMPROVING DIAGNOSIS, CARE AND TREATMENT OF CHILDREN AND ADOLESCENTS LIVING WITH HIV THROUGH STRENGTHENED PARTNERSHIPS WITH FAITH-BASED ORGANIZATIONS

A *Caritas in Veritate* Foundation Report by

FRANCESCA MERICO
HIV Campaign Coordinator, World Council of Churches-Ecumenical Advocacy Alliance (WCC-EAA)

Improving the lives of children living with HIV and securing their right "to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health"[1] continues to be at the center of the EAA's work since 2005.

Founded in 2000 as an ecumenical advocacy network of churches and Christian service delivery and development organizations that speak and act together on justice issues, the EAA became an initiative of the WCC in 2015. The WCC-EAA[2] brings together 85 local, national and international Christian organizations and the 350 WCC member churches, representing more than 500 million Christians around the world.[3] The WCC-EAA is committed to supporting its participating organizations, WCC member churches and FBO partners to strengthen their capacity and engagement in speaking out and acting together against stigma and discrimination, promoting the human rights of all, increasing access to prevention, testing, treatment, care and support, and addressing the root causes of vulnerability to HIV for a more effective and better coordinated response to it.

At the core of the WCC-EAA's work on pediatric HIV stands the principle that "the more we can speak and act together, the better our impact for justice will be". Based on this value, the WCC-EAA builds partnerships and collaborations among different faith traditions, as well as between faith-based and non-faith-based actors; it operates as a platform for networking, information sharing and capacity building to disseminate age-appropriate prevention information in faith communities and to increase the quality of FBO services for HIV-positive children and adolescents. It also mobilizes and builds the capacity of influential religious leaders and FBOs in their advocacy efforts at national and international levels. In collaboration with its partners around the world, the WCC-EAA creates opportunities for religious leaders to use their powerful voices to call for justice, protect the rights of children and adolescents, address stigma and discrimination, and to hold governments and UN agencies accountable for the commitments

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they have made to promote prevention, testing, care and optimal treatment for children living with HIV.

1. Pediatric HIV: a justice issue

The WCC-EAA considers pediatric HIV a justice issue and believes that religious leaders and faith communities have a responsibility to bring about change. Though only 5 percent of PLHIV are children, they account for 12 percent of all AIDS-related deaths. According to the most recent UNAIDS report, "Miles to Go",[4] the advances made for children are not being sustained. Every day, 500 children are infected with HIV, primarily due to the large number of undiagnosed HIV-positive pregnant and breastfeeding women. Additionally, efforts to prevent mother-to-child transmission have been slowed down by inconsistent treatment adherence among pregnant and breastfeeding mothers living with HIV. Identifying HIV in babies and children is another major challenge: globally, only half of infants who are exposed to HIV are tested before eight weeks of age. As a result, two thirds of HIV-positive children under two years of age in Africa, Asia and the Americas start ART with advanced immunodeficiency. Increased access to POC technologies for EID could save the life of many children, but such technology is still not accessible in many high-burden pediatric HIV countries. Access to effective and palatable pediatric HIV formulations is still a major issue. Only 940,000 children, which represents half of all children living with HIV, are receiving treatment. Development of pediatric formulations that are safe, effective, and easy to administer, swallow and store still lags eight to ten years behind that of adult treatments; this discrepancy is mainly due to economic and regulatory challenges, complexity in manufacturing combinations of ARVs for children, and fragmented and low volume markets.[5] In addition, national HIV treatment policies, supply chain strategies, stigma and discrimination can delay and limit access to treatment for children living with HIV.

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2. Partnerships for change

The pressing need for optimal, age-appropriate pediatric formulations of ARV medicines was most recently addressed by a series of key collaborative initiatives, such as the GAP-f[6] and the Pediatric HIV Action Plan[7] adopted in 2017 on the occasion of the Vatican High Level Dialogue on Pediatric HIV (the full length of the Action Plan is included in this publication – Page 135). Faithful to its principle of collaboration, the WCC-EAA is involved in both initiatives in order to facilitate and accelerate the development, finalization, production, registration, introduction and roll-out of optimal pediatric ARV formulations and diagnostics for children living with HIV. Working together

with the WHO, EGPAF, PEPFAR, UNAIDS, *Caritas Internationalis* and the organizations which are part of GAP-f, the WCC-EAA contributed to the drafting and adoption of the Pediatric HIV "Rome Action Plan" and continues to be part of the monitoring team which advocates for the commitments of the Plan to be upheld. The WCC-EAA is also a member of the planning team for the "High Level Dialogue to Scale up Diagnosis and Treatment of Pediatric HIV", which Cardinal Peter Kodwo Appiah Turkson is convening in the Vatican on 6 and 7 December 2018.

The "Framework for Dialogue" between religious leaders and networks of PLHIV is an interfaith collaborative initiative led by the WCC-EAA. Other organizations involved are UNAIDS, the GNP+ and the INERELA+. This collaborative effort aims at creating opportunities for dialogue and joint actions for stigma reduction between faith-based and non-faith-based actors. The Dialogue process has been implemented in Uganda, Malawi, Ethiopia, and Nigeria (a subsequent section will analyze the *Caritas* Nigeria experience – Page 99) and is continuing in Kenya and DRC as part of the PEPFAR/UNAIDS Faith Initiative – Strengthening Faith Community Partnerships for Fast-Track. In Ethiopia, a Sermon Guide for the Orthodox Church on gender-based violence, elimination of vertical transmission of HIV, and HIV-related stigma has been developed, and communities are being instructed in its use. In Uganda, participants have committed to further dialogue on critical issues related to families and HIV – such as marriage and discordant relationships, and faith healing in relation to ART – and strategies have been identified to overcome each key challenge. The collaborative structure of the "Framework for Dialogue" provides an effective, national-level tool for increasing mutually beneficial, systematic, inclusive and sustained dialogue and joint action between PLHIV and faith communities, governments, and international and civil society organizations. It can also address the stigma and discrimination faced by PLHIV, and it helps to combat factors that increase vulnerability to HIV by such work as identifying strategies for improving adherence and retention.

"Leading by Example: Religious Leaders and HIV Testing" is a WCC-EAA interfaith campaign which engages more than 1500 religious leaders from different faith traditions to promote testing and linkage to services in faith communities. Religious leaders are advised to get tested and to encourage their faith communities to do the same. The religious leaders who are part of the campaign share information about HIV in their places of worship, with the support of sermon guides and up-to-date information on testing shared by the WCC-EAA. They invite people to discover their HIV *status* when there has been a risk of infection, and they encourage mothers to bring in their babies and other family members for testing. This initiative promotes a strong linkage between faith communities and

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health-care facilities, and it provides an excellent base for speaking out and ensuring more children are tested and retained for treatment.

The "WCC-EAA Faith Pediatric HIV Champions" are powerful agents for action on pediatric HIV in their countries and at global levels. These Champions are identified in collaboration with local churches and national partners, and they call on governments and other key stakeholders to reach the 2020 Prevention and Treatment Targets for Children and Adolescents Living with HIV, as agreed upon by all UN Member States in the 2016 "Political Declaration on Ending AIDS".

The "WCC-EAA Faith Pediatric HIV Champions" are powerful agents for action on pediatric HIV in their countries and at global levels. These Champions are identified in collaboration with local churches and national partners, and they call on governments and other key stakeholders to reach the 2020 Prevention and Treatment Targets for Children and Adolescents Living with HIV, as agreed upon by all UN member States in the 2016 "Political Declaration on Ending AIDS". Champions for Children and Adolescents Living with HIV are asked to support the following actions:

sign the WCC-EAA Call to Action,

- "Act now for Children Living with HIV",[8] and promote it;
- Share information on children and adolescents with HIV within their faith community, including through sermons (aided by resources such as "Khutbah and Christian Sermon Guides on children and HIV");[9]
- Advocate for key decision makers to address pediatric HIV bottlenecks at the global level and in their country, and set up meetings with them;
- Issue video messages on pediatric HIV, on testing and treatment for adolescents, and against stigma and discrimination, to be shared in their place of worship's website and social media;
- And organize events in their communities to raise awareness about children and adolescents living with HIV.

Under the PEPFAR/UNAIDS Faith Initiative, the WCC-EAA – in collaboration with EDARP and INERELA+ Kenya – a large gathering of more than 500 children, youth, religious leaders, government representatives and UN agencies was organized on 19 and 20 November 2018 in Nairobi; workshops and training on pediatric HIV for faith leaders and young people were offered during the gathering.

Media and capacity building: The WCC-EAA works with journalists and faith-based media at local, national, and international levels to inform the public about children and adolescents with HIV and to raise the level of awareness. The WCC-EAA also provides capacity building for faith leaders on pediatric HIV and TB at country and global levels, involving local community, government, civil society and international partners. Additionally, the WCC-EAA organizes training and workshops on pediatric HIV for faith leaders and FBOs to improve strategies for case-finding and to strengthen the linkage of children and adolescents to services and treatment by making use of places of worship, religious schools and faith communities. The training helps equip faith leaders and FBO

representatives to become stronger advocates for optimal diagnostics and treatment of children and adolescents living with HIV.

"Children's Letter Writing Campaign": Faith communities taking action with children living with HIV[10] is a letter writing action for children, adolescents and youth in faith communities and religious schools. Children, adolescents and young people, especially those aged 11 to 24, are encouraged to write letters to government ministries, First Ladies, and to specific pharmaceutical and diagnostic companies, asking them to improve access to age-appropriate HIV information, testing and treatment for children and adolescents. Ideas are also given to students and youth groups to help raise awareness of these issues in local newspapers and other media forms. The teachers are given a guide written by WCC-EAA that aims to engage children, adolescents and young people to become advocates for better diagnostics and treatment for their peers living with HIV. It also provides an opportunity to share age-appropriate prevention information on HIV and to empower youths to take action on behalf of, and in solidarity with, others who live with HIV. The children and youth letter writing action is part of the CIFF and the WCC-EAA Pediatric HIV Advocacy Project. Additionally, activities are being undertaken in South Africa and Kenya, which include dialogues between adolescents, youth and faith leaders.

3. Conclusion

Faith leaders, FBOs, places of worship and religious schools provide crucial opportunities for imparting HIV and AIDS information and services. Most faith traditions share the belief in the inherent dignity and value of each human person, a dedication to end injustice and a commitment to care for the most vulnerable and marginalized in society. These principles, combined with opportunities to equip and empower faith leaders and faith communities, are essential for affecting change; and partnerships are needed to facilitate and accelerate greater access to optimal testing and treatment for children and adolescents living with HIV and to help them survive and thrive.

The intense collaboration and constant interchange between local and global levels, and among faith and other sectors, characterizes the work of the WCC-EAA. All of the activities are implemented in collaboration with local churches and faith leaders, as well as bringing in the expertise of national and international partners. The WCC-EAA has become a platform for sharing, networking and capacity building among FBOs and faith-based and non-faith-based actors. It creates opportunities for the voices of faith leaders to be heard and the engagement of FBOs to be known at the UN and in other global fora. The Interfaith Preconference to the AIDS

The WCC-EAA has become a platform for sharing, networking and capacity building among FBOs and faith-based and non-faith-based actors. It creates opportunities for the voices of faith leaders to be heard and the engagement of FBOs to be known at the UN and in other global fora.

Conference,[11] the Interfaith Prayer Breakfast and the FBOs coordinated participation in international events and policy negotiations[12] have contributed to the heightened visibility and role of faiths in the global HIV response. It is this constant interface which ensures dialogue and exchange from local to global levels/organizations (and vice-versa), and among different sectors that can guarantee a greater impact and improvement of diagnosis, care and treatment of children and adolescents living with HIV.

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A SPECIAL FOCUS ON ACCESS TO EARLY DIAGNOSIS AND TREATMENT FOR ORPHANS AND VULNERABLE CHILDREN LIVING WITH HIV

A *Caritas in Veritate* Foundation Report by

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In 1943, CRS was established by the Roman Catholic Bishops of the United States to help war-torn Europe and its refugees recover. CRS also supported the Sisters of Charity to help feed and care for thousands of children in the day nurseries of Paris.

More than 75 years later, and guided by the principles of Catholic Social Teaching, CRS continues to practice "an option for the poor" (serving the poorest of the poor) and subsidiarity by working in partnership with local organizations to strengthen responses to local problems and challenges. CRS continually seeks to help those most in need without regard to race, creed, or nationality. As the official international relief and development arm of the United States Conference of Catholic Bishops, children have always been at the heart of CRS's efforts.

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CRS supported its first project to assist people living with HIV and AIDS in East Africa in 1986. CRS and its partners collaboratively promote innovative and effective community-based programs that mitigate the effects of HIV/AIDS, address its underlying causes, and help reduce the spread of HIV. Programs launched by CRS use a holistic approach that covers the continuum of care and treatment interventions and addresses

AIDSRelief achievements in pediatric ART

- More than 66,000 children connected to care and treatment
- More than 27,000 children started on ART
- Viral suppression—the gold standard for measuring treatment success—was 88.2 percent
- Family-centered care model—more than 200,000 children and families accessed care and treatment
- Strong PMTCT program

the entire person, including the medical, physical, psycho-social, financial, cultural, and spiritual aspects of human life.

By 2002, CRS was supporting 75 projects in 20 countries, valued at $2 million. These projects supported prevention of HIV, care and support for PLHIV, and care and support for OVC—many of whom were orphaned because their parents had died of AIDS.

Although ARV medications had made HIV and AIDS manageable in wealthier nations, treatment was far out of reach for people in low-income countries. In 2003, when President George W. Bush announced PEPFAR, many people were skeptical that it would even be possible to deliver high-quality, sustainable HIV treatment in low-resource settings. ART was too complicated, the environment too risky, and the patients faced too many challenges. Others feared the long-term financial commitment was not sustainable.

In early 2004, CRS was awarded three PEPFAR Track 1.0 global, multicountry five-year grants for:

- Support of OVC in five PEPFAR focus countries;
- HIV prevention work in three PEPFAR focus countries; and
- AIDSRelief, CRS's flagship HIV program to provide ART in nine PEPFAR focus countries for 138,000 people living with HIV, through 200-plus local faith-based health institutions.

AIDSRelief was the largest grant ever awarded to an FBO for HIV at $335 million. Over the next nine years, AIDSRelief and other PEPFAR implementing partners transformed HIV care and treatment, exceeding all expectations.

By 2010, CRS was supporting 280 HIV projects, including AIDSRelief, in 62 countries with a collective annual budget of more than $170 million per year. By 2014, AIDSRelief had served more than 700,000 people—including almost 400,000 enrolled in ART through 276 health facilities—and was successfully transitioning to local partners in ten countries: Ethiopia, Guyana, Haiti, Kenya, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia. After almost a decade, AIDSRelief was able to complete program transfer to local partners, who now use the national, regional, and local systems we built together to continue to reach people with lifesaving ART. AIDSRelief was an exemplary partnership involving U.S. government, CRS, and other partners in the United States, as well as many local partners in all 10 countries.

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AIDSRelief was a strong voice for maternal-child health, advocating for the most effective regimens for pregnant women and their children. Some countries were initially reluctant to adopt the recommendation to put all HIV-infected pregnant women on an ART cocktail consisting of three ARV drugs until they finished breastfeeding their babies.[1] These countries

also had concerns about expense and feasibility, but AIDSRelief-supported sites advocated for and provided women with this cocktail treatment. AIDSRelief's superior patient outcomes influenced policy changes in other countries, including Nigeria and Uganda. This treatment recommendation became widely accepted around the world and has prevented millions of new HIV infections in children.

The following strengths and challenges of CRS's AIDSRelief Program for HIV-positive pregnant women and their infants were identified as follows:[2]

Strengths	Challenges
Access to drug pipeline: Consistent, uninterrupted access to ARVs and prophylactic drugs via their respective, designated pipelines.	**Wrap-around/community support services:** Limited funding for pediatric counseling and peer support groups.
Family-centered care: All women presenting for ANC were offered HIV testing; babies born to HIV-positive mothers were enrolled in pediatric ART and tested through 18 months; and clinic staff were trained to encourage family testing when one member tested positive.	**Disclosure:** Insufficient trained staff for comprehensive disclosure counseling; lack of specific "disclosure strategies" for partner disclosure and age-appropriate disclosure to children.
Home-based care for adherence: Home-based care teams included clinicians, volunteers, and a spiritual leader. If problems were identified at the community level, more extensive follow-up was done with child and parent.	**Human resources for home visit teams:** Limited funding for training and retaining community volunteers.
Unique interventions: Implemented to help children and adolescents stay physically and emotionally "well." Adolescent peer groups used song, dance, and drama to promote healing; monthly pediatric counseling sessions were provided.	**Infant feeding options:** Infant formula is expensive or unavailable, and there is no steady supply of clean water. Therefore, mothers are limited to breastfeeding their children; inability to offer other options.

Epidemic Control 90-90-90 (EpiC 3-90)—a PEPFAR-supported ART project in Zambia—is the only remaining CRS ART program. EpiC 3-90 works to strengthen the capacity of FBOs to accelerate comprehensive and integrated HIV/AIDS/TB/STI care, treatment, and prevention services. Implementing partners provide comprehensive ART services, including PMTCT. AIDSRelief was, and now EpiC 3-90 is, an important contributor to the reduction of HIV vertical transmission between mother and child. According to UNAIDS, more than 80 percent of pregnant women living

with HIV are receiving ART, and vertical transmission has dropped from 14 percent to 10 percent between 2010 and 2016.[3]

The current CRS HIV portfolio consists predominantly of OVC support projects and work with adolescent girls and young women—16 projects in 18 countries, serving over 7.5 million people of which more than 1.3 million are direct beneficiaries. Coordinating Comprehensive Care for Children (4Children) is a five-year, USAID-funded CRS project to improve the health and wellbeing of vulnerable children affected by HIV and AIDS and other adversities. 4Children and CRS's other OVC projects work to strengthen OVC case management and linkages between health and social service systems, the local community, and households supporting orphans and other vulnerable children. Many vulnerable infants and children might otherwise never access health or HIV services. As OVC are often the object of stigma and discrimination, these efforts are accompanied by community sensitization to decrease stigma and discrimination—which is especially important for children attending school. CRS also works to empower women—often the principal caregivers for OVC—to improve access to basic services such as water, health services, and targeted food supplements where there is household food insecurity.

Many vulnerable infants and children might otherwise never access health or HIV services. As OVC are often the object of stigma and discrimination, these efforts are accompanied by community sensitization to decrease stigma and discrimination—which is especially important for children attending school.

Based on the fundamental principle that everyone living with HIV should have access to ART, PEPFAR and the CIFF launched the Accelerating Children's HIV/AIDS Treatment (ACT) Initiative in 2014—a public-private partnership that will enable an additional 300,000 children living with HIV to receive ART in nine countries over a two-year period. CRS contributes to the successful achievement of this goal in Kenya, Uganda, Cameroon, and Zambia. "The Initiative's results are key to "Start Free, Stay Free, AIDS Free"—a "Super-Fast-Track" Approach to ending AIDS among children, adolescents, and young women, with goals for 2018 and 2020."[4]

One of the challenges for AIDSRelief to getting infant diagnoses confirmed and the infants quickly on treatment after the PMTCT protocol, was the relative unavailability of PCR of DBS testing for HIV-exposed infants. PCR machines were expensive and required special training to operate and maintain, and thus were only available in the larger tertiary hospitals and national laboratories. While home-based care providers could follow up with mother-infant pairs in the community and be trained to collect DBS samples, the long wait for results after samples were transported to the lab and the many opportunities for the sample to be separated from its paperchain link to the infant/child from whom the sample was collected resulted in huge delays in confirming a definitive HIV diagnosis of many children as well as delayed initiation of lifesaving ART. This is still the unfortunate and unacceptable case in many countries.

Wider availability of POC diagnostic equipment for timely EID is urgent and critical for the work of ART providers like EpiC 3-90 in Zambia. CRS's

OVC programs often work closely with PMTCT providers to follow up with mother-infant pairs in the community.

Home-based care providers and OVC psychosocial workers are often the first point of contact for caregivers of OVC infants and children in the community who otherwise might not access health and HIV services. CRS's OVC support projects are considering whether POC EID availability in community settings by home-based care providers and OVC psychosocial workers could help unburden over-stretched health facilities providing ART services. Access to the new POC EID equipment would ensure that infants get into treatment sooner and improve their treatment outcome.

Finally, an additional benefit of following up with mother-infant pairs in the community is that it not only opens the door for OVC programs to provide other supportive services for these infants, but also provides an entry point into the household, where it is then possible to bring HIV testing services to other children and household members. CRS's OVC programs have found the mother/caregiver is often receptive to having other older children in the household tested, and the family environment affords opportunity to offer testing of other adults in the household.

The introduction of POC EID is expected to significantly improve the linkage to treatment rates for infants and should be instituted widely as soon as possible.

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Notes

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OVERVIEW OF THE WORK OF CARITAS INTERNATIONALIS IN EARLY DIAGNOSIS AND TREATMENT

A *Caritas in Veritate* Foundation Report by

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> "Love of neighbor, grounded in the love of God, is first and foremost a responsibility for each individual member of the faithful, but it is also a responsibility for the entire ecclesial community at every level: from the local community to the particular Church and to the Church universal in its entirety."[1]

Caritas Internationalis is at the heart of this Church's responsibility, a sign of the love that God has for humanity in Jesus Christ. The name *Caritas Internationalis* means "love between nations" and expresses our hope for the Kingdom of God in which all enmity and division will be defeated. *Caritas*, as an expression of the mission of the Church, gives witness to the presence of God's love for all people and, above all, for the most deprived persons, the poor.[2]

The Confederation of *Caritas Internationalis* has, therefore, an ecclesial mission: it exercises its responsibility for charitable, social, and humanitarian work on behalf of the Roman Catholic Church as a whole. This responsibility is thus assumed with the support of and in partnership with several institutions of the Holy See,[3] in particular with its Dicastery for Promoting Integral Human Development.

The heart of *Caritas Internationalis* throbs for serving those who live in the most resource-limited settings, both in developing and developed countries. *Caritas Internationalis* finds its very reason for existence in the service rendered by hundreds of thousands of professionals and volunteers who, organized in 165 national *Caritas* spread in 200 countries and territories of the world, day by day and night by night distribute lifesaving commodities among millions of people in need, being with them and for them in every circumstance—not only during emergencies or crises, but also before and after.

The heart of *Caritas Internationalis* throbs for serving those who live in the most resource-limited settings, both in developing and developed countries.

In turn, the charity of the Church presupposes that the Church and its members participate in local and worldwide justice and charity according to context on the basis of goodwill. It entails proposing and providing support from charity undertakings established by the Church, especially in cases where such intervention is indispensable.[4]

However, these daily actions will never suffice if they do not inspire—and, consequently, are not complemented by—broader and targeted global efforts aimed at eliminating the root causes that make people vulnerable, facilitating access to integral human development for all.

Caritas Internationalis, which traces its engagement in health care to the example of Jesus' concern for and healing of many sick persons as is recounted in the Christian gospels,[5] cannot be silent in front of this heart-taking call—and it is not. A particular case in point is the outstanding efforts made by *Caritas Internationalis* in the response to the HIV pandemic.

This engagement dates back to 1987, when the Confederation accorded priority attention to both global and local responses to the pandemic of HIV and AIDS, including the related epidemic of TB. Since that time, *Caritas Internationalis* has organized training of its own staff and volunteers, as well as those engaged in other Catholic Church structures, to develop compassionate, non-judgmental responses to those living with or affected by HIV, as well as value-based prevention education that is in full conformity to the Catholic Social Teaching.

One of the most devastating consequences of the global HIV pandemic has been the impact on children, particularly in sub-Saharan Africa.[6] In fact, for children, the course of HIV is particularly aggressive: the virus multiplies rapidly, destroying their defenses against infection and facilitating the development of pneumonia, TB and other opportunistic infections. Without adequate care and treatment, as many as one-third of children born with HIV will die before their first birthday, and half of them will die before they are two years old. If children living with HIV do not gain access to treatment that is appropriate to their needs, their physical development, and the conditions of the setting in which they live, they are subjected to unnecessary suffering and die faster than do HIV-positive adults.[7]

Without adequate care and treatment, as many as one-third of children born with HIV will die before their first birthday, and half of them will die before they are two years old.

An HIV-positive 12-year-old child of the Camillian Social Center of Rayong, Thailand, once said: "I ask other people to help me, to treat me with kindness and to give me a chance to develop and be happy in society."

For these reasons (such as acknowledging past accomplishments and recognizing the potential for greater engagement of FBOs to facilitate more prompt and effective achievement of testing and treatment goals for children living with HIV), PEPFAR, UNAIDS, and *Caritas Internationalis* have joined efforts to convene a series of consultations focused on the theme of "Early Diagnosis and Treatment for HIV-Positive Children—Strengthening Regional Engagement of FBOs."

1. International consultations in Vatican City (April and May 2016 and November 2017)

Caritas Internationalis played a key role in organizing the above-mentioned dialogues which have been described in other articles included in this publication. In all three of these meetings, leadership and staff from *Caritas Internationalis* at the global level, as well as representatives of *Caritas* Member organizations participated. In this way, they could bring the experience and concerns of those directly engaged in HIV testing and treatment of both children and adults as field level as well the policy and advocacy concerns of *Caritas* at both global and national levels. *Caritas* also has been engaged in the follow-up activities that were discussed and included in the Rome Action Plan for Scaling up Early Diagnosis and Treatment of Children and Adolescents (included in this publication on Page 135) that emerged from these meetings.

2. Early diagnosis and treatment for HIV-positive children—strengthening regional engagement of FBOs, Abuja, Nigeria (14–16 June 2017)

Caritas Internationalis has continued to promote wider engagement of national and local FBOs, national governments, and pharmaceutical and diagnostic companies in the overall program of action toward implementing the "AIDS Free" prong of the UNAIDS Strategy "Start Free, Stay Free, AIDS Free" as well as the call to action that emerged from the Vatican City meeting, held in November 2017. In this regard, *Caritas Internationalis*, in collaboration with *Caritas* Nigeria, organized a regional multi-stakeholder consultation in Abuja, Nigeria (14–16 June 2017). That Regional Consultation was organized in close collaboration with national governments, UNAIDS and PEPFAR offices, and other key stakeholders. Special consideration was given to regional, national, and community-based religious organizations of different faiths and traditions. At the end of this Regional Consultation, participants drafted national action plans for Nigeria, the Democratic Republic of Congo, and Zimbabwe aimed at strengthening the engagement of FBOs in early diagnosis and treatment for HIV-positive children.

At the end of this Regional Consultation, participants drafted national action plans for Nigeria, the Democratic Republic of Congo, and Zimbabwe aimed at strengthening the engagement of FBOs in early diagnosis and treatment for HIV-positive children.

3. The GRAIL Project: Catalyzing HIV/AIDS response by FBOs in Nigeria and the Democratic Republic of Congo

In order to assure wider national ownership on the national action plans drafted during the Regional Consultation "Early Diagnosis and Treatment for HIV-Positive Children—Strengthening Engagement of

FBOs" held in Abuja, Nigeria on 14–16 June 2017, as well as increase knowledge and demand on pediatric HIV to contribute to global efforts on reaching complete access to testing and treatment for HIV-positive children by 2020 ("AIDS Free"), *Caritas Internationalis*, in collaboration with *Caritas* Nigeria and *Caritas* Congo, has given support to nationally-based activities aimed at strengthening capacity-building interventions for Catholic Church-related health facilities and other FBOs. Support also has been provided to reinforce the capacity of national partners to deliver appropriate and scientific-based messaging on pediatric HIV. The implementation logic depends on priests and religious leaders of Catholic Church communities who, after being trained on pastoral and scientific considerations in HIV pathology, can deliver audience-appropriate HIV prevention and stigma reduction messaging to their congregations. In addition, such "activated" clergy will serve as a bridge between identified health centers and their congregations by leading teams of Church health advisors who will target high-risk mother-and-child pairs by tracking (1) immunization *status*; (2) recurrence of symptoms of communicable diseases like fevers, diarrheal disease, respiratory tract infection and skin infections; and (3) provide or refer for HIV testing and counselling and ART initiation where indicated. This project is implemented in the PEPFAR/UNAIDS Faith Initiative, which has been launched in September 2015 with the aim of strengthening the capacity of faith-based leaders and organizations to advocate for and deliver a sustainable HIV response. The article by Fr. E. Bassey, of *Caritas* Nigeria, offers more detail concerning these ongoing initiatives (Page 99).

The implementation logic depends on priests and religious leaders of Catholic Church communities who, after being trained on pastoral and scientific considerations in HIV pathology, can deliver audience-appropriate HIV prevention and stigma reduction messaging to their congregations.

Any *Caritas* organization has, above all, a Church mission. On the basis of this Roman Catholic mission of justice and charity, each *Caritas* assumes its mission and the responsibility for works of general interest. Sometimes charity requires the establishment of reliable long-term projects similar to the path undertaken by *Caritas Internationalis* since 1987.

Maybe all our efforts are just a drop in the ocean, but "the ocean would be less because of that missing drop."[8]

Notes

1. Pope Benedict XVI, Encyclical Letter *Deus Caritas Est*, paragraph 20.
2. Rev. Fr. Gustavo Gutiérrez OP and Rev. Fr. Timothy Radcliff OP, *Caritas* at the Heart of the Church's Life and Mission, in H.E. Oscar Andrés Card. Rodriguez Maradiaga SdB, *Caritas*, Love Received and Given.
3. Rev. Fr. Jean-Paul Durand OP, Justice and Charity: the Apostolic Diakonia and Humanitarian Service of the *Caritas Internationalis* Confederation, in H.E. Oscar Andrés Card. Rodriguez Maradiaga SdB, *Caritas*, Love Received and Given.
4. *Ibid.*
5. Catechism of the Catholic Church, #1503 and #1509.

6. Dr. Andrew Prendergast, Dr. Shaffiq Essajee, Dr. Martina Penazzato, HIV and the Millennium Development Goals.
7. *Caritas Internationalis*, HAART for Children Campaign.
8. Saint Theresa of Calcutta.

Case Studies by Faith-Based Organizations

CREATING DEMAND FOR HIV TESTING AND TREATMENT SERVICES FOR CHILDREN THROUGH FAITH-BASED ORGANIZATIONS: THE CARITAS NIGERIA EXPERIENCE

A *Caritas in Veritate* Foundation Report by

FR. EVARISTUS BASSEY
Director, *CARITAS* Nigeria
OLAWALE FELIX FADARE, OLARENWAJU OLAYIWOLA, AND AMANA EFFIONG
CARITAS Nigeria

1. Introduction to *Caritas* Nigeria and its developmental projects in child health

> "What kind of world do we want to leave to those who come after us, to children who are now growing up?"[1]

Caritas Nigeria programs have attempted to answer this question by prioritizing children as beneficiaries in line with its vision of contributing to "fullness of life for everyone." Officially incorporated in 2010 as the Developmental Agency of the Catholic Bishops Conference of Nigeria, *Caritas* Nigeria serves as the umbrella organization supporting the 54 dioceses (grouped into nine provinces) of the Catholic Church in Nigeria and implements projects in public health, peace building and conflict resolution, emergency and humanitarian services, good governance, education, agriculture, water, sanitation and hygiene (WASH), and livelihoods. This prioritization of child health activities is not misplaced, with several of the SDGs linked directly to childhood-related vulnerabilities.[2] *Caritas* Nigeria builds on the extensive experience of the Catholic Church in Nigeria responding to humanitarian crises that worsened the vulnerability of children, dating back to malnutrition, abuse, and deprivation cases during the Nigerian Civil War.

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Since the emergence of HIV/AIDS as a public health threat in Nigeria in 1986 and the commencement of a coordinated programmatic response to the epidemic in 2003, *Caritas* Nigeria has delivered HIV care and treatment programs of increasing scope and coverage. At the end of September 2017, *Caritas* Nigeria closed out a five-year, PEPFAR-funded HIV/AIDS care and treatment grant covering 12 of the 37 States in Nigeria that worked

Since October 2017, *Caritas* Nigeria has taken over the care, treatment, and psychosocial support of 3,387 children (out of over 50,000 beneficiaries) in a new five-year program supporting both government and faith-based health facilities in four States in Nigeria. A total of 816 boys and 838 girls make up the beneficiaries aged zero to nine years, while there are 824 male and 909 female adolescents aged ten to nineteen years, respectively.

with 144 faith-based health facilities to reach about 3,700 children (out of the 66,000 beneficiaries of all ages living with HIV). Since October 2017, *Caritas* Nigeria has taken over the care, treatment, and psychosocial support of 3,387 children (out of over 50,000 beneficiaries) in a new five-year program supporting both government and faith-based health facilities in four States in Nigeria. A total of 816 boys and 838 girls make up the beneficiaries aged 0 to 9 years, while there are 824 male and 909 female adolescents aged ten to nineteen years, respectively.

However, program analyses and comparisons with national and international modeling projections suggest that *Caritas* Nigeria and indeed the national HIV response in Nigeria is missing out on a large number of children who are HIV positive and should be on life-preserving ART.[3] In response to these findings, *Caritas* Nigeria has aligned with the global Super-Fast-Track Approach of UNAIDS, the Start Free, Stay Free, AIDS Free Framework, whose objective is to :

> "Eliminate new HIV infections among children by reducing the number of children newly infected annually to less than 40,000 by 2018 and 20,000 by 2020; to reduce the number of new HIV infections among adolescents and young women to less than 100,000 by 2020; to provide 1.6 million children and 1.2 million adolescents living with HIV with antiretroviral therapy by 2018; and to provide 1.4 million children and 1 million adolescents with HIV treatment by 2020."

This strategy, which is clearly enshrined in SDG 3 (ensure healthy lives and promote well-being for all at all ages), aims to "end AIDS in children, adolescents, and young people by 2020."[4]

2. The HIV epidemic in Nigeria through pediatric lenses

With a population of over 180 million,[5] Nigeria has a generalized HIV epidemic with a national prevalence of 3.0 percent and an estimated 3.4 million PLHIV.[6] This constitutes 9 percent of the global HIV burden and is second only to South Africa in sub-Saharan Africa. Nigeria has an estimated 380,000 children living with HIV, with approximately 250,000 of them requiring ART but an unmet pediatric HIV treatment burden of 80 percent.[7] Nigeria therefore bears the highest burden of pediatric HIV globally. The Federal Ministry of Health estimates that:

> "Every year approximately 37,000 new HIV infections are recorded among children in Nigeria and the current MTCT rate in Nigeria remains high at 13 percent at 6 weeks, while the final MTCT rate is 28 percent. Of the total number of children living with HIV in

> Nigeria, only 21 percent of them are on ART. Out of the 160,000 annual AIDS-related deaths in Nigeria, about 24,000 of them (15 percent) are children."[8]

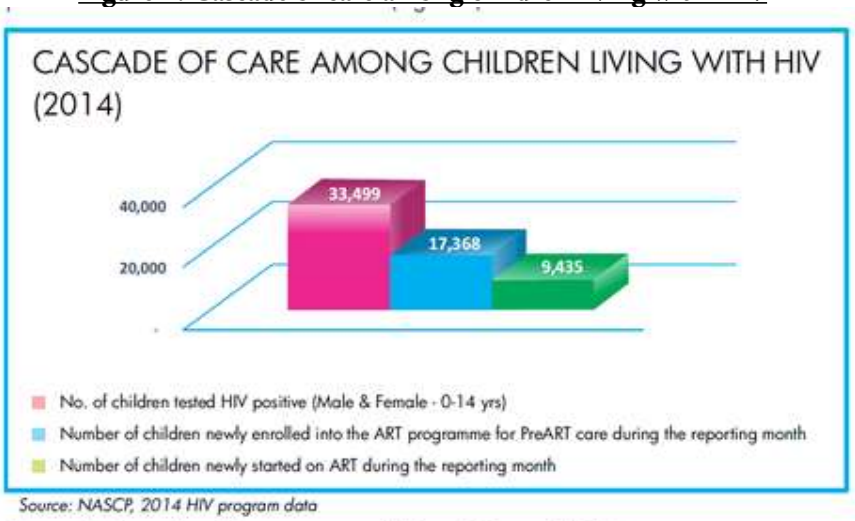
Transmission of HIV to the pediatric age group is predominantly through MTCT. In Nigeria, only 32 percent of HIV-infected pregnant women receive ART for PMTCT, leaving a huge gap.[9] Also, the early infant diagnosis coverage for HIV-exposed infants currently stands at 11 percent, which contributes to suboptimal identification of HIV-infected children. Furthermore, missed opportunities abound in the identification of children living with HIV, in the form of suboptimal HTS for children of HIV-infected adults and low uptake of provider-initiated testing and counselling amongst symptomatic children presenting at health facilities.

3. The strategic focus on pediatric diagnosis and treatment

As an implementing organization, *Caritas* Nigeria sees greater opportunities for programmatic impact in the pursuit of more timely identification and linkage of children living with HIV to treatment. Drawing inspiration from the concern of Jesus for and healing of sick persons[10] as well as His love for children and wanting to draw them to Himself, *Caritas* Nigeria has made pediatric ART a key deliverable in all its health interventions.

Linking newly identified HIV-positive children to treatment has been a recurrent challenge. Although there have been recent improvements, there is need to further intensify efforts to optimize ART linkages.

Figure 1: Cascade of care among children living with HIV[12]



Source: NASCP, 2014 HIV program data

Figure 1: Cascade of Care among children living with HIV

The current ART coverage of about 21 percent is further complicated by a suboptimal 12-month retention rate of 70 percent. It is noteworthy that UNAIDS has a negative projective for improving pediatric HIV outcomes

if case identification is restricted to standard HIV testing approaches alone, observing that:

> "HIV testing facilities are rarely child friendly, and caregivers may be reluctant to have a child tested for HIV. The rate of increase in the number of children on treatment has slowed in recent years, falling to an annual increase of 6 percent in 2016 from an annual increase of over 10 percent in previous years. At the current rate of increase, the world risks not reaching the target of providing antiretroviral therapy to 1.6 million children by 2018."[11]

Several interventional strategies have been proposed to mitigate the challenges identified above and contribute to closing the pediatric ART treatment gap in Nigeria. Some of these strategies include:

- Intensified pediatric HIV case finding, which involves family index testing as well as HIV testing across high yielding testing streams, including at TB/DOTS centers, nutrition clinics, and inpatient wards and outpatient departments;
- Risk profiling among children using screening tools like the Bandason tool[12] for pediatric HIV testing (aimed to ensure targeted testing with optimum resources utilization);
- Engagement of community volunteers to support HTS at service delivery points in health facilities to bridge HRH gaps; and
- Optimization of EID services with the addition of the COMBED Initiative.

Caritas Internationalis, with funding from UNAIDS and PEPFAR, is working with _Caritas_ Nigeria as its local implementation partner to champion major efforts in conjunction with the Nigerian government to drive some of the listed interventions.

These strategies align with ongoing pediatric HIV-focused collaborations being implemented between *Caritas* Nigeria and key national and international stakeholders. *Caritas Internationalis*, with funding from UNAIDS and PEPFAR, is working with *Caritas* Nigeria as its local implementation partner to champion major efforts in conjunction with the Nigerian government to drive some of the listed interventions.

Following the international consultation in the Vatican in April 2016 and the call to action that challenged FBOs to do more on the "AIDS Free" prong of the UNAIDS Global Strategy, a regional consultation with the theme "Early Diagnosis and Treatment for HIV-Positive Children—Strengthening Regional Engagement of FBOs" was convened in June 2017 in Abuja, Nigeria with *Caritas* Nigeria serving as the host and local organizing team (with support from *Caritas Internationalis*, UNAIDS, PEPFAR, and several local civil society organizations and FBOs). The Abuja Regional Consultation set priorities for government and FBOs from Nigeria on how to increase knowledge and demand for pediatric HIV services to contribute to global efforts for complete access to testing and treatment for HIV-positive children by 2020 ("AIDS Free"). *Caritas* Nigeria supported

the NACA to host a Nigerian stakeholders' meeting in November 2017 for FBOs supporting the National HIV Response, with the goal of re-activating the national interfaith platform for driving national HIV issues, particularly the unmet pediatric treatment needs in Nigeria.

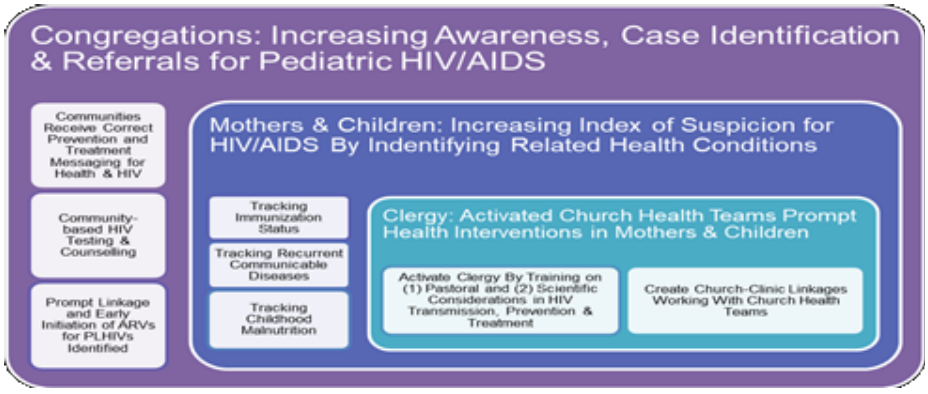
The product of the stakeholders' meeting was a National Consultation held in March 2018 to develop a Strategic Plan for the new Nigeria Faith-Based Coalition on HIV/AIDS; a strategic document that highlights key activities that FBOs should champion in alignment with the National HIV/AIDS Strategic Framework 2017–2022. This coalition would depend on the influence of religious leaders and institutions in reaching HIV-positive children and ensure linkages to care and treatment services.

On the implementation level, *Caritas* Nigeria and *Caritas Internationalis* adopted a congregation-based strategy that builds a pediatric HIV/AIDS case identification system around priests and religious in the Church. With funding and technical support from UNAIDS and PEPFAR for the GRAIL project, religious leaders were trained on the scientific basis of HIV transmission, prevention, and treatment so that they can dispel myths that drive HIV stigma during homilies and in the course of their vocation. In addition, using tools like the Bandason risk assessment tool, clergy will prompt the caregivers of children with symptoms suggestive of severe compromised immunity (recurrent fevers, chest infections including tuberculosis, skin infections, diarrheal diseases, malnutrition, and other communicable diseases).

With funding and technical support from UNAIDS and PEPFAR for the GRAIL project, religious leaders were trained on the scientific basis of HIV transmission, prevention, and treatment so that they can dispel myths that drive HIV stigma during homilies and in the course of their vocation.

Still in its first year of implementation, the GRAIL project has conducted three of four planned trainings for about 153 priests and religious from 27 of the proposed 35 dioceses in Nigeria. These dioceses coincide with the UNAIDS 5+1 priority HIV States in Nigeria as well as the 10 States with the greatest unmet need for pediatric HIV.[13] Early reports estimate that at least 2,868 children (aged 0 to 10 years) have been tested for HIV as a result of referrals initiated by the trained Pediatric HIV Champions and all 21 confirmed cases have been commenced on ART.[14]

Figure 2: Increasing awareness, case identification and referrals for pediatric HIV/AIDS



In order to successfully deliver on the objectives of this Strategy, *Caritas* Nigeria will build upon her experience, implementing a similar congregation-based strategy for demand creation in PMTCT of HIV and working with the pioneer of the Baby Shower Congregational Approach Framework for PMTCT, Dr. Echezona Ezeanolue.[15]

4. Sustainability planning: the role of champions in pediatric HIV programs

By the nature of its establishment, goals, and distribution, the Church is a veritable structure for the sustainability of developmental programs. In addition to providing implementation platforms, prominent, expressive members of the Body of Christ can play the roles of anchorpersons and champions who reiterate the root causes, the rationale for intervention, and the proposed solution being implemented.

For instance, since the onset of the Nigerian HIV response, one prominent champion for pediatric HIV has been Cardinal John Onaiyekan, Archbishop of Abuja. At the Regional Consultation on Pediatric HIV in Abuja in June 2017, Cardinal Onaiyekan advocated thus:

> "HIV is an illness which we all need to come together to tackle. We keep hearing that there are antiretroviral drugs to help those who are HIV positive to reduce the consequences of the condition, that we have not gotten the cure yet, just treatment. But even for this treatment, what percentage of Nigerians who are HIV positive have access to these drugs? There is no reason why a child should die of HIV/AIDS."

This willingness to be at the forefront of a campaign is what champions often do—with little prompting but with sufficient information and the far-reaching sphere of influence to catch attention of policy makers, implementers, and beneficiaries. Sustainability is essential, and bearing in mind the funding limitations currently faced by many developmental programs including pediatric HIV, the GRAIL project has the recruitment, training, and catalytic activities of the pediatric ART champions as a cornerstone of its implementation strategy. The pediatric ART champions are already mobilizing their congregations and followers as sources of correct information and advocates towards action; commitments that will yield tangible fruits for the pediatric HIV response in Nigeria.

The pediatric ART champions are already mobilizing their congregations and followers as sources of correct information and advocates towards action; commitments that will yield tangible fruits for the pediatric HIV response in Nigeria.

5. Conclusion

Tackling pediatric HIV in Nigeria requires global synergy and partnership. It is known that successful reduction in the burden of pediatric HIV in Nigeria will go a long way towards the

achievement of global targets of tackling pediatric HIV. This process must explore implementation strategies outside the orthodox clinic-based interventions to reach children with HIV testing services and link those diagnosed with HIV to treatment services. Evidence from Nigeria and other high-burden HIV countries suggests that unexplored opportunities in community-based strategies can be better harnessed, especially if tied to community influencers and leaders such as the clergy. Early results indicate that engagement and capacity building of the clergy to engage congregations with accurate messaging can stimulate increased demand for pediatric HIV testing, thereby ensuring increased rates of diagnosis and treatment.

Evidence from Nigeria and other high-burden HIV countries suggests that unexplored opportunities in community-based strategies can be better harnessed, especially if tied to community influencers and leaders such as the clergy.

Notes

1. Pope Francis (2015), Encylical Letter, *Laudato Si'*, para. 160
2. UNICEF (2018). Briefing notes on SDG global indicators related to children; Available at https://data.unicef.org/resources/sdg-global-indicators-related-to-children/. [Accessed 11 November 2018]
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12. Bandason T. et al (2016). Validation of a screening tool to identify older children living with HIV in primary care facilities in high HIV prevalence settings; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937807/.
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THE CONTINUING LONG JOURNEY TO HIV PEDIATRIC CARE AND TREATMENT - THE EXPERIENCE OF CHILDREN OF GOD RELIEF INSTITUTE—NYUMBANI IN KENYA

A *Caritas in Veritate* Foundation Report by

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"These children are going to die anyway: get into prevention."

This was the response Fr. Angelo D'Agostino, SJ, MD and I received when we approached an international agency for funding support to set up a facility for abandoned HIV-infected children back in 1991. The Children of God Relief Institute—Nyumbani is the story of how one person came up against the injustice of HIV-infected children being neglected, abandoned through fear and ignorance, and rejected because their care was daunting and costly, and did something about it.

Starting with a residential facility on 8 September 1992 called Nyumbani Home, all we could do was give our children the best possible care for the 3 to 5 years of life that would be theirs: quality nutrition boosted by supplements, immediate medical treatment for opportunistic infections, and loving care. Several of our first children are alive today. Sadly, most passed away. In those days, the cost of ARV medicine was unbelievably prohibitive. But, trusting in God's Providence, we kept going, and God led us forward.

Starting with a residential facility on 8 September 1992 called Nyumbani Home, all we could do was give our children the best possible care for the 3 to 5 years of life that would be theirs: quality nutrition boosted by supplements, immediate medical treatment for opportunistic infections, and loving care.

Right from the beginning, Fr. D'Agostino began advocating for access to ARVmedication. Our first source of access to ARVs was through donors who responded to our appeal to sponsor a child in dire need of ART. Then, through Fr. D'Agostino's diplomatic advocacy, the Ambassador to Kenya at the time (from Brazil) enabled us to receive a large donation of AZT in June 2001, and again in November 2002. This was a very generous gesture that, later, sadly fell between the stools of bureaucracy. When CIPLA India manufactured a generic triple cocktail combination therapy in 2001, Fr. D'Agostino would brook no obstacle to getting access for our children, to the extent that, if our application to the Kenya Government to allow the waiving of the patent on two of the components was not granted, he announced: "They can arrest me at the airport." Such was his passionate commitment to override the injustice of denying ARV medication to

our children. Again, after receiving the first consignment, bureaucracy intervened.

Finally, in 2005, PEPFAR made access to ARVs for children possible, two years after adults gained access. In 1998, we started a community-based program, Lea Toto, for HIV-infected children living with their family in the informal communities surrounding the city of Nairobi. Again, quality care was all we could offer, but with the support for the caregiver as well. These children also benefited from PEPFAR, as did our third program, Nyumbani Village. But then, in the developing world, we had to cope with the guidelines for access to ART, starting with: "Once the CD4 count falls below 200 or below 15 percent for babies […]." It was only in 2016 that "Test and Start" was allowed, years after what had been the situation in the developed world.

Next, we came up against the challenge of PMTCT, virtually eliminating vertical transmission of HIV in the developed world, with the result that the pharmaceutical companies were no longer producing pediatric formulations. So we had to split tablets and break open capsules. In addition, the dose was not necessarily spread evenly in the tablets.

From 2005, aggravated by the blind prescription of ARVs, treatment failure became a challenge. We were privileged to start gaining access to genotyping in 2006 and up to 2010 through Kanazawa University in Japan, when we managed to acquire a genetic analyzer for our laboratory. The prohibitive cost of reagents for genotyping still prevents the majority of children and adults in Kenya from accessing what I consider is a basic health right for children/PHIV. Late 2007 brought another challenge: getting access to third-line ARVs. One of our boys developed resistance to all first- and second-line ARVs available in Kenya. Sadly, before we could get access to third-line ARVs, he had a brain stroke, which led to his gradual wasting away over eight months. We resolved to never again let that happen. It took over two years lobbying governments, NGOs, and advocacy groups to get access to third-line ARVs until, finally, we had no recourse but to lobby the two pharmaceutical companies ourselves. Thank God, we did so successfully in 2011 for two boys who were about to die. In 2012, two-year-old Margaret's resistance test showed that she had developed high resistance to all but third-line ARVS. She too is alive and well today.

The prohibitive cost of reagents for genotyping still prevents the majority of children and adults in Kenya from accessing what I consider is a basic health right for children/PHIV.

Where are we today? In 2015, dolutegravir—a more potent ARV with a high barrier to resistance—became available in the developed world. With more than two-thirds of our children having now reached mid and late adolescence and some on irregular regimens since the early 2000s, access to dolutegravir, ideally TLD, would greatly help with the challenges adolescents experience adhering to medicine (e.g., needing to conceal their taking ARVs from their companions in boarding school or being stigmatized when their friends discover that they are taking ARVs). If and when our adolescents gain access to TLD and the number of pills they need to take is

reduced to one or two per day, adherence will be greatly enhanced. Another formulation we have been lobbying to access is the pellet formulation of LPR/r, again available in the developed world but taking time to reach us.

As I reflect on our experience over 25 years in endeavouring to use all means possible to give life to our children, it gives me great joy to see our alumni re-integrated into the wider community, self-reliant, and living full lives. However, during these years, we continuously came up against consistent neglect of the rights of children living with HIV. Right from the beginning, Fr. D'Agostino, as a member of the Kenya Coalition for Access to Essential Medicines, was on the advocacy forefront and stood out at the risk of his personal reputation in the test case of importation of the CIPLA generic triple cocktail. Again, in early 2004, at the launch of a Vatican Stamp in Rome to draw attention to orphaned children left behind by the HIV pandemic, Fr. D'Agostino, because of the exorbitant costs of ARVs, accused the pharmaceutical companies of genocide. It took similar advocacy to get children access to ARV medication as a right. All through, we experienced the unjust difference between the developed world and our developing world, such as limited guidelines for access to ART; delays in access; fixed regimens with no access to new, more enhanced ARVs; and the Surveillance for Emergence of Antiretroviral Resistant Genotypes, which is still extant rather than availing genotyping. Even the World Bank, for World AIDS Day 2009, issued a document in which access to third-line ART in the developing world was conditionally recommended.[1] Sometimes, in desperation, when giving a talk I would say: "If the right of our children to access basic HIV health care does not move the world to help us, maybe the possibility of our passing a highly resistant virus through the tourist trade may move them."

All through, we experienced the unjust difference between the developed world and our developing world, such as limited guidelines for access to ART; delays in access; fixed regimens with no access to new, more enhanced ARVs; and the Surveillance for Emergence of Antiretroviral Resistant Genotypes, which is still extant rather than availing genotyping..

In their December 2008 article entitled, "A Question of Life or Death: Treatment Access for Children Living with HIV in Kenya,"[2] Human Rights Watch drew stark attention to this neglect, but we are yet to see the full implementation of this right in the developing world. There were also other rights of HIV-infected children being denied. Our children had to take the Government to court in 2004 in order to get access to free primary education in public schools, which was made available in 2003. Other rights that were being infringed upon were access to birth certificates and national identity registration, access to inheritance from deceased parents, and, above all, the right to have their dignity respected and protected. The dreadful injustice of stigmatizing people living with HIV gives the message that these children/adults are not meant to live.

I truly value all the research on HIV that has been done and continues to be done, and I have benefited from meeting with researchers. I truly value International World AIDS Conferences, subsequent follow-ups, PEPFAR and UNAIDS meetings, and the two meetings to which I was invited by *Caritas Internationalis* in 2016 and 2017, followed by the "Rome Action

However, when I am back on the ground still struggling to get access to the present care and treatment our children need, and have to wait, wait, wait, I keep wondering how we can wake up our world to take immediate action to make full pediatric care and treatment available to children living with HIV.

Plan". However, when I am back on the ground still struggling to get access to the present care and treatment our children need, and have to wait, wait, wait, I keep wondering how we can wake up our world to take immediate action to make full pediatric care and treatment available to children living with HIV. Surely, FBOs together can initiate this needed action now.

The path God called Fr. D'Agostino to walk was unchartered, fraught with opposition and challenge. In walking it, he created a blueprint for the care and treatment of HIV infected children which we in Nyumbani endeavour to follow. Nyumbani children have and are benefiting, if not ideally. But what about the millions of HIV-infected children, especially in the developing world, who are dying daily because of lack of care and treatment?

Notes

1. World Health Organization, Rapid Advice Antiretroviral Therapy for HIV Infection in Adults and Adolescents (November 2009)

2. Human Rights Watch, A Question of Life or Death; Treatment Access for Children Living With HIV in Kenya (December 2008)

CHILDREN AND TEENAGERS LIVING WITH HIV AND THE FUNDACIÓN EUDES EXPERIENCE

A *Caritas in Veritate* Foundation Report by

RENE REY AND JORGE LUIS DIAZ
Fundación Eudes

MTCT of HIV—the causal agent of AIDS—could occur during pregnancy, birth, or lactation. In 2017, around two million children and adolescents worldwide under 15 years of age were living with the virus, of which only 43 percent had access to ART.[1] Thanks to early screening strategies in pregnancy, the incidence of these cases has been decreasing from 2010 to 2016 by 47 percent.[2]

MTCT of HIV—the causal agent of AIDS—could occur during pregnancy, birth, or lactation.

Despite being highly preventable, this route of transmission is still frequent in developing countries. Colombia is one of them. In 2017, according to the National Institute of Health, 49 children were born with the virus, representing 0.4 percent of the total 13,311 new cases. During this same year, 334 Colombian pregnant women with HIV were diagnosed.[3]

Although the figures are remarkably low compared to other probable mechanisms of transmission—the sexual route represents 99 percent of new cases[4] —it is worrying that these cases persist when there is knowledge and technology to apply effective primary prevention strategies, which indicates weaknesses in the health system to contain the epidemic, affecting the most vulnerable populations.

Colombia has a general social health system that provides this service through health provider entities known as EPS, with huge participation from private companies. By law, every person who is part of this system must receive attention. The system contemplates access to ART. The coverage of this treatment is carried out by the State, which pays these EPS entities according to a standard monthly value per capita fixed. As a general principle, the State prioritizes the attention of all children. But according to Tailandia Rodríguez, pediatrician and infectious disease specialist who was a volunteer at the Fundación Eudes, the diagnosis may take more than a month in some cases. However, in other systems (e.g., the Chilean one), a diagnosis can be reached in less than 48 hours.[5]

In this adverse context, the Fundación Eudes, a non-profit organization, works with people living with HIV in two ways. On the one hand, from the angle of early prevention of diseases and health promotion and, on the other, by assisting with houses that serve as shelter-homes in several cities of Colombia. .

In this adverse context, the Fundación Eudes, a non-profit organization, works with people living with HIV in two ways. On the one hand, from the angle of early prevention of diseases and health promotion and, on the other, by assisting with houses that serve as shelter-homes in several cities of Colombia. It can be said that this process, already in operation for 30 years, demands a living and permanent act of compassion and mercy.

Since 1987, we have received 110 children and adolescents in four homes located in Bogotá, Medellin, Cartagena, and Neiva. This story is a fabric of joys and sorrows. We feel joy when we receive boys and girls, and we offer love to them. They normally come from very poor families and have lost one or two of their parents. The love we provide manifests itself through charity assistance, which provides for the coverage of vital services so that the children can enjoy a dignified life where their food, clothing, housing, health, and educational needs are met. In addition, they can count on an

interdisciplinary team of professionals who support them at a psychological, social, and spiritual level for the realisation of their life projects. Fundación Eudes admits these children, on average, at four years of age, although Eudes is also ready to admit newborn infants.

However, sometimes sadness is mixed with joy. Our first generation of children, because of lack of full access to ART, suffered otitis, bronchitis, or pneumonia. The reason for these occurrences was that they only took zidovudine as the first and only medication, accompanied by acyclovir to treat some opportunistic infections. Fortunately, the following generations had access to a complete and timely scheme of lopinavir/ritonavir plus zidovudine/lamivudine. Among other hard events to recount are the deaths of two children, one (aged 13) because of resistance to treatment, and the other (aged 17) due to bacterial hydrocephalus. In addition, some of them, upon reaching adulthood, have decided to walk toward new horizons. Watching them leave their home is difficult; even though this is part of the life cycle, it also causes pain. Anyway, the exercise of love and mercy teaches us to let go, as well as to overcome sorrow and grief.

One observation among this group of children that calls for attention is that a third of the population does not evidence a growth pattern that corresponds with peers in the same average age group. In fact, the average height denotes three or four years less than the normal average for this group.[6] Now, we must consider that these children have a particular history of their immune system, affected by the immune response and the evolution of their viral load.[7] Apparently, the lack of effectiveness in early treatment in some of these children, especially in the first two years of life, may have been a possible factor causing this abnormality in growth. Some of these children come from places outside the city where access is a problem because of geographical conditions, which may have resulted in weak medical attention and delayed ART.[8] In addition, these children come with severe malnutrition conditions. Finally, Fundación Eudes (with the support of an interdisciplinary team of professionals and, occasionally, some of the children's relatives) accompanies the children to medical check-ups and regular testing and monitoring. Now, as a result of the reflection on the experience of these children, it can be said that having a permanent

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caretaker-mother-coordinator for 20 years has been a factor of success for ensuring that these children can effectively live with HIV.[9]

Notes

1. UNAIDS (2018). Fact sheet. Latest statistics on the status of the AIDS epidemic. [Online] Available at: http://www.unaids.org/es/resources/fact-sheet [Accessed 1 November 2018]

2. *Ibid.*

3. Instituto Nacional de Salud (2018). Informe del evento: VIH/SIDA Colombia 2017. [Online] Available on: https://www.ins.gov.co/buscador-eventos/Informesdeevento/VIH-SIDA%202017.pdf [Accessed 1 November 2018]

4. *Ibid.*

5. Tailandia Rodriguez, pediatrician and infectious disease specialist, works in the Simon Bolívar Hospital in Bogotá. She is formerly of Fundación Eudes. Actually, she still attends our children.

6. According to our own data at IPS Fulano, health care center of Fundación Eudes (2018).

7. Ministerio de Salud Pública y Bienestar Social. *Normas Nacionales de Tratamiento Antirretroviral en Niños/as*. [Online] Available at: http://www.paho.org/hq/dmdocuments/2010/Paraguay%20NINOS.2009.pdf [Accessed 1 November 2018]

8. 2010 World Health Organization guidelines recommend extending the initiation of systematized ART to children under 2 years of age, regardless of the CD4 number and the clinical situation. Ministerio de sanidad interior, servicios sociales e igualdad. Documento de consenso del CEVIHP/SEIP/AEP/SPNS respecto al tratamiento antirretroviral en niños y adolescentes infectados por el VIH. Panel de expertos del Colaborativo Español para la Infección VIH Pediátrica (CEVIHP), Sociedad Española de Infectología Pediátrica (SEIP) de la Asociación Española de Pediatría (AEP) y Secretaria del Plan Nacional del Sida.

9. These pictures, taken by our Pastoral Unit, narrate a spiritual experience with our children in Bogota. All rights reserved.

THE STORY OF THE MAI TAM HOUSE OF HOPE—A SHELTER FOR ORPHANS AND VULNERABLE CHILDREN LIVING WITH HIV/AIDS

A *Caritas in Veritate* Foundation Report by

FR. JOHN TOAI, MI
Camillian Fathers

1. Background

From 2002 to 2005, the HIV/AIDS epidemic was at its peak level in Vietnam. The estimated number of PLHIV at that time was about 280,000, and more than 10,000 people had died of AIDS. Awareness of HIV prevention and the available treatments was limited, and many people were suffering not only from AIDS, but also from the stigma and discrimination attached to it. As a consequence, many children living with HIV/AIDS were abandoned, left on the streets, at hospitals, or isolated at home. Many pregnant women with HIV were also rejected by their families. Seeing the need to alleviate the pain and suffering of mothers and children with HIV/AIDS, the Camillian religious opened the Mai Tam House of Hope under the patronage of the AIDS Pastoral Office of the Archdiocese of Ho Chi Minh City.

Awareness of HIV prevention and the available treatments was limited, and many people were suffering not only from AIDS, but also from the stigma and discrimination attached to it. As a consequence, many children living with HIV/AIDS were abandoned, left on the streets, at hospitals, or isolated at home.

The Mai Tam shelter has two main objectives:

- Relieve the pain and suffering of orphaned children living with HIV/AIDS by providing them with shelter, care, treatment, and education;
- Improve the quality of life of single mothers living with HIV/AIDS by assisting them with shelter, treatment access, livelihood support, and PMTCT.

2. The story of Mai Tam's HIV treatment for children

The Mai Tam House of Hope began with five orphans living with HIV and three single mothers who became the caregivers at the shelter in July 2005. After one year, the numbers grew to 25 children and 10 mothers. We were struggling to find funding, medications for the treatment of opportunistic infection, and ART. At that time, treatment was not yet widely available. We had to use leftover medications

from patients who had died of AIDS for the children, dividing the adult ARV medication into smaller doses. We also witnessed the deaths of children in our communities from advanced development of AIDS due to a late diagnosis. By the year 2007, thanks to the support of *Caritas* Germany and the PEPFAR program, we were able to provide shelter and care for more than 50 children living with HIV and 20 young single mothers. At the same time, we also provided home-based care services to more than 100 children living in the communities, helping them to access treatment from the local government-run HIV outpatient clinic.

With access to ART, the health of the children improved rapidly, but they still faced strong stigma and discrimination in the community. Eventually, by the end of 2008, due to the fear and stigma in the community, all the children and mothers receiving care from Mai Tam were forced to move to a location outside of the city centre.

Thanks to the help of the GCSF, the Hope for Tomorrow Foundation, and the many benefactors of Mai Tam, we were able to relocate the children to a new place in 2009. In the new location, the children could also attend public school. Recently, one of the girls who grew up in the Mai Tam House of Hope has just graduated from nursing school, and there are several other children who are preparing to enter university. Along with being able to prevent the infection of HIV to their children, the young mothers and women at Mai Tam were also able to receive vocational training and begin working at the flower shop and the sewing factory to support themselves.

Since 2005, more than 370 orphaned and vulnerable children living with HIV/AIDS have received care, treatment, and support from the Mai Tam House of Hope.

Along with being able to prevent the infection of HIV to their children, the young mothers and women at Mai Tam were also able to receive vocational training and begin working at the flower shop and the sewing factory to support themselves. Since 2005, more than 370 orphaned and vulnerable children living with HIV/AIDS have received care, treatment, and support from the Mai Tam House of Hope.

3. The challenges of sustaining HIV treatment for children at the Mai Tam Shelter today

In the year 2016, UNAIDS estimated that there are around 250,000 adults and children living with HIV/AIDS in Vietnam. Among them, approximately 5,800 children are living with HIV. Only around 50 percent of PLHIV (116,000) have received ART. The number of orphans with AIDS aged 0 to 17 is around 85,000 children.[1] There is still a great need to provide care for these orphaned children with HIV, especially when it comes to helping them adhere to their treatment and access better medication. Recently, the Ministry of Health of Vietnam has informed the media that the country was facing many challenges due to the withdrawal of funding from the ADB for HIV prevention and treatment by the end of 2017. On the other hand, the PEPFAR program will stop its support by the end of 2018.[2] The withdrawal of international support for HIV programs in Vietnam will put more burden on the government in sustaining ART for people with HIV in general, and especially for the vulnerable children with HIV.

Among them, 66 children are receiving ART, 3 infants are receiving ARV prophylactic to prevent MTCT, and the remaining 18 children were successfully prevented from HIV through PMTCT.

At present, the Mai Tam House of Hope shelters 87 children. Among them, 66 children are receiving ART, 3 infants are receiving ARV prophylactic to prevent MTCT, and the remaining 18 children were successfully prevented from HIV through PMTCT.

In the communities, Mai Tam still continues to provide social support for more than 200 poor children (aged 0 to 17) living with HIV so that they can continue to adhere to medication. Yet despite the reduction of stigma and discrimination surrounding HIV in recent years, there are still many barriers preventing children with HIV from better access to pediatric ART.

A. So many pills to take and hard to swallow

Most of the children have to take a cocktail of pills for their ARV treatment every day. Some children have to take more than 15 large pills per day. For the toddlers living with HIV, we have to divide the dose for them by breaking the pills in half. Some of these pills are bitter and hard to swallow.

B. The poverty of families in the communities

Recently, many international agencies in Vietnam have scaled down their support for HIV/AIDS programs. ARV syrup, used for infants for the PMTCT, has to be stored in a refrigerator for the conservation of the medicine. For some poor mothers, this is very difficult. Additionally, for many poor families, the children often rely on their relatives to help them and to remind them to take ARV medications on time. Yet, most of their relatives have to work in the field or in factories, and

very often we see children left without care and without proper guidance to take their medication. Some of the families do not have enough money to travel the long distance to the outpatient clinic to get ARV medication, and they often skip the medication for several days. As a result, many children develop ARV resistance and have to change to a second line of medication despite the fact that there will be fewer resources and limited choices for the medication in the future due to the funding cut. Mai Tam has to create a network of community-based volunteers to reach out to these families and help them travel to the clinic to receive medication.

Additionally, for many poor families, the children often rely on their relatives to help them and to remind them to take ARV medications on time. Yet, most of their relatives have to work in the field or in factories, and very often we see children left without care and without proper guidance to take their medication. Some of the families do not have enough money to travel the long distance to the outpatient clinic to get ARV medication, and they often skip the medication for several days. As a result, many children develop ARV resistance and have to change to a second line of medication despite the fact that there will be fewer resources and limited choices for the medication in the future due to the funding cut.

C. The psychological influence on adolescents living with HIV/AIDS

Many adolescents living with HIV/AIDS struggle with their identity. At Mai Tam, we witness many orphaned children enter into a psychological crisis when they reach the age of adolescence. One reason for this could be from their early insecure attachment due to the death of their parents and the rejection of their relatives. Another reason could be that the reality of HIV has left a great impact on who they are. Despite ongoing counselling and support, it is still difficult to heal their inner wounds caused by feeling left out, being rejected, and living with HIV/AIDS. Some children attempt to give up their treatment, and others attempt suicide due to anger and depression. We are convinced that the corporal healing of HIV has to go together with inner healing, though it is easier to help the children gain better quality of life with ART than it is to help them access their wounded hearts and allow inner healing to take place. However, we also see many children forgive their relatives or their parents despite the fact that they have been abandoned and rejected before. This forgiveness often takes place after the children have experienced true unselfish love from their caregivers and peers in the shelter, where they are told they are worth loving no matter who they are.

4. Conclusion

Despite the gloomy future on treatment access and resources for children with HIV, we will continue to remain the "Shelter of Hope," as our name, Mai Tam, means in Vietnamese. Mai Tam's moto is "not one less," and we will continue to tell the world that even in our little corner of Asia, there is still a great number of orphaned children with HIV/AIDS who need treatment, care, and love. We continue to advocate for better access and pediatric treatment for HIV-positive children. With our limited capacity, we will try to open our shelter to all these children with our unconditional love and reawaken in them hope and faith in life.

Mai Tam's moto is "not one less," and we will continue to tell the world that even in our little corner of Asia, there is still a great number of orphaned children with HIV/AIDS who need treatment, care, and love.

Notes

1. http://www.unaids.org/en/regionscountries/countries/vietnam [Accessed 8 November 2018]
2. http://vietnamnews.vn/society/416125/hiv-aids-funding-sources-running-out.html#pqftdeSlCTrgiOEg.97 [Accessed 8 November 2018]

SECTION TWO:

THE CHURCH AND UNIVERSAL ACCESS TO MEDICINES

CATHOLIC CHURCH TEACHING AND TRADITION TO PROMOTE EQUAL ACCESS TO DIAGNOSIS AND TREATMENT OF MARGINALIZED GROUPS, INCLUDING CHILDREN AND ADOLESCENTS LIVING WITH HIV

A *Caritas in Veritate* Foundation Report by

MONSIGNOR ROBERT J. VITILLO
Attaché, Permanent Observer Mission of the Holy See to the United Nations and Other International Organizations in Geneva

1. Care and advocacy for the sick: At the heart of the Catholic Church Teaching and action

The Catechism of the Catholic Church leaves no room for doubt about the Church's dedication to its healing mission:

> "[Jesus'] preferential love for the sick has not ceased through the centuries to draw the very special attention of Christians toward all those who suffer in body and soul. It is the source of tireless efforts to comfort them[1] […] Heal the sick! (Mt. 10:8) The Church has received this charge from the Lord and strives to carry it out by taking care of the sick as well as by accompanying them with her prayer of intercession."[2]

At the turn of time to the third Christian millennium, Pope John Paul II challenged the global human family with piercing questions that were rooted in the Scriptural and Church teachings to serve the most needy and marginalized people:

> "Our world is entering the new millennium burdened by the contradictions of an economic, cultural, and technological progress which offers immense possibilities to a fortunate few, while leaving millions of others not only on the margins of progress but in living conditions far below the minimum demanded by human dignity. How can it be that even today there are still people dying of hunger? Condemned to illiteracy? Lacking the most basic medical care? Without a roof over their heads?"[3]

"Our world is entering the new millennium burdened by the contradictions of an economic, cultural, and technological progress which offers immense possibilities to a fortunate few, while leaving millions of others not only on the margins of progress but in living conditions far below the minimum demanded by human dignity."

In many instances, there is a positive convergence between the Catholic Church and other faith teachings and the initiatives of governments or civil society to make access to quality health care available to all persons who

need it. Pope Francis highlighted such convergence between faith traditions and the world at large during an audience granted to the participants in an annual UN FAO Conference:

> "[…] in the present international context, […] the human person and human dignity are not simply catchwords, but pillars for creating shared rules and structures capable of passing beyond purely pragmatic or technical approaches in order to eliminate divisions and to bridge existing differences."[4]

2. Recent efforts to promote equal access to diagnosis and treatment for children living with HIV

In both April and May 2016, Cardinal Peter Kodwo Appiah Turkson, former President of the Pontifical Council for Justice and Peace, in partnership with UNAIDS, PEPFAR, and *Caritas Internationalis*, invited a small group of chief executive officers from major pharmaceutical and medical technology companies to two dialogues for the High-Level Discussion at the Pontifical Academy of Sciences in Vatican City. The participants included representatives of other multi-lateral organizations, governments, and those directly engaged in services to children living with HIV, especially those located in low- and middle-income countries. The major focus of the meeting was to explore how pharmaceutical and diagnostic equipment companies could play a critical role through increased research, innovation, and collaboration in the development and delivery of medicines for HIV, specifically affordable, accessible, and acceptable long-term ARV treatment, including child-friendly formulations and dosages as well as diagnostic and monitoring tools for use in low- and middle-income countries where access to newer technologies is scarce.

Some key statements that set the tone and discussion during these meetings included the following:

> "Despite tremendous global progress, many challenges remain, particularly in low- and middle-income countries, but also among poor and marginalized populations in high-income countries. Babies are still being born with HIV, adults and children cannot access the second- and third-line HIV medicines they need, and health infrastructure often lacks basic services, such as water and electricity. We must all be part of the story and part of the solution to delivering accessible, affordable care for our vulnerable brothers and sisters." Cardinal Peter Kodwo AppiahTurkson, Former President, Pontifical Council for Justice and Peace, Presently Serving as Prefect of the Dicastery for Promoting Integral Human Development, Holy See

"Despite tremendous global progress, many challenges remain, particularly in low- and middle-income countries, but also among poor and marginalized populations in high-income countries."

> "Faith-based organizations were there long before the United States President's Emergency Plan for Aids Relief and The Global Fund to Fight AIDS, Tuberculosis and Malaria. They have much to teach us as they are at the forefront of innovative and alternative service delivery models."
> Her Excellency Deborah Birx, Ambassador-at-Large and Coordinator of the U.S. Government Activities to Combat HIV/AIDS

"Faith-based organizations were there long before the United States President's Emergency Plan for Aids Relief and The Global Fund to Fight AIDS, Tuberculosis and Malaria. They have much to teach us as they are at the forefront of innovative and alternative service delivery models."

> "Science has gone far, but we have not yet been able to link all people to the latest advances. Success without equity is not success. Faith-based organizations can provide the link between people and science and ensure that services are delivered equitably to all."
> Dr. Luiz Loures, Former Deputy Executive Director, UNAIDS and Assistant Secretary-General of the United Nations

> "Faith-based organizations have led the way in reducing new infections among children and are now leading the way to ensure that all children with HIV receive treatment."
> Dr. Mark Dybul, Former Executive Director, Global Fund to Fight AIDS, Tuberculosis and Malaria

Pope Francis sent a personal message to the participants in the first of these meetings, thereby issuing an urgent challenge to them and to all engaged in the search to eliminate HIV as a public health emergency:

> "Let it (the dialogue) continue until we find the will, the technical expertise, the resources and the methods that provide access to diagnosis and treatment available to all, and not simply to a privileged few for […] there is no human life that is qualitatively more significant than another."

On 17 November 2017, Cardinal Peter K. A. Turkson, Prefect of the Vatican Dicastery for Promoting Integral Human Development, convened key stakeholders[5] to participate in the Third High-Level Dialogue to Assess Progress and Intensify Commitment to Scaling Up Early Diagnosis and Treatment of Children and Adolescents. The latter Dialogue and its outcomes are described more comprehensively in the article by Mr. C. Lyons, which also appears in this publication (Page 129). On the day after this meeting, Pope Francis addressed the participants in a larger group of medical and scientific experts convened to reflect on the theme of "Addressing Global Health Inequalities." He made specific reference to the challenge of early diagnosis and treatment of children and adolescents living with HIV. In so doing, he offered sage advice to gain every greater progress in closing the gap in this field:

> "I would like to address the representatives of the several pharmaceutical companies who have been invited to Rome to discuss the issue of access to antiretroviral therapies by paediatric patients. I would like to offer for your consideration a passage of the [Vatican's] New Charter for Healthcare Workers. It states: 'Although it cannot be denied that the scientific knowledge and research of pharmaceutical companies have their own laws by which they must abide—for example, the protection of intellectual property and a fair profit to support innovation—ways must be found to combine these adequately with the right of access to basic or necessary treatments, or both, especially in underdeveloped countries. Health care strategies aimed at pursuing justice and the common good must be economically and ethically sustainable. Indeed, while they must safeguard the sustainability both of research and of health care systems, at the same time they ought to make available essential drugs in adequate quantities, in usable forms of guaranteed quality, along with correct information, and at costs that are affordable by individuals and communities'[6]."[7]

3. Follow-up actions by FBOs

FBOs have continued their advocacy and service efforts to attain early diagnosis and treatment of children and adolescents. The activities of *Caritas Internationalis* are well described in the articles by Fr. E. Bassey (Page 99), of *Caritas* Nigeria, and by Mr. Stefano Nobile (Page 91), of *Caritas Internationalis*.

In addition, WCC-EAA has articulated a global call to action to mobilize faith communities around the target of providing 1.6 million children and 1.2 million adolescents living with HIV with ART by 2018, with the ultimate goal of ending AIDS in children by 2020. One component of this initiative involved religious leaders from a range of faith communities in Kenya marching through the streets of Nairobi on the Day of the African Child, 16 June 2017, and speaking up publicly for the rights of children and adolescents living with HIV. They were accompanied by hundreds of people, among them children from six Nairobi-based schools, as well as dozens of youth volunteers. The theme of the march was developed by the children: "It's time to take action — Let's make this virus powerless." That event was followed by an interactive session between religious leaders and local school children, where open dialogue addressed issues concerning access to testing and treatment for children as well as the stigma and discrimination still surrounding the virus. Another component of the initiative was to develop sermon guides on HIV information for Christian and Muslim clerics, including the issue of eliminating HIV-related stigma

and discrimination. Further activities of the WCC-EAA is outlined in the article of F. Merico – Page 79.

The issues related to testing and treatment for children and adolescents living with HIV also received major attention in both Catholic Church-related and interfaith pre-conferences in conjunction with the 2018 International AIDS Conference. Moreover, the role of FBOs in the overall response to HIV received much more attention than in past years during the Main Conference. In all of the above, the field experience of faith-based projects was shared and highlighted as good practices for other community-based responses to HIV. Given the burden of care that is shouldered by FBOs, strong appeals were made to include these programs at the table of policy- and decision-making and to provide access to equitable funding so that FBOs could sustain their services that reach a broad spectrum of beneficiaries, especially among the most rural and marginalized populations.

Notes

1. Catechism of the Catholic Church., paragraph 1503.
2. *Ibid.*, paragraph 1509.
3. Pope John Paul II, *Novo Millennio Ineunte*, paragraph 50, Available at http://www.vatican.va/holy_father/john_paul_ii/apost_letters/documents/hf_jp-ii_apl_20010106_novo-millennio-ineunte_en.html. [Accessed 1 November 2018]
4. Pope Francis, Address to the Plenary of the FAO Conference, 2013; Available at http://www.vatican.va/holy_father/francesco/speeches/2013/june/documents/papa-francesco_20130620_38-sessione-fao_en.html [Accessed 1 November 2018]
5. List of participants of the High-Level Dialogue on Scaling Up Early Diagnosis and Treatment of Children and Adolescents, Annex 1 of Pediatric HIV Rome Action Plan; Availabe at: http://www.pedaids.org/wp-content/uploads/2018/02/Rome_Action_Plan_2017.pdf. [Accessed 1 November 2018]
6. New Charter for Healthcare Workers, paragraph 92
7. Pope Francis, Address to the Participants in the 32nd Conference, Addressing the Theme "Addressing Global Health Inequalities," 18 November 2017, Vatican City.

ORIGINS AND OUTCOME OF THE ACTION PLAN FOR SCALING UP EARLY DIAGNOSIS AND TREATMENT OF CHILDREN AND ADOLESCENTS

A *Caritas in Veritate* Foundation Report by

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1. Introduction

The Action Plan for Scaling Up Early Diagnosis and Treatment of Children and Adolescents, adopted by the participants of the Third Vatican High-Level Dialogue to Assess Progress and Intensify Commitment to Scaling Up Early Diagnosis and Treatment of Children and Adolescents in November 2017, was a landmark achievement within a broader effort to expand access to ARV medicines for children living with HIV. Since 2015, the groundwork for the "Rome Action Plan" was laid out via initiatives undertaken by a wide range of global health stakeholders, all highly motivated to see better health outcomes for such children. The political space for successful negotiation was provided by Cardinal Peter Kodwo Appiah Turkson, then Prefect of the Dicastery for Promoting Integral Human Development, whose convocation to meet at the Vatican, supported by PEPFAR and UNAIDS, provided the political weight and moral impetus needed to move decisively forward. Together, these elements enabled the development of a comprehensive and concrete Action Plan and an ethos of respect for its commitments.

2. Context for the Action Plan

Children living with HIV have long suffered from a lack of attention to their particular biomedical needs and specific social and economic impediments to accessing HIV services. The 2011–2015 Global Plan Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping their Mothers Alive provided long-awaited political and financial backing to the prevention of pediatric HIV, but pediatric treatment remained a low priority element within the Global Plan's four core areas of work. By late 2015, the Global Plan's success in

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significantly reducing new pediatric infections stood in stark contrast to the lamentable progress on pediatric HIV treatment.

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One oft-cited factor in low pediatric treatment rates has been the lack of availability of optimal ARVs for children. Long delays typically exist between the development of new, better performing and less toxic drugs for adults and their conversion into child-friendly formulations. Those drugs that have been developed are often bitter; difficult to swallow, administer, or store; or toxic for young bodies, making it difficult for children to start and stay on treatment. To address these challenges, the former Vatican's Pontifical Council for Justice and Peace convened two meetings of pharmaceutical CEOs and other key stakeholders in April and May 2016 to entreat them to act with greater resolve and to begin to define a better way forward. These meetings are described in greater detail in the article by Msgr. Vitillo (Page 123).

During the meeting held in May 2016, a broader group of concerned actors strategized on how to place pediatric treatment on a "Super-Fast-Track" and raise the visibility of the issue among global leaders. Advocacy by FBOs such as the WCC-EAA and World Vision, the Elizabeth Glaser Pediatric AIDS Foundation helped translate this ambition into a target in the High-Level Dialogue Political Declaration of putting 1.6 million children living with HIV on treatment by 2018. Around the same time, PEPFAR and UNAIDS launched the "Start Free, Stay Free, AIDS Free" Framework as a follow-up to the Global Plan, this time giving equal weight to the pediatric treatment component ("AIDS Free") and setting treatment targets for both 2018 and 2020. Meeting these ambitious targets would necessitate accelerated action by countries in identifying and diagnosing children living with HIV and providing them with optimal ARVs.

Yet, after a promising 2016, global interest in reaching the pediatric treatment goals seemed to falter in 2017, and there was a risk that momentum would be lost at a time when it was needed most. On the question of pediatric formulations, the previous consultations held by the Vatican were useful in signalling high-level political interest to the leaders of drug manufacturing companies but did not result in specific commitments or follow-up strategies. So, in the fall of 2017, PEPFAR, UNAIDS, and the newly established Vatican Dicastery for Promoting Integral Human Development joined together with WCC-EAA, WHO, *Caritas Internationalis*, and EGPAF to plan another high-level meeting. The organizers were aware that in order to attract high-level interest, a third meeting of this kind would need to provide sharper focus and a clear path forward. They decided to propose an Action Plan with a set of mutually reinforcing commitments by stakeholders across the pediatric ARV R&D spectrum, as well as an accountability system.

3. Commitments and follow-up

The resulting Joint Action Plan developed at the Vatican Academy of Sciences, in November 2017, known informally as the "Rome Action Plan"[1], benefited from several previous consultations among stakeholders from the public, private, intergovernmental, and nonprofit sectors. These meetings, called on various occasions by the International AIDS Society, PEPFAR, WHO, CHAI, and others, had established a general consensus on ways to reduce barriers to the timely development and introduction of optimal pediatric ARV formulations. The novelty of the November 2017 Event was to transform these insights into a set of concrete commitments centred around the need (1) to focus in on a limited set of priority formulations for children (the "PADO list"); (2) to accelerate their development, approval, and roll-out; and (3) to collaborate more closely on the technical, financial, and political elements of pediatric ARV R&D and uptake. The previous consultations, plus the establishment of engagements for all actors present, meant the commitments proposed at the Vatican were accepted with little debate in what participants described as a highly positive and constructive event. A number of participants even proposed additional steps for their organizations to take, a sign of further good will and interest in a meaningful outcome.

The "Rome Action Plan" was further strengthened by the inclusion of a system for monitoring its implementation and "holding actors to account." Responsibility for this accountability mechanism was taken by the co-chairs of the AIDS Free Working Group, WHO and EGPAF, supported by a small project management team, including representatives from WHO, EGPAF, PEPFAR and the faith-based community. The team's role has been to systematically track progress on all commitments, follow up on specific actions as needed, and communicate consistently with the "Rome Dialogue" participants. The team sends out regular updates that both showcase specific actors' efforts and signal areas needing more effort. Additionally, the project management team has set up a user-friendly online tracking platform. Webinars have also been organized to ensure effective dissemination of information and foster continued dialogue among the "Rome Dialogue" participants. This continuous spotlight on implementation efforts has created a positive pressure to perform, with actors often vying to show the most progress.

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4. What are the results?

Since the adoption of the "Rome Action Plan", there has been notable progress on pediatric ARVs, both qualitative and quantitative. On the qualitative side, most stakeholders have displayed a positive attitude towards the commitments they undertook, as well as an interest in seeing

The "Rome Action Plan" appears to be a key consideration in the actions of pediatric ARV pharmaceutical executives, policymakers, donors, and other key stakeholders, who commonly cite the Vatican initiative as the context for related efforts since November 2017. The "Rome Action Plan" has also been referenced by, or integrated into, related global, regional, and bilateral initiatives on pediatric treatment.

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Several actors, including PEPFAR, WHO, IAS, and WCC-EAA, have not only moved forward on their own commitments, but have also advocated with others to uphold theirs. They have also communicated to a wider group of research networks, civil society groups, pharmaceutical companies, and SRAs on the content of the Action Plan and the need to accelerate development and uptake of optimal ARVs. Continued positive momentum has been supported by the collaborative nature of the follow-up process, with good results shared and slower progress treated in a constructive, forward-looking manner.

On the quantitative side, an informal analysis showed stakeholders reporting full or partial implementation of over 90 percent of their commitments. Some steps taken have been remarkable, owing their origins completely or in large part to the Rome Action Plan. Many other actions are smaller-scale or incomplete but are certainly movements forward since the meeting held in November 2017; still others represent the continuation of ongoing efforts, though they may have been enhanced or expedited by the Rome Action Plan. Those actions that were the most loosely framed and/or without a fixed objective or timeline (i.e., non-"SMART" goals) are those with the least visible results. An additional meeting will be an occasion to refine these goals with sharper targets and timelines, as well as to add commitments by additional actors to fill remaining gaps.

Perhaps the clearest example of a Vatican-inspired outcome was the clarification by one SRA, FDA, of a number of regulatory requirements that could accelerate pediatric drug R&D. Another valuable step inspired by the Vatican meeting was the effort by the GNP+ to encourage its members to give greater attention to the critical need to expand the uptake of pediatric HIV testing and treatment. And the Vatican's interest in convening a similar dialogue on pediatric diagnosis has already led to a series of productive meetings on both the case-finding of children and better access to diagnostics, which will culminate in a high-level consultation at the Vatican in December 2018.

On the central question of new formulation development, no timelines have been advanced due to the "Rome Action Plan", and some targets set at the meeting will be missed. But most manufacturers now seem aware of the imperative to act more quickly because of the urgency for children as well as the need to enhance their external image.[2] Several originator companies reconfirmed to PEPFAR their willingness to provide drugs at access price until generics are available, and one has reported devoting more high-level

staff and resources to pediatric R&D. Two generic companies followed up on their commitments to increase availability of a much needed fixed-dose combination for young children. Only one party has acted in a manner that seems at odds with the spirit of the plan, prioritizing a formulation that is not on the optimal pediatric ARV list over one that is. Yet even in this case, several groups were motivated to engage in bilateral advocacy with the company to promote full compliance with its Rome Action Plan commitment.

More generally, good progress has been made by donors to encourage the procurement of optimal drugs and formulations, and the WHO revised its pediatric treatment guidelines in July 2018 to include more potent regimens for neonates and children in line with PADO recommendations. A number of actors across the R&D spectrum are collaborating more closely than before on plans for in-country registration and introduction of those products in the pipeline for 2019 or 2020. Less information is available at this relatively early stage on meeting longer-term goals, such as expediting the regulatory review (both SRA and NRA) of priority formulations and shortening the R&D pathway for new pediatric drugs.

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In summary, the actions and attitudes of a variety of stakeholders have been positively affected by the Vatican Initiative on pediatric formulations and the "Rome Action Plan". Holding the meeting at the hallowed grounds of the Vatican, with the support of FBOs before, during, and after the meeting, provided a weight and moral imperative that other venues or conveners could not have achieved. And including stakeholder-assigned action points with a system of oversight and regular reporting has kept the pressure on to demonstrate progress. The ultimate tests will be whether children living with HIV soon start having access to long-awaited optimal drugs and the amount of time they will have to wait to access the next innovative drugs developed for adults.

Notes

1. The full version of the Rome Action Plan is outlined under the subsequent point (page 135)

2. An entire article is devoted to ViiV's work in this regard (see page 69)

ACTION PLAN FOR SCALING UP EARLY DIAGNOSIS AND TREATMENT OF CHILDREN AND ADOLESCENTS

PONTIFICAL ACADEMY OF SCIENCES, VATICAN CITY
17 November 2017

Introduction

On 17 November 2017, leaders of major pharmaceutical and medical technology companies, multilateral organizations, donors, governments, organizations providing or supporting services for children living with HIV, and other key stakeholders participated in a High-Level Dialogue on Scaling Up Early Diagnosis and Treatment of Children and Adolescents. The meeting was convened by His Eminence Peter Kodwo Appiah Cardinal Turkson, Prefect of the Dicastery for the Promotion of Integral Human Development, with PEPFAR, UNAIDS and *Caritas Internationalis*, and in close collaboration with the World Council of Churches-Ecumenical Advocacy Alliance, WHO, and EGPAF.[1]

Participants gathered to discuss how to reduce morbidity and mortality among children living with HIV, particularly by accelerating the development and introduction of priority paediatric formulations of antiretroviral drugs (ARVs). In contrast to the regular development of better ARVs for adults living with HIV over the past 20 years, there have been very few new optimal medicines made available for children. Existing ARVs are often bitter tasting, difficult to administer, inappropriate for low-resource settings, and with toxic side effects for growing bodies. The lack of suitable ARVs for children has contributed in part to low levels of treatment initiation, retention in care, and viral load suppression. Better paediatric formulations could save countless lives. More focused, accelerated, and coordinated action is therefore of the highest urgency.

With this in mind, concerned stakeholders have gathered on several occasions in 2016 and 2017 to exchange views on the policies and practices they believe should be changed to facilitate and expedite the research, development, approval, introduction and uptake of optimal drugs and formulations for infants, children and adolescents. Proposals have included both steps to make priority drugs in the pipeline quickly available in the short term as well as innovative mechanisms that could be put in place to facilitate and accelerate the development of paediatric formulations of drugs for HIV and other life-threatening diseases over the longer term. The High-Level Dialogue provided an opportunity for stakeholders to build

on these conversations by putting forward a set of concrete actions they could take to better support the research, development, and introduction spectrum. These commitments, which also build on work within the Global Accelerator for Paediatric Formulations (GAP-f)[2] and the Start Free, Stay Free, AIDS Free Framework, form the basis of the Action Plan below.

Action Plan

In recognition of the urgency of making more optimal paediatric ARV formulations available in 2018 and beyond, the participants of the High-Level Dialogue[3] agreed to the following good faith commitments to focus, accelerate, and collaborate on the development, registration, introduction, and roll-out of the most optimal paediatric formulations and diagnostics:[4]

I. FOCUS on priority paediatric drugs and formulations

WHO committed to:

- Action 1: Continue to host the Paediatric ARV Drug Optimization (PADO) process and update the list of priority products with a view to providing a consistent, clear, and harmonized set of products that will be communicated to industry and regulators in a timely manner, and ensure inclusion of PADO priority products in the WHO Expression of Interest list as soon as dosing is provided.
- Action 2: Update treatment guidelines in a timely manner to ensure that more effective drugs are recommended for children as soon as pharmacokinetic (PK) and safety data is available.
- Action 3: Continue to use the Paediatric ARV Working Group (PAWG) mechanism to provide recommendations on optimal dosing and ratios for formulation development.
- Action 4: In collaboration with other partners, continue to revise the Optimal ARV Formulary and ensure its inclusion in Essential Medicine List.

Research networks committed to:

- Action 5: Focus research efforts on optimal drugs and formulations as defined by PADO.

Pharmaceutical companies committed to:

- Action 6: Prioritize PADO products in research and development plans.

SRAs committed to:

- Action 7: Prioritize the review of Pediatric Study Plans (PSPs) and Paediatric Investigation Plans (PIPs) for paediatric ARVs on the list of PADO priority products over lower priority drugs.

Donors committed to:

- Action 8: Support and fund clinical and implementation research to inform development and approval as well as use of paediatric formulations included in the PADO list.
- Action 9: Only fund the procurement of drugs and formulations recommended by WHO that are included in the Optimal Formulary[5].

Implementing Partners committed to:

- Action 10: Promote the revision of national procurement plans to align with WHO recommended regimens and the Optimal Formulary, and support the provision of reliable forecasts and the consolidation of orders.

II. ACCELERATE the development, review, and introduction of paediatric formulations

WHO committed to:

- Action 11: Continue to convene the PAWG to provide advice to innovators prior to submission of PSPs/PIPs, communicate technical opinions to SRAs in a timely manner, and provide dosing and ratio recommendations to generics for development of new FDCs.
- Action 12: Re-establish the Paediatric Regulatory network to accelerate national registration and facilitate in-country registration of specific products under the Collaborative procedure established by WHO.

Pharmaceutical companies committed to:

- Action 13: In pre-clinical and clinical development, initiate paediatric formulation development as soon as a given drug shows potential public health impact in adults, soon after Phase II trials are completed.
- Action 14: Include adolescents when conducting initial adult efficacy trials, where possible and practical, or conduct parallel trials with the goal of providing information to support licencing for adolescents at the same time as adults.
- Action 15: In the design of paediatric PK and safety studies, use weight-based dosing and enroll all children above 4 weeks concurrently, unless a strong rationale exists for not doing so.
- Action 16: Assess acceptability and palatability of formulations for low-resource settings at early stages of the formulations development.

- Action 17: Engage in early and regular consultations with the PAWG on PIP/PSPs, as well as recommended dosing and ratios for FDC development.
- Action 18: Take all possible measures to rapidly complete development of priority paediatric drugs and formulations in the pipeline, with the goal of providing the maximum number of new formulations by end of 2018, especially for infants and young children.

Research networks committed to:

- Action 19: Undertake studies that use weight-based dosing, enroll all paediatric weight-band groups concurrently irrespective of age, and maximize opportunities to accelerate enrollment of subjects.

SRAs committed to:

- Action 20: Accept and encourage the accelerated steps outlined in Actions 14-18 when evaluating paediatric development plans and reviewing drug applications and encourage formulation development to begin soon after Phase II dosing selection.

Donors committed to:

- Action 21: Provide funding to support actions required for quickly introducing and scale-up new, optimal paediatric formulations.

Implementing Partners, and Faith-Based Organizations committed to:

- Action 22: Support the early adoption of priority formulations and diagnostics and take steps to facilitate their wider roll-out, including by developing introductory guidance, materials, and other tools for health facilities.

The Global Accelerator Partners committed to:

- Action 23: Call on regulatory authorities to expedite and simplify the review of priority paediatric formulations and diagnostics, including by:

  - Making better use of sub-regional collaborative regulatory approval processes and the WHO Collaborative procedure for accelerated registration;
  - Increasing reliance on evaluations and opinions of stringent regulatory authorities (SRAs) and the WHO prequalification program, up to providing full waivers for high priority paediatric drugs;
  - Allowing compassionate use until drugs are registered; and
  - Ending requirements for local clinical trials when sufficient PK and safety data exists, even when no innovator equivalent exists.

- Action 24: Develop a toolkit to set standards and support accelerated research, development, and introduction of priority paediatric formulations.

UNICEF committed to:

- Action 25: Work with countries on creating demand for paediatric HIV treatment services including generation of age disaggregated data to inform the better planning and supply forecasting.
- Action 26: Through UNICEF supply Division, support rapid country adoption of new recommended regimens by including them on the UNICEF procurement services product lists and tenders for long term agreements.

Networks of PLHIV, Implementing Partners, and Faith-Based Organizations committed to:

- Action 27: Mobilize their networks and work with communities to help build treatment literacy, generate demand, and expand access to ARVs among children.
- Action 28: Raising awareness in global fora about the unmet diagnostic and treatment needs of children with HIV.
- Action 29: Promote uptake by mobilizing their networks of hospitals and community structures to distribute paediatric medicines in hard to reach places and in situations of conflict and crisis.

III. COLLABORATE on expedited development and introduction of paediatric products

Pharmaceutical companies committed to:

- Action 30: Strengthen and expand collaboration to overcome intellectual property challenges and otherwise facilitate technology transfer and knowledge sharing that can promote faster paediatric formulation development, including on challenges like taste-masking.

All stakeholders committed to:

- Action 31: Work together in a coordinated and transparent manner to ensure paediatric formulations are rapidly registered, introduced, and made widely available at an affordable cost in a maximum of high-burden countries.
- Action 32: Identify alternative incentives and innovative financial mechanisms for the research, development and sustained supply of paediatric formulations, including advanced purchase commitments or other interventions.

- Action 33: In addition to paediatric drugs and formulations in the pipeline, support the greater use of currently available WHO prequalified diagnostics and drugs in the WHO recommended regimens.

Implementing Partners committed to:

- Action 34: Increase efforts to share information on the roll-out of new paediatric formulations, including lessons learned.

UNAIDS and PEPFAR as co-chairs of Start Free, Stay Free AIDS Free Framework committed to:

- Action 35: Provide high level political leadership and advocacy at global, country and regional levels to scale up access to paediatric HIV medications for children; production of high quality data to support implementation; and Country level support to roll out.
- Action 36: Continue to convene and coordinate stakeholders at a high level, including the pharmaceutical industry, FBO and civil society service providers, national governments and multilateral partners, and partners in the Start Free, Stay Free, AIDS Free Framework.

The Co-Chairs of the AIDS Free Working Group of the Start Free, Stay Free, AIDS Free framework committed to:

- Action 37: Take responsibility for monitoring implementation of the Action Plan and holding actors to account, including monthly calls of principals, tracking progress towards milestones, and regularly communicating with participants about progress on their commitments and overall implementation of the Plan.
- Action 38: Develop a set of milestones in 2018 to highlight progress on the Action Plan and establish opportunities for stakeholders to take on more specific commitments.
- Action 39: GAP-f partners develop a work plan for finalization, roll-out and increasing demand for and accelerating access to 2-3 high priority drugs planned for approval in 2018.
- Action 40: Continue to refine the Global Accelerator for Paediatric Formulations concept as a key component of the AIDS Free work stream, including by establishing leadership, roles and responsibilities, and a financing mechanism.
- Action 41: Organize a follow-up meeting focused on diagnostics for children in Q1 2018.

Annex 1: Participating Organizations

Faith-based Organizations	ICAP, Columbia University
Caritas Congo ASBL	Istituto Superiore della Sanità
Caritas Internationalis	Medicines Patent Pool
Caritas Nigeria	MSF
Caritas Zimbabwe	PEPFAR
Catholic Health Association of the United States	The Global Fund to Fight AIDS, TB and Malaria
Catholic Relief Services	The Global Network of People Living with HIV
CMMB	UNAIDS
Comunità Sant'Egidio	UNICEF
Medical Mission Institute Wuerzburg	UNITAID
Nyumbani	University of Roma Tor Vergata - Bambino Gesù Hospital
World Council of Churches - Ecumenical Advocacy Alliance	WHO
Governments	**Pharmaceutical and Diagnostics Companies**
DRC - Programme national multisectoriel de lutte contre le sida	Abbot/Alere
Republic of Zimbabwe - Ministry of Health and Child Care	Becton-Dickinson
Republic of Zimbabwe	Cepheid
Holy See	Cipla
Cardinal Archbishop of Abuja	Diagnostics for the Real World Ltd
Dicastery for Promoting Integral Human Development	Gilead Sciences, Inc.
Holy See - Permanent Observer Mission to UNOG	Hetero Labs Ltd
International Organizations and Donors	Johnson & Johnson
Clinton Health Access Initiative	Merck Sharp and Dome
Drugs for Neglected Diseases initiative (DNDi)	Mylan
Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)	ViiV Healthcare
ELMA	**Regulators**
	US Food and Drug Administration

Annex 2: Individual Commitments

In addition to their support for the commitments in the Action Plan, several stakeholders participating in the High-Level Discussion made individual commitments, each of which made a significant contribution to the goals of the meeting. They include the following:

1. The US FDA committed to a number of adjustments to the regulatory approval process for paediatric formulations and to make them public on World AIDS Day:
    - Paediatric formulation development should begin soon after adult Phase 2-b trials and dosing selection;
    - Adolescents should be included in initial registrational efficacy (Phase 3) trials in adults or adolescent trials should be conducted in parallel with adults;
    - Studies of drugs across the paediatric spectrum of ages/weights (at least down to age 4 weeks) should be conducted in parallel rather than in series (unless a particular product has a specific safety or drug disposition factor that warrants a different approach).
    - Drug development studies in children should be based on weight rather than age and should align with the WHO weight bands.
2. PEPFAR committed to work with countries on a system of shared data and rotating locations for implementation studies; to develop a proposal for further expediting the regulatory approval process; and to fund the procurement of only optimal paediatric ARVs.
3. CHAI will commit full-time staff to assist EGPAF, WHO, PEPFAR, UNITAID and others to develop, coordinate and implement a detailed work plan to achieve the goals of the initiative; to assist with reaching agreements with companies, governments, donors and regulators to accelerate the introduction of optimal formulations and diagnostics for children and adolescents both short term and long term; and to work with governments and faith based organizations to scale up identification and treatment of HIV infected children and adolescents in the target countries.
4. Gilead committed to having clinical data ready for a low-dose TAF based regimen for children 2-12 years by late 2018/early 2019.
5. Merck & Co., Inc., is committed to make pediatric Raltegravir available at no profit in low income, least developed countries and across Sub-saharan African countries until generics are available.
6. ViiV Healthcare committed to deploy people, resources and technical expertise to speed up as much as possible the generation of data for regulatory approval of medicines for children living with HIV, including the ongoing development of Dolutegravir for children.

7. ViiV Healthcare committed to make paediatric Dolutegravir available at cost of production in low income countries, least developed countries and across Sub-Saharan African countries until generics are available.
8. Cipla committed to scale-up production of Lopinavir/Ritonavir (LPVr) pellets to 30,000 bottles per month in 2018 and to submitting the new "4-in-1" (ABC/3TC/LPV/r) pellets in 2018.
9. Mylan committed to submitting LPV/r granules for regulatory approval in 2017; "4-in-1" (ABC/3TC/LPV/r) granules in 2018; and a paediatric ABC/3TC/DTG formulation in 2019, subject to the WHO providing paediatric DTG dosing guidance in early 2018.
10. The Global Network of People living with HIV (GNP+) committed to mobilize their networks, in particular women living with HIV, to increase demand generation, advocacy, and monitoring to increase access to treatment for children living with HIV.
11. Cardinal Turkson committed the Catholic Church to mobilize their networks of both hospitals, and community structures to distribute paediatric medicines in hard to reach places and in situations of conflict and crisis.

Notes

1. WHO and EGPAF are co-conveners of the AIDS Free Working Group of the Start Free, Stay Free, AIDS Free framework.

2. The Global Accelerator for Paediatric Formulations is a global partnership created to promote faster development, regulatory approval, and uptake of priority, optimal pediatric drugs and formulations to treat HIV.

3. See Annex 1 for List of Participants.

4. For additional, individual commitments made at the Consultation see Annex 2.

5. http://www.who.int/hiv/pub/paediatric/iatt-paediatric-hiv-2016/en/

COLLECTION
OF RECENT DOCUMENTS
FROM THE CHURCH'S ENGAGEMENT
ON UNIVERSAL ACCESS TO MEDICINES

CATECHISM OF THE CATHOLIC CHURCH

(Selected Excerpts)

2402. In the beginning God entrusted the earth and its resources to the common stewardship of mankind to take care of them, master them by labor, and enjoy their fruits. [186] The goods of creation are destined for the whole human race. However, the earth is divided up among men to assure the security of their lives, endangered by poverty and threatened by violence. The appropriation of property is legitimate for guaranteeing the freedom and dignity of persons and for helping each of them to meet his basic needs and the needs of those in his charge. It should allow for a natural solidarity to develop between men.

[…]

2403. The universal destination of goods remains primordial, even if the promotion of the common good requires respect for the right to private property and its exercise.

[…]

2406. Political authority has the right and duty to regulate the legitimate exercise of the right to ownership for the sake of the common good. [188]

NOTES

[186] Cf. Gen 1:26-29.
[188] Cf. GS 71 # 4; SRS 42; CA 40; 48.

COMPENDIUM OF THE SOCIAL DOCTRINE OF THE CHURCH

(Selected Excerpts)

164. The principle of the common good, to which every aspect of social life must be related if it is to attain its fullest meaning, stems from the dignity, unity and equality of all people. According to its primary and broadly accepted sense, the common good indicates "the sum total of social conditions which allow people, either as groups or as individuals, to reach their fulfilment more fully and more easily". [346]

[…]

172. The universal right to use the goods of the earth is based on the principle of the universal destination of goods. Each person must have access to the level of well-being necessary for his full development. The right to the common use of goods is the "first principle of the whole ethical and social order" [363] and "the characteristic principle of Christian social doctrine" [364]. For this reason the Church feels bound in duty to specify the nature and characteristics of principle. It is first of all a natural right, inscribed in human nature and not merely a positive right connected with changing historical circumstances; moreover it is an "inherent" [365] right. It is innate in individual persons, in every person, and has priority with regard to any human intervention concerning goods, to any legal system concerning the same, to any economic or social system or method: "All other rights, whatever they are, including property rights and the right of free trade must be subordinated to this norm [the universal destination of goods]; they must not hinder it, but must rather expedite its application. It must be considered a serious and urgent social obligation to refer these rights to their original purpose" [366].

[…]

179. The present historical period has placed at the disposal of society new goods that were completely unknown until recent times. This calls for a fresh reading of the principle of the universal destination of the goods of the earth and makes it necessary to extend this principle so that it includes the latest developments brought about by economic and technological progress. The ownership of these new goods — the results of knowledge, technology and know-how — becomes ever more decisive, because "the

wealth of the industrialized nations is based much more on this kind of ownership than on natural resources". [379]

New technological and scientific knowledge must be placed at the service of mankind's primary needs, gradually increasing humanity's common patrimony. Putting the principle of the universal destination of goods into full effect therefore requires action at the international level and planned programmes on the part of all countries. "It is necessary to break down the barriers and monopolies which leave so many countries on the margins of development, and to provide all individuals and nations with the basic conditions which will enable them to share in development". [380]

[…]

331. The relation between morality and economics is necessary, indeed intrinsic: economic activity and moral behaviour are intimately joined one to the other. The necessary distinction between morality and the economy does not entail the separation of these two spheres but, on the contrary, an important reciprocity. Just as in the area of morality one must take the reasons and requirements of the economy into account, so too in the area of the economy one must be open to the demands of morality: "In the economic and social realms, too, the dignity and complete vocation of the human person and the welfare of society as a whole are to be respected and promoted. For man is the source, the centre, and the purpose of all economic and social life". [692] Giving the proper and due weight to the interests that belong specifically to the economy does not mean rejecting as irrational all considerations of a meta-economic order. This is so because the purpose of the economy is not found in the economy itself, but rather in its being destined to humanity and society. [693] The economy, in fact, whether on a scientific or practical level, has not been entrusted with the purpose of fulfilling man or of bringing about proper human coexistence. Its task, rather, is partial: the production, distribution and consumption of material goods and services.

332. The moral dimension of the economy shows that economic efficiency and the promotion of human development in solidarity are not two separate or alternative aims but one indivisible goal. Morality, which is a necessary part of economic life, is neither opposed to it nor neutral: if it is inspired by justice and solidarity, it represents a factor of social efficiency within the economy itself. The production of goods is a duty to be undertaken in an efficient manner, otherwise resources are wasted. On the other hand, it would not be acceptable to achieve economic growth at the expense of human beings, entire populations or social groups, condemning them to indigence. The growth of wealth, seen in the availability of goods and services, and the moral demands of an equitable distribution of these

must inspire man and society as a whole to practise the essential virtue of solidarity, [694] in order to combat, in a spirit of justice and charity, those "structures of sin" [695] where ever they may be found and which generate and perpetuate poverty, underdevelopment and degradation. These structures are built and strengthened by numerous concrete acts of human selfishness.

333. If economic activity is to have a moral character, it must be directed to all men and to all peoples. Everyone has the right to participate in economic life and the duty to contribute, each according to his own capacity, to the progress of his own country and to that of the entire human family. [696] If, to some degree, everyone is responsible for everyone else, then each person also has the duty to commit himself to the economic development of all. [697] This is a duty in solidarity and in justice, but it is also the best way to bring economic progress to all of humanity. When practised morally, economic activity is therefore service mutually rendered by the production of goods and services that are useful for the growth of each person, and it becomes an opportunity for every individual to embody solidarity and live the vocation of "communion with others for which God created him". [698] The effort to create and carry out social and economic projects that are capable of encouraging a more equitable society and a more human world represents a difficult challenge, but also a stimulating duty for all who work in the economic sector and are involved with the economic sciences. [699]

[…]

365. An adequate solidarity in the era of globalization requires that human rights be defended. In this regard, the Magisterium points out that not only the "vision of an effective international public authority at the service of human rights, freedom and peace has not yet been entirely achieved, but there is still in fact much hesitation in the international community about the obligation to respect and implement human rights. This duty touches all fundamental rights, excluding that arbitrary picking and choosing which can lead to rationalizing forms of discrimination and injustice. Likewise, we are witnessing the emergence of an alarming gap between a series of new 'rights' being promoted in advanced societies – the result of new prosperity and new technologies – and other more basic human rights still not being met, especially in situations of underdevelopment. I am thinking here for example about the right to food and drinkable water, to housing and security, to self-determination and independence – which are still far from being guaranteed and realized". [755]

[…]

376. Faced with the rapid advancement of technological and economic progress, and with the equally rapid transformation of the processes of production and consumption, the Magisterium senses the need to propose a great deal of educational and cultural formation, for the Church is aware that "to call for an existence which is qualitatively more satisfying is of itself legitimate, but one cannot fail to draw attention to the new responsibilities and dangers connected with this phase of history ... In singling out new needs and new means to meet them, one must be guided by a comprehensive picture of man which respects all the dimensions of his being and which subordinates his material and instinctive dimensions to his interior and spiritual ones ... Of itself, an economic system does not possess criteria for correctly distinguishing new and higher forms of satisfying human needs from artificial new needs which hinder the formation of a mature personality. Thus a great deal of educational and cultural work is urgently needed, including the education of consumers in the responsible use of their power of choice, the formation of a strong sense of responsibility among producers and among people in the mass media in particular, as well as the necessary intervention by public authorities". [772]

[…]

447. The Church's social doctrine encourages forms of cooperation that are capable of facilitating access to the international market on the part of countries suffering from poverty and underdevelopment. "Even in recent years it was thought that the poorest countries would develop by isolating themselves from the world market and by depending only on their own resources. Recent experience has shown that countries which did this have suffered stagnation and recession, while the countries which experienced development were those which succeeded in taking part in the general interrelated economic activities at the international level. It seems therefore that the chief problem is that of gaining fair access to the international market, based not on the unilateral principle of the exploitation of the natural resources of these countries but on the proper use of human resources". [930] Among the causes that greatly contribute to underdevelopment and poverty, in addition to the impossibility of acceding to the international market, [931] mention must be made of illiteracy, lack of food security, the absence of structures and services, inadequate measures for guaranteeing basic health care, the lack of safe drinking water and sanitation, corruption, instability of institutions and of political life itself. There is a connection between poverty and, in many countries, the lack of liberty, possibilities for economic initiative and a national administration capable of setting up an adequate system of education and information.

[…]

457. The results of science and technology are, in themselves, positive. "Far from thinking that works produced by man's own talent and energy are in opposition to God's power, and that the rational creature exists as a kind of rival to the Creator, Christians are convinced that the triumphs of the human race are a sign of God's grace and the flowering of His own mysterious design" [950]. The Council Fathers also emphasize the fact that "the greater man's power becomes, the farther his individual and community responsibility extends" [951], and that every human activity is to correspond, according to the design and will of God, to humanity's true good [952]. In this regard, the Magisterium has repeatedly emphasized that the Catholic Church is in no way opposed to progress [953], rather she considers "science and technology are a wonderful product of a God-given human creativity, since they have provided us with wonderful possibilities, and we all gratefully benefit from them" [954]. For this reason, "as people who believe in God, who saw that nature which he had created was 'good', we rejoice in the technological and economic progress which people, using their intelligence, have managed to make" [955].

NOTES

1. [346] Second Vatican Ecumenical Council, *Gaudium et Spes*, 26: AAS 58 (1966), 1046; cf. Catechism of the Catholic Church, 1905-1912; Pope John XXIII, Encyclical Letter *Mater et Magistra*: AAS 53 (1961), 417-421; Pope John XXIII, Encyclical Letter *Pacem in Terris*: AAS 55 (1963), 272-273; Pope Paul VI, Apostolic Letter *Octogesima Adveniens*, 46: AAS 63 (1971), 433- 435.

2. [363] Pope John Paul II, Encyclical Letter *Laborem Exercens*, 19: AAS 73 (1981), 525.

3. [364] Pope John Paul II, Encyclical Letter *Sollicitudo Rei Socialis*, 42: AAS 80 (1988), 573.

4. [365] Pope Pius XII, Radio Message for the fiftieth anniversary of *Rerum Novarum*: AAS 33 (1941), 199.

5. [366] Pope Paul VI, Encyclical Letter *Populorum Progressio*, 22: AAS 59 (1967), 268.

6. [379] Pope John Paul II, Encyclical Letter *Centesimus Annus*, 32: AAS 83 (1991), 832.

7. [380] Pope John Paul II, Encyclical Letter *Centesimus Annus*, 35: AAS 83 (1991), 837.

8. [692] Second Vatican Ecumenical Council, Pastoral Constitution *Gaudium et Spes*, 63: AAS 58 (1966), 1084.

9. [693] Cf. Catechism of the Catholic Church, 2426.

10. [694] Pope John Paul II, Encyclical Letter *Sollicitudo Rei Socialis*, 40: AAS 80 (1988), 568-569.

11. [695] Pope John Paul II, Encyclical Letter *Sollicitudo Rei Socialis*, 36: AAS 80 (1988), 561.

12. [696] Cf. Second Vatican Ecumenical Council, Pastoral Constitution *Gaudium et Spes*, 65: AAS 58 (1966), 1086-1087.

13. [697] Pope John Paul II, Encyclical Letter *Sollicitudo Rei Socialis*, 32: AAS 80 (1988), 556-557.

14. [698] Pope John Paul II, Encyclical Letter *Centesimus Annus*, 41: AAS 83 (1991), 844.

15. [699] Pope John Paul II, Message for the 2000 World Day of Peace, 15-16: AAS 92 (2000), 366-367.

16. [755] Pope John Paul II, Message for the 2003 World Day of Peace, 5: AAS 95 (2003), 343.

17. [772] Pope John Paul II, Encyclical Letter *Centesimus Annus*, 36: AAS 83 (1991), 838-839.

18. [930] Pope John Paul II, Encyclical Letter *Centesimus Annus*, 33: AAS 83 (1991), 835.

19. [931] Pope Paul VI, Encyclical Letter *Populorum Progressio*, 56-61: AAS 59 (1967), 285-287.

20. [950] Second Vatican Ecumenical Council, Pastoral Constitution *Gaudium et Spes*, 34: AAS 58 (1966), 1053.

21. [951] Second Vatican Ecumenical Council, Pastoral Constitution *Gaudium et Spes*, 34: AAS 58 (1966), 1053.

22. [952] Cf. Second Vatican Ecumenical Council, Pastoral Constitution *Gaudium et Spes*, 35: AAS 58 (1966), 1053.

23. [953] Pope John Paul II, Address given at Mercy Maternity Hospital, 28 November 1986: L'Osservatore Romano, English edition, 9 December 1986, p. 13.

24. [954] Pope John Paul II, Meeting with scientists and representatives of the United Nations University, 25 February 1981, 3: AAS 73 (1981), 422.

25. [955] Pope John Paul II, Meeting with employees of the Olivetti workshops in Ivrea, 19 March 1990, 5: L'Osservatore Romano, English edition, 26 March 1990, p. 7.

ENCYCLICAL LETTER PACEM IN TERRIS

POPE JOHN XXIII

11 April 1963

(Selected Excerpts)

11. But first We must speak of man's rights. Man has the right to live. He has the right to bodily integrity and to the means necessary for the proper development of life, particularly food, clothing, shelter, medical care, rest, and, finally, the necessary social services. In consequence, he has the right to be looked after in the event of illhealth; disability stemming from his work; widowhood; old age; enforced unemployment; or whenever through no fault of his own he is deprived of the means of livelihood. [8]

NOTES

1. [8] Pope Pius XI, Encyclical Letter *Divini Redemptoris*, 19 March 1937, AAS 29 (1937), 78; and Pope Pius XII, Broadcast message, Pentecost, 1 June 1941, AAS 33 (1941), 195-205.

ENCYCLICAL LETTER POPULORUM PROGRESSIO

POPE PAUL VI

26 March 1967

(Selected Excerpts)

17. The reality of human solidarity brings us not only benefits but also obligations.

[…]

26. However, certain concepts have somehow arisen out of these new conditions and insinuated themselves into the fabric of human society. These concepts present profit as the chief spur to economic progress, free competition as the guiding norm of economics, and private ownership of the means of production as an absolute right, having no limits nor concomitant social obligations. This unbridled liberalism paves the way for a particular type of tyranny, rightly condemned by Our predecessor Pius XI, for it results in the "international imperialism of money." [26] Such improper manipulations of economic forces can never be condemned enough; let it be said once again that economics is supposed to be in the service of man. [27]

[…]

29. We must make haste. Too many people are suffering. While some make progress, others stand still or move backwards; and the gap between them is widening.

[…]

34. Organized programs designed to increase productivity should have but one aim: to serve human nature. They should reduce inequities, eliminate discrimination, free men from the bonds of servitude, and thus give them the capacity, in the sphere of temporal realities, to improve their lot, to further their moral growth and to develop their spiritual endowments. When we speak of development, we should mean social progress as well as economic growth.

It is not enough to increase the general fund of wealth and then distribute it more fairly. It is not enough to develop technology so that the earth may become a more suitable living place for human beings. The mistakes of those who led the way should help those now on the road to development

to avoid certain dangers. The reign of technology—technocracy, as it is called—can cause as much harm to the world of tomorrow as liberalism did to the world of yesteryear. Economics and technology are meaningless if they do not benefit man, for it is he they are to serve. Man is truly human only if he is the master of his own actions and the judge of their worth, only if he is the architect of his own progress. He must act according to his God-given nature, freely accepting its potentials and its claims upon him.

NOTES

1. [26] Pope Pio XI, Encyclical Letter *Quadragesimo Anno*, 15 May 1931: AAS 23 (1931), 212.

2. [27] Cf., for example, Colin Clark, The Conditions of Economic Progress, 3rd ed., New York: St. Martin's Press (1960), 3-6.

ENCYCLICAL LETTER SOLLICITUDO REI SOCIALIS

POPE JOHN PAUL II

30 December 1987

(Selected Excerpts)

28. One of the greatest injustices in the contemporary world consists precisely in this: that the ones who possess much are relatively few and those who possess almost nothing are many. It is the injustice of the poor distribution of the goods and services originally intended for all. This then is the picture: there are some people - the few who possess much - who do not really succeed in "being" because, through a reversal of the hierarchy of values, they are hindered by the cult of "having"; and there are others - the many who have little or nothing - who do not succeed in realizing their basic human vocation because they are deprived of essential goods. The evil does not consist in "having" as such, but in possessing without regard for the quality and the ordered hierarchy of the goods one has. Quality and hierarchy arise from the subordination of goods and their availability to man's "being" and his true vocation.

This shows that although development has a necessary economic dimension, since it must supply the greatest possible number of the world's inhabitants with an availability of goods essential for them "to be," it is not limited to that dimension. If it is limited to this, then it turns against those whom it is meant to benefit.

The characteristics of full development, one which is "more human" and able to sustain itself at the level of the true vocation of men and women without denying economic requirements, were described by Paul VI. [53]

[…]

42. Today, furthermore, given the worldwide dimension which the social question has assumed, [76] this love of preference for the poor, and the decisions which it inspires in us, cannot but embrace the immense multitudes of the hungry, the needy, the homeless, those without medical care and, above all, those without hope of a better future. It is impossible not to take account of the existence of these realities. To ignore them would mean becoming like the "rich man" who pretended not to know the beggar Lazarus lying at his gate. [77]

[…]

It is necessary to state once more the characteristic principle of Christian social doctrine: the goods of this world are originally meant for all.[78] The right to private property is valid and necessary, but it does not nullify the value of this principle. Private property, in fact, is under a "social mortgage,"[79] which means that it has an intrinsically social function, based upon and justified precisely by the principle of the universal destination of goods. Likewise, in this concern for the poor, one must not overlook that special form of poverty which consists in being deprived of fundamental human rights, in particular the right to religious freedom and also the right to freedom of economic initiative.

NOTES

1. [53] Pope Paul VI, Encyclical *Letter Populorum Progressio*, 26 March 1967, nn. 20-21: loc. cit., pp. 267f.

2. [76] Pope Paul VI, Encyclical Letter *Populorum Progressio*, 26 March 1967, n. 3: loc. cit., p. 258.

3. [77] Pope Paul VI, Encyclical Letter *Populorum Progressio* 26 March 1967, n. 47: loc. cit., p. 280; Congregation for the Doctrine of the Faith, Instruction on Christian Freedom and Liberation, *Libertatis Conscientia* (March 22, 1986), n. 68: AAS 79 (1987), pp. 583f.

4. [78] Second Vatican Ecumenical Council, Pastoral Constitution on the Church in the Modern World, *Gaudium et Spes*, n. 69; Pope Paul VI, Encyclical Letter *Populorum Progressio*, 26 March 1967, n. 22: loc. cit., p. 268; Congregation for the Doctrine of the Faith, Instruction on Christian Freedom and Liberation, *Libertatis Conscientia* (March 22, 1986), n. 90: AAS 79 (1987), p. 594; St. Thomas Aquinas, *Summa Theol. IIa IIae*, q. 66, art. 2.

5. [79] Address at the Opening of the Third General Conference of the Latin-American Bishops (28 January 1979): AAS 71 (1979), pp. 189-196; *Ad Limina* Address to a group of Polish Bishops, (17 December 1987), n. 6.

MESSAGE TO THE GROUP "JUBILEE 2000 DEBT CAMPAIGN"

POPE JOHN PAUL II

23 September 1999

(Selected Excerpt)

So many men, women and children are unable to realize their God-given potential. Poverty and gross inequalities remain widespread, despite enormous scientific and technological progress. All too often, the fruits of scientific progress, rather than being placed at the service of the entire human community, are distributed in such away that unjust inequalities are actually increased or even rendered permanent.

The Catholic Church looks at the situation with great concern, not because she has any concrete technical model of development to offer, but because she has a moral vision of what the good of individuals and of the human family demands. She has consistently taught that there is a "social mortgage" on all private property, a concept which today must also be applied to "intellectual property" and to "knowledge". The law of profit alone cannot be applied to that which is essential for the fight against hunger, disease and poverty.

LETTER TO THE PRESIDENT OF THE PONTIFICAL COUNCIL FOR HEALTH PASTORAL CARE

POPE JOHN PAUL II

11 February 2001

To My Venerable Brother
Archbishop Javier Lozano Barragán
President of the Pontifical Council for Health Pastoral Care

In the peace which comes from God, I greet you and all who are gathered in Saint Mary's Cathedral in Sydney for the Eucharistic Sacrifice that is the very heart of the Ninth World Day of the Sick. I ask you to convey to Cardinal Edward Clancy and to the Church in Sydney and throughout Australia the assurance of my closeness in prayer as you meet to reflect on how the new evangelization needed at the beginning of the Third Christian Millennium must respond to the many complex questions arising in the field of health care, always in the light of the Cross of Christ, in which human suffering finds "its supreme and surest point of reference" [1].

Few areas of human concern are as subject to the profound social and cultural changes affecting contemporary life as health care. This is one of the reasons why in 1985 I established the body which has become the Pontifical Council for Health Pastoral Care, over which you diligently preside. Down the years, the Pontifical Council has rendered an invaluable service not only to those directly involved in Catholic health care, but to the wider community as it grapples with the many issues which have become still more pressing in the time since the Council was established. For that service, I give fervent thanks to Almighty God.

At the dawn of the new millennium, it is more urgent than ever that the Gospel of Jesus Christ should permeate every aspect of health care, and therefore I welcome the choice of theme for this World Day of the Sick: "The New Evangelization and the Dignity of the Suffering Person". Evangelization must be new – new in method and new in ardour – because so much has changed and is changing in the care of the sick.

Not only is health care facing unprecedented economic pressures and legal complexities, but at times there is also an ethical uncertainty which tends to obscure what have always been its clear moral foundations. This uncertainty can become a fatal confusion, manifested as a failure to understand that the essential purpose of health care is to promote and safeguard the well-being of those who need it, that medical research and practice must always be tied to ethical imperatives, that the weak and those who may seem unproductive to the eyes of a consumer society have an inviolable dignity

that must always be respected, and that health care should be available as a basic right to all people without exception.

Regarding all of this I would apply to the work of the Pontifical Council and the discussions of your Conference what I said in my recent Apostolic Letter *Novo millennio ineunte* at the close of the Jubilee Year: it has become increasingly important "to explain properly the reasons for the Church's position, stressing that it is not a case of imposing on non-believers a vision based on faith, but of interpreting and defending the values rooted in the very nature of the human person" [2].

The World Day of the Sick has a vital word to say, and the Pontifical Council has an indispensable role to play, in the Church's mission of proclaiming the Gospel of life and love to the world.

As you gather on this day dedicated to Our Lady of Lourdes, in the Cathedral dedicated to Mary Help of Christians, I commend you and Cardinal Clancy, the Pontifical Council for Health Pastoral Care and all taking part in the World Day of the Sick to the loving intercession of Mary Most Holy, the Woman whom the Church invokes as "Health of the Sick". As a pledge of joy and peace in her Son, the Redeemer of the world, I gladly impart my Apostolic Blessing.

Notes

1. [1] Pope John Paul II, Apostolic Letter *Salvifici Doloris*, 11 February 1984, 31.
2. [2] Pope John Paul II, Apostolic Letter *Novo Millennio Ineunte*, 6 January 2001, 51.

MESSAGE TO THE PLENARY COUNCIL OF THE WORLD TRADE ORGANIZATION ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

ARCHBISHOP DIARMUID MARTIN, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

20 June 2001

The AIDS crisis, together with the worrying return and diffusion of older infectious diseases, such as malaria and tuberculosis, constitutes a global disaster of dramatic magnitude. Most poor people suffering from these diseases receive only very inadequate health care. In so many of the poorest countries, lack of basic medicines together with poor health infrastructures, prevents an appropriate response to urgent public health needs. A heavy burden of disease has considerable negative effects on economic development. A reduction in disease, on the other hand, promotes human well-being, with a consequent improvement in the quality of those human resources which are the essential driving force of the what should be the fundamentally pro-development stance of the WTO.

The Holy See is aware that the availability of medicines is not the only aspect of access to health. It is, however, an essential aspect. Without access to essential medicine, there is no cure at all! Access to basic medicines depends on a series of factors, such as efficient infrastructure and logistics, informed drug choice and use, adequately controlled production, research and development aimed at specific diseases. Accessible price, however, always remains a determinant factor.

The high price of new drugs seems to be determined both by the burden of research and development of the product itself and by the role each medicine plays in the maintenance of a complex research and development structure. It is not possible, however, ethically to justify a rationale of fixing the highest possible prices in order to attract investors and to maintain and strengthen research, while leaving aside consideration of fundamental social factors. To condition the international reaction to any other natural or human-made disaster (such as earthquakes, floods, accidents or terrorism) on the victims being able to pay for the treatment and to contribute to the research and development of new assistance devices, would rightly be considered a crime.

The legal protection of Intellectual property, especially through patents, gives to the patentees monopoly rights over the product or process, during the patent life-span. Such a right may indeed allow a patentee to produce and

supply the product only when and where it is possible to recover, through pricing policies, the costs of the investments contained in its development, as well as the expected revenues, while disregarding those who cannot afford the product prices. Within a open free trade system, intellectual property rights constitute an exceptional monopoly regime. As an exception within a legal regime, its use must be narrowly interpreted and must take due account of and, where necessary be subordinated to, other important principles. IP legal theory and practice have, in fact, created regimes, such as compulsory licences, to curb social/patent abuses. Compulsory licenses have thus been included in the TRIPS framework, to be used as remedies in situations of national emergency or other circumstances of extreme urgency, provided that such mandatory uses respect the rule of law and preserve some essential rights of the patent owner.

It must, of course, be recognized that prices are not the only component contributing to the lack of access to health, and that IP protection is necessary for progress and for the just compensation of researchers and producers. But in order to cope with a world health emergency, IP regimes must be integrated into a broader framework. The unity of humankind and the universality of human rights (among which the right to health) requires that all the economic and political actors involved (international organizations, governments, private foundations, corporations and NGOs) work together, pooling their differentiated responsibility for resolving a global crisis, leaving aside narrow individual or sectorial interest.

In the case of medicines, the supply stakeholders (scientific institutions, pharmaceutical companies and the governments of developed countries) should work together to ensure an adequate supply of urgently needed drugs at prices adequate to the cost of living in a particular country, especially LDCs or HIPCs countries. They should also be open and flexible in an equitable manner to the granting of voluntary licenses for import, production and distribution of basic drugs. They should not create obstacles to national production of drugs in third countries; they should where possible help them, rather, to develop such production in ways that are consistent with their IP duties. Compulsory licenses and other safeguards, as worded in TRIPS, should however be maintained, because they are a national safeguard against eventual imperfections of the IP enforcement.

Full and efficient universal access to basic medicines will most likely require the enactment of an innovative differential pricing system, which can still preserve the incentive for future research and development. Luxury and non essential pharmaceutical products, for example, such as cosmetics, could well share a greater part of the burden of research and development of essential medicines.

A broad-based commitment of solidarity is the best way to prevent poor countries from falling into the temptation of weakening the Intellectual Property rights framework.

The solution to the problem of access to basic medicines is far beyond the mandate and the means of the Council for TRIPS. It is the common responsibility of many other international organizations as well as national governments, and in an appropriate manner also of the private sector. However, the Council for TRIPS could make a fundamental contribution, by means of an authoritative interpretation of the TRIPS rules,

- consistent with a unified vision of law,
- based on respect for human rights,
- and applying those articles of the WTO treaty that call for a pro-development interpretation of the whole legal body.

Such a legal interpretation might affirm

- that any TRIPS clause should not be understood in a way that becomes a practical obstacle to rapid, efficient and universal access to basic medicines, for those who are the victims of the actual dramatic health emergency, and
- that nothing in the TRIPS should prevent countries, including small countries with limited domestic manufacturing ability, from implementing sound health policies.

This would contribute to a broad and not restrictive interpretation of articles 30 and 31, which allow that licensing fees may be fixed in accordance with the real purchasing capacity of the poorest countries, balanced with a system that blocks the re-exports of the licensed products to the original markets.

The Holy See, consistent with the traditions of Catholic social thought, underlines that there is a «social mortgage» on all private property, namely, that the reason for the very existence the institution of private property is to ensure that the basic needs of every man and woman are met and sustained. This «social mortgage» on private property must also be applied today to «intellectual property» and to «knowledge» [1]. The law of profit alone cannot be applied to that which is essential for the fight against hunger, disease and poverty. Hence, whenever there is a conflict between property rights, on the one hand, and fundamental human rights and concerns of the common good, on the other, property rights should be moderated by an appropriate authority, in order to achieve a just balance of rights.

NOTES

1. [1] Pope John Paul II, Message to the "Jubilee 2000 Debt Campaign" Group, 23 September 1999.

MESSAGE TO THE SECRETARY-GENERAL OF THE UNITED NATIONS ORGANIZATION

POPE JOHN PAUL II

21 June 2001

To His Excellency Mr Kofi Annan
Secretary-General of the United Nations Organization

The holding of a Special Session of the General Assembly of the United Nations in New York on 25-27 June to examine the various aspects of the HIV/AIDS problem is a most opportune initiative. To you and to all the delegations present I send my best wishes, in the hope that your deliberations will mark a decisive step in the struggle against the disease.

The HIV/AIDS epidemic is undoubtedly one of the major catastrophes of our time, especially in Africa. It is not only a health problem, since the disease has tragic consequences for the social, economic and political life of peoples.

I welcome the efforts presently being made at the national, regional and international level to face this challenge through the implementation of a plan of action aimed at prevention and treatment of the disease. Your announcement that a World "AIDS and Health" Fund will be set up in the near future gives hope to all. It is my sincere wish that the initial favourable reactions will quickly find practical expression in effective support.

The daunting spread of HIV/AIDS is one aspect of a social context marked by a serious crisis of values. In this area, as in others, the international community cannot ignore its moral responsibility.

On the contrary, in the fight against the epidemic, the international community should draw its inspiration from a constructive vision of human dignity and focus its attention on young people, by helping them to attain responsible emotional maturity.

The Catholic Church, through her Magisterium and her commitment to the victims of HIV/AIDS, continues to affirm the sacred value of life. Her efforts with regard to prevention and assistance to those affected, often in cooperation with the institutions of the United Nations, are in keeping with her mission of love and service to the lives of all, from conception to natural death.

Two current problems: transmission from mother to child and lack of access to medical care. I am particularly concerned about two problems, which I am sure will be treated with serious attention during the debates of the Special Session.

The transmission of HIV/AIDS from mother to child is an extremely distressing problem. While in developed countries there has been success in noticeably reducing the number of children born with the virus, thanks to suitable treatment, in developing countries, particularly in Africa, those who come into the world with the disease are very numerous and this is a cause of great suffering for families and the community.

When we add to this gloomy picture the distress of the orphans of parents who have died from AIDS, we are faced with a situation to which the international community cannot fail to respond.

The second problem is that of access of AIDS patients to medical care, and as far as possible, to anti-retroviral treatment. We know that the prices of these medicines are excessively high, sometimes even exorbitant, in relation to the resources of the citizens of the poorest countries. The problem includes various economic and legal aspects, among which are certain interpretations of the right to intellectual property.

In this regard, it seems appropriate to recall what the Second Vatican Council emphasized regarding the common destination of the world's goods, which I mentioned in my Encyclical *Centesimus Annus*: "Of its nature private property also has a social function which is based on the law of the common purpose of goods" [1]. On account of this social mortgage, included in international law by the affirmation, among other things, of every individual's right to health, I ask the rich countries to respond to the needs of HIV/AIDS patients in poorer countries with all available means, so that those men and women afflicted in body and soul will be able to have access to the medicines they need to treat themselves.

I cannot end this message without thanking the scientists and researchers of the whole world for their efforts to find treatments for this terrible illness. My gratitude also goes to health-care professionals and volunteers for the love and competence which they demonstrate in the human, religious and medical assistance they give to their brothers and sisters.

Upon all engaged in the struggle against HIV/AIDS, particularly those living with the disease and their families, as well as upon all taking part in the Special Session, I invoke the blessings of Almighty God.

NOTES

1. [1] Pope Paul VI, Pastoral Constitution on the Church in the Modern World *Gaudium et Spes*, 7 December 1965, 7,1; cf. Pope John Paul II, Encyclical Letter *Centesimus Annus*, 1 May 1991, 30.

STATEMENT AT THE 4TH MINISTERIAL CONFERENCE OF WORLD TRADE ORGANIZATION

ARCHBISHOP DIARMUID MARTIN, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

12 November 2001

(Selected Excerpts)

I wish to address just two specific trade-related questions that are of special interest to fostering human development for the poorest countries today. The first is the relationship between trade rules, and especially intellectual property rules, and health. Governments have a primary responsibility to protect the lives and security of their citizens. The Ministerial Conference should give a clear message that there is nothing in the rules of the international trading system that should prevent governments from addressing urgent public health needs. Where flexibility exists within such rules, then there should a concerted attempt to make that flexibility work fully, rapidly and in an unobstructed way.

[…]

A more equitable application of a rules-based global trading system is an essential dimension of development policy. The poorer countries will enjoy greater success in trade related questions if these are pursued within a broad understanding of development and solidarity.

Technical assistance must be made available to facilitate implementation of existing WTO agreements, but also to improve the trading capacity of poorer countries. Access to medicine must accompanied by programmatic investment in an effective health system.

STATEMENT AT THE 6TH MINISTERIAL CONFERENCE OF WORLD TRADE ORGANIZATION

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

18 December 2005

(Selected Excerpts)

Free trade is not an end in itself but rather a means for better living standards and the human development of people at all levels. The universal destination of the goods of the earth requires that the poor and marginalized should be the focus of particular concern [1]. Trade exchanges should enable all people to have access to these goods. Thus, essential services such as health, education, water, and food are not normal goods since citizens cannot choose not to use them without harm to themselves and high social costs for society.[2] These public goods often require government intervention in markets to ensure equitable access to them.[3] It is the task of the State to provide for the defense and preservation of common goods which cannot simply be addressed by market forces. There exist important human needs which escape the market logic.

[…]

In today's world, where the knowledge economy is becoming such an essential requirement, the concern for the TRIPS Agreement takes on new significance. While there is a need to protect intellectual property rights as an incentive for innovation and technology creation, it is also important to ensure broad access to technology and knowledge especially for low income countries. The new goods derived from progress in science and technology are key to world trade integration.

[…]

Further, we welcome the recent amendment to the TRIPS Agreement on Public Health. This amendment could assure poor countries access to the means for the production and importation of essential drugs needed to face the main pandemics suffered by their populations. It balanced the two important objectives of intellectual property rules: creating incentives for innovation and spreading the benefits of the innovations as widely as possible. However, care should he taken that this amendment not be

weakened by regional and bilateral agreements containing "TRIPS plus" variants, which are more onerous for poor developing countries.

Notes

1. [1] Cf. Compendium of the Social Doctrine of the Church, § 182.

2. [2] Cf. Pope John Paul II, at FAO Headquarter, 5 December 1992, § 4. We realize that 'food aid can do much good for recipient countries. However, it should not be used by donor countries so at to result in commercial displacement of food commodities. In the long term, food security problems will not be solved by increasing food aid dependency of entire populations' that should 'receive an education that prepares them to provide healthy and sufficient foodstuffs on their own'.

3. [3] Cf. Trade Justice, Catholic Social Justice Series, 54 (2005).

ENCYCLICAL LETTER DEUS CARITAS EST

POPE BENEDICT XVI

25 December 2005

(Selected Excerpt)

20. Within the community of believers there can never be room for a poverty that denies anyone what is needed for a dignified life.

ADDRESS TO THE PARTICIPANTS IN THE 21ST INTERNATIONAL CONGRESS ORGANIZED BY THE PONTIFICAL COUNCIL FOR HEALTH PASTORAL CARE

POPE BENEDICT XVI

24 November 2006

Dear Brothers and Sisters,

I am pleased to meet you on the occasion of the International Conference organized by the Pontifical Council for Health Pastoral Care.

I address my cordial greeting to each one of you, and in the first place to Cardinal Javier Lozano Barragán, whom I thank for his courteous words.

The choice of the theme: "Pastoral aspects of the treatment of infectious diseases", affords you an opportunity for reflecting, from various points of view, on the infective pathologies that have always accompanied humanity's journey. The number and variety of ways in which, even in our time, they are often a mortal threat to human life is striking.

Terms such as "leprosy", "the plague", "tuberculosis", "AIDS" and "Ebola" evoke dramatic scenes of sorrow and fear: sorrow for the victims and their loved ones, often crushed by a feeling of powerlessness in the face of the inexorable gravity of the illness; fear for the population in general and for those who, because of their profession or their own choice, are in contact with people suffering from these diseases.

Despite the beneficial effects of prevention that the progress in science, medical technology and social policies has brought, the persistence of infectious diseases continues to take a heavy toll of victims and highlights the inevitable limitations of the human condition.

The task of humanity, however, must be to never cease seeking the most effective means and ways to intervene in order to combat these illnesses and reduce patient suffering.

In the past, multitudes of men and women put their skills and their reserve of human generosity at the disposal of sick people with repulsive pathologies. In the context of the Christian Community, "Many consecrated persons have given their lives in service to victims of contagious diseases, confirming the truth that dedication to the point of heroism belongs to the prophetic nature of the consecrated life". [1]

However, these highly praiseworthy initiatives and generous acts of love are still obstructed by many forms of injustice.

How can we forget the numerous people afflicted by infectious diseases who are forced to live in segregation and sometimes humiliatingly

stigmatized? These deplorable situations appear all the more serious in the social and financial disparity between the world's North and the South.

It is important to respond to them with practical interventions that encourage closeness to the sick person by a more lively evangelization of culture and by proposing inspiring motives for the financial and political programmes of governments.

In the first place, closeness to the sick person afflicted by an infectious disease: this is a goal for which the Ecclesial Community should always strive.

The example of Christ who, breaking with the customs of his time, not only permitted lepers to approach him but also restored their health and dignity as persons, has "infected" many of his disciples down through the two millennia of Christian history.

The kiss that Francis of Assisi gave the leper has not only been imitated by heroic figures such as Bl. Damian de Veuster, who died on the Island of Molokai while treating lepers there, and Bl. Teresa of Calcutta as well as the Italian women religious who were killed a few years ago by the Ebola virus, but also by many who champion initiatives for the infectious sick, especially in developing countries.

This rich tradition of the Catholic Church should be kept alive so that, through the exercise of charity to those who are suffering, the values inspired by authentic humanity and by the Gospel are made visible: the dignity of the person, mercy and Christ's identification with the sick person.

No intervention will be adequate if it does not reveal love for the human being, a love nourished by the encounter with Christ.

The indispensable closeness to the sick person should go hand in hand with the evangelization of the cultural context in which we live.

Prejudices that hinder or restrict effective help to the victims of infectious diseases include the attitude of indifference and even of exclusion and rejection that surface from time to time in an affluent society.

This attitude is also encouraged by images of men and women mainly concerned with the physical beauty, health and biological vitality that are conveyed in the media. This is a dangerous cultural trend that leads to putting oneself at the centre, shutting oneself in one's own small world and turning one's back on the commitment to serve those in need.

My venerable Predecessor John Paul II, in his Apostolic Letter *Salvifici Doloris*, expressed the hope that suffering would instead help to "unleash love in the human person, that unselfish gift of one's "I' on behalf of other people, especially those who suffer".

And he added: "The world of human suffering unceasingly calls for, so to speak, another world: the world of human love; and in a certain sense man owes to suffering that unselfish love which stirs in his heart and actions"[2].

What is further needed is a pastoral service that can uplift the sick as they face suffering and help them transform their own condition into a moment

of grace, for themselves and for others, through lively participation in Christ's mystery.

Lastly, I would like to reaffirm the importance of collaboration with the various public bodies so that social justice may be implemented in this sensitive area of the treatment and nursing of contagious patients.

I wish to mention, for example, the fair distribution of resources for research and treatment, as well as the promotion of living standards which help to prevent the occurrence and limit the spread of contagious diseases.

In this, as in other areas, the "mediated" task of contributing "to the purification of reason and to the reawakening of those moral forces without which just structures are neither established nor prove effective in the long run", is incumbent upon the Church, whereas "the direct duty to work for a just ordering of society, on the other hand, is proper to the lay faithful... called to take part in public life in a personal capacity"[3].

Thank you, dear friends, for the commitment you devote to the service of a cause in which the healing and saving work of Jesus, the divine Samaritan of souls and bodies, is put into practice.

Notes

1. [1] Pope John Paul II, Apostolic Exhortation *Vita Consecrata*, 25 March 1996, 83.
2. [2] Pope John Paul II, Apostolic Letter *Salvifici Doloris*, 11 February 1984, 29.
3. [3] Pope Benedict XVI, Encyclical Letter *Deus Caritas Est*, 25 December 2005, 29.

LETTER TO DR. ANGELA MERKEL, CHANCELLOR OF THE FEDERAL REPUBLIC OF GERMANY

POPE BENEDICT XVI

16 December 2006

(Selected Excerpts)

The Holy See has repeatedly insisted that, while the Governments of poorer countries have a responsibility with regard to good governance and the elimination of poverty, the active involvement of international partners is indispensable. This should not be seen as an "extra" or as a concession which could be postponed in the face of pressing national concerns. It is a grave and unconditional moral responsibility, founded on the unity of the human race, and on the common dignity and shared destiny of rich and poor alike, who are being drawn ever closer by the process of globalization.

[…]

Moreover, a substantial investment of resources for research and for the development of medicines to treat AIDS, tuberculosis, malaria and other tropical diseases is needed. In this regard, the first and foremost scientific challenge facing developed countries is the discovery of a vaccine against malaria. There is also a need to make available medical and pharmaceutical technology and health care expertise without imposing legal or economic conditions.

STATEMENT AT THE 60TH WORLD HEALTH ASSEMBLY

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

16 May 2007

(Selected Excerpts)

My delegation wishes to commend, for particular attention by this Assembly, the resolutions and recommendations with regard to the pandemics of Tuberculosis, Malaria, and HIV, as well as those related to the projected exacerbation of Avian and Pandemic Influenza. Much of the threat to health security caused by such diseases could adequately be addressed were the global human family to commit itself to affordable and action-oriented programmes of research, vaccination, treatment, and preventive education respectful of the natural moral law. On 23-25 November 2006, the Vatican's Pontifical Council for Health Pastoral Care convened more than 500 experts to reflect on "Pastoral aspects of the treatment of infectious diseases." In addressing those gathered, His Holiness Pope Benedict XVI emphasized the need to implement social justice in the sensitive area of treatment and nursing and therefore to ensure a fair distribution of resources for research and treatment.[3] In this same perspective, as the Chancellor of Germany prepared to assume the presidency of both the G8 countries and the European Union, the Holy Father, in a letter to her, expressed the hope that there would be "… a substantial investment of resources for research and for the development of medicines to treat AIDS, tuberculosis, malaria, and other tropical diseases is needed … There is also a need to make available medical and pharmaceutical technology and health care expertise without imposing legal or economic conditions". [4]

The Holy See shares the concern expressed by the Secretariat of WHO in its Report on "Better Medicines for Children", for the tragic loss of life each year among some 10.5 million children under five years of age; many of these children die of diseases that are treatable in adults but for which appropriate dosages and formulations have not yet been developed for paediatric use.[5] Attention to this serious concern seems all the more compelling in light of the recently-released report on "Scaling up priority HIV/AIDS interventions in the health sector", which noted, with much regret, that only 15% of HIV-positive children in need of anti-retroviral treatment actually have access to these life-saving therapies. Such treatment coverage is approximately one-half that achieved for HIV-positive adults. [6] The international community can no longer turn a deaf ear to the life-

threatening needs of children, many of whom can be counted among our most needy citizens but who represent, as well, the future of the human community. While steps are being taken to develop "Better Medicines for Children" and to revise and regularly update the Model List of Essential Medicines in order to include those appropriate for paediatric use, research that is ethically-based, transparent, and carefully-monitored, must be conducted on the safety of such medicines before they are approved for treatment of diseases affecting children.

As we approach the thirtieth anniversary of the historic Alma Ata Declaration on Primary Health Care, the Holy See Delegation is pleased to note the strategic attention being encouraged at this World Health Assembly on such crucial topics as Prevention and Control of Non-communicable Diseases, Rational Use of Medicines, and, in particular, Health Promotion in a Globalized World with a special focus on primary health care. In all the deliberations during this Assembly and in the subsequent implementation of World Health Assembly Resolutions at national and local levels, my delegation urges a perspective on health security that is grounded on an anthropology respectful of the human person in his or her integrity and looks far beyond the absence of disease to the full harmony and sound balance of the physical, emotional, spiritual and social forces within the human person.[7]

NOTES

1. [3] Pope Benedict XVI, Address to the Participants in the 21st International Congress Organized by the Pontifical Council for Health Pastoral Care, 24 November 2006.
2. [4] Pope Benedict XVI, Letter to Her Excellency Dr. Angela Merkel, Chancellor of the Federal Republic of Germany, 16 December 2006.
3. [5] World Health Organisation (WHO), Better Medicines for Children, Report by the Secretariat, Sixtieth World Health Assembly, A60/25, 17 April 2007.
4. [6] Towards Universal Access: Scaling up priority HIV/AIDS interventions in the health sector, Progress Report by WHO, UNAIDS, UNICEF, April 2007, p. 6.
5. [7] Pope John Paul II, Message of the World Day of the Sick, 11 February 2000, 13.

STATEMENT AT THE 7TH SESSION OF THE HUMAN RIGHTS COUNCIL

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

11 March 2008

(Selected Excerpts)

Mr. President,

The Holy See delegation welcomes the opportunity to offer its observations on the Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health [1]. First of all, we are pleased to note that the Report identifies this right as a "fundamental building block of sustainable development, poverty reduction, and economic prosperity."[2] In a similar manner, Pope Benedict XVI recently affirmed that "[t]he building of a more secure future for the human family means first and foremost working for the integral development of peoples, especially through the provision of adequate health care [and] the elimination of pandemics like AIDS …" [3].

The Report, Mr. President, appropriately calls attention to the single policy framework for health that was embodied in the Declaration of Alma-Ata on primary health care, promulgated, thirty years ago, by the world's Health Ministers. This framework outlined the underlying principles to assure equitable exercise of the right to health as well as the implementation of essential interventions to assure strong links between health and development.

[…]

We note that the Report gave due recognition to "health as a public good" which requires "international cooperation" on "trans-boundary health issues." Urgent attention much be accorded to such issues since, in many countries, refugees, other migrants, and internally-displaced persons are deprived by host governments even of the most basic life-saving health services. In an attempt to fill such gaps, once again religious organizations often provide care, support, and treatment to such populations without concern for their national or ethnic origins.

Thank you.

NOTES

1. [1] UN Document A/HRC/7/11, 31 January 2008.
2. [2] *Ibid.*,12.
3. [3] Pope Benedict XVI, Address to H.E. Mrs. Mary Ann Glendon, Ambassador of the United States of American to the Holy See, 29 February 2008.

ADDRESS TO PARTICIPANTS IN THE 23RD INTERNATIONAL CONGRESS ON THE PASTORAL CARE

POPE BENEDICT XVI

5 November 2008

(Selected Excerpts)

Your Eminence,
Venerable Brothers in the Episcopate and in the Priesthood,
Distinguished Professors,
Dear Brothers and Sisters,

I am glad to meet you on the occasion of the 23rd annual International Congress organized by the Pontifical Council for Health Pastoral Care. I cordially greet Cardinal Javier Lozano Barragán, President of the Dicastery, and thank him for his courteous words on your behalf. I extend my gratitude to the Secretary, to the collaborators of this Pontifical Council, to the speakers, to the academic authorities, to the important figures, to those in charge of health-care institutions, to health-care workers and to those who have offered their collaboration by taking part in various ways in the organization of the Congress whose theme this year is: "Pastoral care in the treatment of sick children". I am sure that these days of reflection and discussion on such a topical subject will contribute to sensitizing public opinion on the duty to give children all the attention they need for their harmonious physical and spiritual development. If this applies to all children, it is even more important for those who are sick and in need of special medical treatment.

Thanks to the contribution of experts of world renown and people directly in touch with children in difficulty, the theme of your Congress, which ends today, has enabled you to highlight the difficult situation in immense regions of the earth in which a rather large number of children are still living and to propose necessary, indeed, urgent interventions to come to their help. Medicine has certainly made considerable progress in the past 50 years: this has led to a substantial reduction of infant mortality, although much still remains to be done with this in view. It suffices to remember, as you pointed out, that each year four million newborn babies die within 26 days of birth.

In this context, the treatment of the sick child is a topic that cannot fail to raise attentive interest of all those who are dedicated to health pastoral care. A detailed analysis of the current state of affairs is indispensable in order to undertake, or continue, a decisive action aimed at preventing illnesses

as far as possible and, when they are present, at curing the small patients by means of the most modern discoveries of medical science as well as by promoting better standards of hygiene and sanitation, especially in the less fortunate countries. The challenge today is to ward off the onset of many pathologies once characteristic of childhood and, overall, to encourage the growth, development and maintenance of good health for all children.

All are involved in this vast action: families, doctors and social and health-care workers. Medical research is sometimes confronted by difficult decisions when it is a question, for example, of reaching a proper balance between the continuation or abandonment of therapy to ensure adequate treatment for the real needs of the small patients without succumbing to the temptation of experimentation. It is not superfluous to remember that the focus of every medical intervention must always be to achieve the true good of the child, considered in his dignity as a human being with full rights. Thus it is always necessary to care for him lovingly, to help him to face suffering and sickness, even before birth, as his situation requires. Then taking into account the emotional impact of the illness and treatment to which the child is subjected which are quite often particularly invasive, it is important to ensure constant communication with his relatives. If health-care workers, doctors and nurses feel the burden of the suffering of the little patients they are assisting, one can easily imagine how much more acutely their parents must feel it!

The medical and human aspects must never be separated and it is the duty of every nursing and health-care structure, especially if it is motivated by a genuine Christian spirit, to offer the best of both expertise and humanity. The sick person, especially the child, understands in particular the language of tenderness and love, expressed through caring, patient and generous service which in believers is inspired by the desire to express the same special love that Jesus reserved for children. "*Maxima debetur puero reverentia*" (*Juvenal, Satire* xiv, v. 479): the ancients already acknowledged the importance of respecting the child who is a gift and a precious good for society and whose human dignity, which he fully possesses even unborn in his mother's womb, must be recognized. Every human being has a value in himself because he is created in the image of God in whose eyes he is all the more precious the weaker he appears to the human gaze. Thus, with what great love should we also welcome a unborn child who is already affected with medical pathologies! "*Sinite parvulos venire ad me*", Jesus says in the Gospel (cf. Mk 10: 14), showing us the attitude of respect and acceptance with which we must look after every child, especially when he is weak and in difficulty, suffering and defenceless. I am thinking above all of little orphans or children abandoned because of the poverty and the disintegration of their family; I am thinking of children who are the innocent victims of AIDS or of war and of the many armed conflicts that are being fought in various parts of the world; I am thinking of children who died because

of poverty, drought and hunger. The Church does not forget her smallest children and if, on the one hand she applauds the initiatives of the richer nations to improve the conditions of their development, on the other, she is strongly aware of the need to invite them to pay greater attention to these brothers and sisters of ours, so that thanks to our unanimous solidarity they are able to look at life with trust and hope.

STATEMENT AT THE HIGH-LEVEL SEGMENT OF THE UNITED NATIONS ECONOMIC AND SOCIAL COUNCIL

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

9 July 2009

(Selected Excerpts)

The Holy See Delegation notes with deep concern predictions by the World Bank that during 2009, an additional 53 to 65 million people will be trapped in extreme poverty and that the number of people chronically hungry will exceed one billion, 800 million of whom live in rural areas where public health is weakest and where innovative health care initiatives are urgent. We can reasonably conclude that significant numbers of those extremely poor and hungry people will be more at risk of contracting both communicable and chronic, non-communicable diseases. Moreover, if they are faced with cutbacks in international aid or if there is an increased number of people seeking care, the already fragile public health systems in developing countries will not be able to respond adequately to the health needs of their most vulnerable citizens. In addressing this problem, even more than an expression of solidarity, it is a matter of justice to overcome the temptation to reduce public services for a short-term benefit against the long-term human cost. In the same line, aid for development should be maintained and even increased as a critical factor in renewing the economy and leading us out of the crisis.

[…]

Another key obstacle to achieving the internationally articulated goals in public health is to address the inequalities that exist both between countries and within countries, and between racial and ethnic groups. Tragically, women continue in many regions to receive poorer quality health care. This situation is well known to people and institutions working on the ground. The Catholic Church sponsors 5,378 hospitals, 18,088 health clinics, 15,448 homes for the elderly and disabled, and other health care programmes throughout the world, but especially in the most isolated and marginalized areas and among people who rarely enjoy access to health care provided under national, provincial or district level governmental health schemes. In this regard, special attention is given to Africa, where the

Catholic Church has pledged to continue to stand alongside the poorest people in this continent in order to uphold the inherent dignity of all persons.

There is an increasing recognition that a plurality of actors, in the respect of the principle of subsidiarity, contribute to the implementation of the human right to primary health care. Among the civil society organizations assuring health care within various national systems, the programmes sponsored by the Catholic Church and other faith-based organizations stand out as key stakeholders. WHO officials have acknowledged that such organizations "provide a substantial portion of care in developing countries, often reaching vulnerable populations living under adverse conditions."[1] However, despite their excellent and documented record in the field of HIV service delivery and primary health care, faith-based organizations do not receive an equitable share of the resources designated to support global, national and local health initiatives.

The mere quantitative tracking of aid flows and the multiplication of global health initiatives alone may not be sufficient to assure "Health for All". Access to primary health care and affordable life-saving drugs is vital to improving global health and fostering a shared globalized response to the basic needs of all. In an increasingly interdependent world, even sickness and viruses have no boundaries, and therefore, greater global cooperation becomes not only a practical necessity, but more importantly, an ethical imperative of solidarity. However, we must be guided by the best healthcare tradition that respects and promotes the right to life from conception until natural death for all regardless of race, disability, nationality, religion, sex and socio-economic status. Failure to place the promotion of life at the center of health care decisions results in a society in which an individual's absolute right to basic health care and life would be limited by the ability to pay, by the perceived quality of life and other subjective decisions which sacrifice life and health in exchange for short-term social, economic and political advantage.

In conclusion, Madame President, the Holy See Delegation wishes to call attention to the need for more than financial solutions to the challenges posed by the economic crisis to global efforts aimed at assuring universal access to health care. In his new encyclical Pope Benedict XVI states: "Economic activity cannot solve all social problems through the simple application of commercial logic. This needs to be directed towards the pursuit of the common good, for which the political community in particular must also take responsibility". [2]

An ethical approach to development is needed which implies a new model of global development centered on the human person rather than profit, and inclusive of the needs and aspirations of the entire human family.

NOTES

1. [1] DeCock, Kevin (2007), "Faith-based organizations play a major role in HIV/AIDS care and treatment in sub-Saharan Africa", as quoted in press release by the World Health Organisation, 9 February 2007.
2. [2] Pope Benedict XVI, Encyclical Letter *Caritas in Veritate*, 29 June 2009, 36.

ENCYCLICAL LETTER CARITAS IN VERITATE
POPE BENEDICT XVI

29 June 2009

(Selected Excerpts)

21. We recognize, therefore, that the Church had good reason to be concerned about the capacity of a purely technological society to set realistic goals and to make good use of the instruments at its disposal. Profit is useful if it serves as a means towards an end that provides a sense both of how to produce it and how to make good use of it. Once profit becomes the exclusive goal, if it is produced by improper means and without the common good as its ultimate end, it risks destroying wealth and creating poverty. The economic development that Paul VI hoped to see was meant to produce real growth, of benefit to everyone and genuinely sustainable.

[…]

22. As John Paul II has already observed, the demarcation line between rich and poor countries is no longer as clear as it was at the time of *Populorum Progressio* [55]. The world's wealth is growing in absolute terms, but inequalities are on the increase. In rich countries, new sectors of society are succumbing to poverty and new forms of poverty are emerging. In poorer areas some groups enjoy a sort of "superdevelopment" of a wasteful and consumerist kind which forms an unacceptable contrast with the ongoing situations of dehumanizing deprivation. "The scandal of glaring inequalities"[56] continues.

[…]

International aid has often been diverted from its proper ends, through irresponsible actions both within the chain of donors and within that of the beneficiaries. Similarly, in the context of immaterial or cultural causes of development and underdevelopment, we find these same patterns of responsibility reproduced. On the part of rich countries there is excessive zeal for protecting knowledge through an unduly rigid assertion of the right to intellectual property, especially in the field of health care.

[…]

30. Knowledge is never purely the work of the intellect. It can certainly be reduced to calculation and experiment, but if it aspires to be wisdom capable of directing man in the light of his first beginnings and his final ends, it must be "seasoned" with the "salt" of charity. Deeds without knowledge are blind, and knowledge without love is sterile. Indeed, "the individual who is animated by true charity labours skilfully to discover the causes of misery, to find the means to combat it, to overcome it resolutely"[75].

[…]

Human knowledge is insufficient and the conclusions of science cannot indicate by themselves the path towards integral human development. There is always a need to push further ahead: this is what is required by charity in truth. [76]

31. This means that moral evaluation and scientific research must go hand in hand, and that charity must animate them in a harmonious interdisciplinary whole, marked by unity and distinction. The Church's social doctrine, which has "an important interdisciplinary dimension", [77] can exercise, in this perspective, a function of extraordinary effectiveness. It allows faith, theology, metaphysics and science to come together in a collaborative effort in the service of humanity.

[…]

36. Economic activity cannot solve all social problems through the simple application of commercial logic. This needs to be directed towards the pursuit of the common good, for which the political community in particular must also take responsibility. Therefore, it must be borne in mind that grave imbalances are produced when economic action, conceived merely as an engine for wealth creation, is detached from political action, conceived as a means for pursuing justice through redistribution.

[…]

40. John Paul II taught that investment always has moral, as well as economic significance. [96] All this — it should be stressed — is still valid today, despite the fact that the capital market has been significantly liberalized, and modern technological thinking can suggest that investment is merely a technical act, not a human and ethical one. There is no reason to deny that a certain amount of capital can do good, if invested abroad rather than at home. Yet the requirements of justice must be safeguarded, with due consideration for the way in which the capital was generated and the harm to individuals that will result if it is not used where it was produced. [97] What should be avoided is a speculative use of financial resources that

yields to the temptation of seeking only short-term profit, without regard for the long-term sustainability of the enterprise, its benefit to the real economy and attention to the advancement, in suitable and appropriate ways, of further economic initiatives in countries in need of development.

[…]

Labour and technical knowledge are a universal good. Yet it is not right to export these things merely for the sake of obtaining advantageous conditions, or worse, for purposes of exploitation, without making a real contribution to local society by helping to bring about a robust productive and social system, an essential factor for stable development.

Notes

1. [55] Pope John Paul II, Encyclical Letter *Sollicitudo Rei Socialis*, 30 December 1987, 28: loc. cit., 548-550.

2. [56] Pope Paul VI, Encyclical Letter *Populorum Progressio*, 26 March 1967, 9: loc. cit., 261-262.

3. [75] Pope Paul VI, Encyclical Letter *Populorum Progressio*, 26 March 1967, 75: loc. cit., 293-294.

4. [76] Pope Benedict XVI, Encyclical Letter *Deus Caritas Est*, 25 December 2005, 28: loc. cit., 238-240.

5. [77] Pope John Paul II, Encyclical Letter *Centesimus Annus*, 1 September 1991, 59: loc. cit., 864.

6. [96] Pope John Paul II, Encyclical Letter *Centesimus Annus*, 1 September 1991, 36: loc. cit., 838-840.

7. [97] Pope Paul VI, Encyclical Letter *Populorum Progressio*, 26 March 1967, 24: loc. cit., 269.

STATEMENT AT THE 14TH ORDINARY SESSION OF THE HUMAN RIGHTS COUNCIL ON THE ISSUE OF ACCESS TO MEDICINES

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

8 June 2010

(Selected Excerpts)

Mr. President,

With regard to the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, my delegation wishes to raise additional concerns regarding the need for effective action in order to guarantee Universal Access to medicines and diagnostic tools for all persons. The Special Rapporteur focused on this issue during his Report to the Eleventh Session of this distinguished Council. [1] However, continued vigilance must be maintained in this regard.

As the members of this Council already are well aware, the right to health is universally recognized as a fundamental right. Article 25 of the Universal Declaration on Human Rights (UDHR) includes the right to health and medical care within the more general rubric of the right "to enjoy an adequate standard of living." Article 12.1 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR), however, directly recognizes the right to enjoy the best physical and mental condition.

The Committee on Economic and Cultural Rights, in its General Comment No. 14, [2] moreover, identified the following minimum requirements for States to ensure: (1) the right of access to health care in a non-discriminatory way, (2) access to basic nutritional level, (3) access to housing, basic sanitation and a sufficient supply of drinking water, (4) the supply of essential drugs, (5) an equitable distribution of benefits and health services, and (6) adoption of national strategies to prevent and combat epidemics.

Mr. President, the Catholic Church provides a major contribution to health care in all parts of the world – through local churches, religious institutions and private initiatives, which act on their own responsibility and in the respect of the law of each country – including the promotion of 5,378 hospitals, 18,088 dispensaries and clinics, 521 leprosaria, and 15,448 homes for the aged, the chronically ill, or disabled people. With information coming from these on-the-ground realities in some of the most

poor, isolated, and marginalized communities, my delegation is obliged to report that the rights detailed in the international instruments already mentioned are far from being realized.

One major impediment to the realization of these rights is the lack of access to affordable medicines and diagnostic tools that can be administered and utilized in low-income, low-technology settings. Among the disturbing trends and findings reported by the Special Rapporteur are the following: "Diseases of poverty" still account for 50 per cent of the burden of disease in developing countries, nearly ten times higher than in developed countries; [3] more than 100 million people fall into poverty annually because they have to pay for health care; [4] in developing countries, patients themselves pay for 50 to 90 per cent of essential medicines; [5] nearly 2 billion people lack access to essential medicines.[6]

One group particularly deprived of access to medicines is that of children. Many essential medicines have not been developed in appropriate formulations or dosages specific to pediatric use. Thus families and health care workers often are forced to engage in a "guessing game" on how best to divide adult-size pills for use with children. This situation can result in the tragic loss of life or continued chronic illness among such needy children. For example, of the 2.1 million children estimated to be living with HIV infection, [7] only 38% were received life-saving anti retroviral medications at the end of 2008. [8] This treatment gap is partially due to the lack of "child friendly" medications to treat the HIV infection.

Thus the Committee on the Rights of the Child has declared: "The obligations of States parties under the Convention extend to ensuring that children have sustained and equal access to comprehensive treatment and care, including necessary HIV-related drugs …on a basis of non-discrimination." [9]. My delegation is well aware of the complexities inherent in the intellectual property aspects related to the issue of access to medicines. These considerations, including the flexibilities available to applying the Agreement on Trade-Related Aspects of Intellectual Property Rights, are well documented in the 2009 Report of the Special Rapporteur. We further recognize that serious efforts already have been undertaken to implement the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, established in 2008 by the 61st World Health Assembly. However, the intense debates recently pursued at the 63rd World Health Assembly demonstrate that the international community has not yet succeeded in its aim to provide equitable access to medicines and indicate the need for further creative reflection and action in this regard.

Mr. President, my delegation urges this Council to renew its commitment as a key stakeholder in efforts to assert and safeguard the right to health by guaranteeing equitable access to essential medicines. We do so with a firm conviction that "… treatment should be extended to every human being"

and as an essential element of "the search for the greatest possible human development… and with a strong belief that "[t]his ethical perspective [is] based on the dignity of the human person and on the fundamental rights and duties connect with it …" [10].

Notes

1. [1] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health to the Eleventh Session of the Human Rights Council, Eleventh Session, A/HRC/11/12, 31 March 2009.
2. [2] Committee on Economic, Social and Cultural Rights, Twenty-second session, 25 April-12 May 2000, E/C.12/2000/4, 11.
3. [3] World Health Organization (WHO), Public Health Innovation and Intellectual Property Rights, A Report of the Commission on Intellectual Property Rights, Innovation and Public Health, 2006, p. 3.
4. [4] World Health Organization (WHO), World Health Report, Primary Health Care Now More than Ever, 2008.
5. [5] A/61/338, para. 75.
6. [6] World Health Organization (WHO), Medicines Strategy: Countries at the Core, 2004- 2007, 2004.
7. [7] UNAIDS, 2009 AIDS Epidemic Update, Geneva, November 2009.
8. [8] Children and AIDS: Fourth Stocktaking Report, UNICEF, 2009, p. 10.
9. [9] Committee on the Rights of the Child, Thirty-Second Session, General Comment No. 3, 2003, HIV/AIDS and the rights of the child, CRC/GC/2003/3.
10. [10] Pope Benedict XVI, Address to The Plenary Assembly of The Pontifical Council for Health Pastoral Care, 22 March 2007.

STATEMENT AT THE 64TH SESSION OF THE UNITED NATIONS GENERAL ASSEMBLY

ARCHBISHOP CELESTINO MIGLIORE, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS IN NEW YORK

9 June 2010

Mr. President,

In the 2001 Declaration of Commitment on HIV/AIDS, Heads of State and Government acknowledged with urgent concern that the spread of HIV constituted "a global emergency and one of the most formidable challenges to human life and dignity" as well as a serious obstacle to the realization of the internationally agreed development goals. [1] Five years later in the Political Declaration on HIV/AIDS they noted with alarm that one quarter of a century into this scourge we are still facing an "unprecedented human catastrophe" [2]. On both occasions they made a commitment to take the necessary action to combat this serious threat to the human community.

Given the significant engagement of Catholic Church-sponsored organizations in providing care in all parts of the world for those with HIV/AIDS, my delegation takes this occasion to note that the global community continues to be confronted by many obstacles in its efforts to respond adequately to this problem, for example, that 7,400 people become infected with HIV every day; that nearly four million people are currently receiving treatment, while 9.7 million people are still in need of such life-saving and life-prolonging interventions; and that for every two people who commence treatment, 5 more become infected (UNAIDS: Country and regional responses to AIDS).

Mr. President,

If AIDS is to be combated by realistically facing its deeper causes and the sick are to be given the loving care they need, we need to provide people with more than knowledge, ability, technical competence and tools. For this reason my delegation strongly recommends that more attention and resources be dedicated to support a value-based approach grounded in the human dimension of sexuality, that is to say, a spiritual and human renewal that leads to a new way of behaving toward others. The spread of AIDS can be stopped effectively, as has been affirmed also by public health experts, when this respect for the dignity of human nature and for its inherent moral law is included as an essential element in HIV prevention efforts.

My delegation is deeply concerned about the gap in available funds for antiretroviral treatment among poor and marginalized populations. Catholic Church-related providers in Uganda, South Africa, Haiti, and

Papua New Guinea, among others, report that international donors have instructed them not to enroll new patients into these programs and express concern about further cutbacks even for those already receiving such treatment. The global community carries a serious responsibility to offer equitable and continuous access to such medications. Failure to do so will not only cause untold loss and suffering to those individuals and families directly affected by the disease but also will have grave public health, social, and economic consequences for the entire human family.

Particularly vulnerable are children living with HIV or HIV/TB co-infection. Access to early diagnosis and treatment is far less accessible to HIV-positive children than adults; without such access at least one-third of such children die before their first birthday and at least one-half die before their second birthday. Such loss of the future generations and leaders can no longer be met with silence or indifference.

Mr. President,

Through their global commitments in 2001 and 2006, Heads of State and Government articulated a vision of equitable access as well as comprehensive and effective action in response to the global HIV spread. The present-day challenges call into question our ability to fulfill such promises. Yet, in the face of the ongoing threat of HIV and AIDS, we must acknowledge the demands of the human family for worldwide solidarity, for honest evaluation of past approaches that may have been based more on ideology than on science and values, and for determined action that respects human dignity and promotes the integral development of each and every person and of all society.

Thank you, Mr. President.

NOTES

1. [1] A/RES/S-26/2
2. [2] A/RES/60/262

STATEMENT AT THE 14TH ORDINARY SESSION OF THE HUMAN RIGHTS COUNCIL ON MATERNAL MORTALITY

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

14 June 2010

Mr. President,

Based on the significant commitment and experience of the Catholic Church in assisting mothers and newborn babies, since the earliest of times, especially through its hospitals and maternity and pediatric clinics, my delegation wishes to express its urgent concerns about the shocking number of maternal deaths that continue to occur – estimated by reliable indicators at 350,000 a year – most especially among the poorest and most marginalized and disenfranchised populations.[1]

The Holy See's approach to Maternal Mortality is holistic, since it gives priority to the rights of mothers and child, both those already born and those awaiting birth in the womb of the mother. Not surprisingly, a strong correlation is revealed between statistics related to Maternal Mortality and those related to Neonatal Death, indicating that many measures aimed at combating maternal mortality, in fact, also contribute to a further reduction of child mortality. Moreover, we should not forget that 3 million babies die annually during their first week of life, another 3 million are stillborn, 2.3 million children die each year during their first year of life.

Mr. President,

Improvements to reduce Maternal Mortality have been made possible due to higher per capita income, higher education rates for women and increasing availability of basic medical care, including "skilled birth attendants". A recent study on Maternal Mortality has suggested that maternal mortality in Africa could be significantly reduced if HIV-positive mothers were given access to antiretroviral medications. The availability of emergency obstetric care, including the provision of universal pre and post-natal care, and adequate transport to medical facilities (when necessary), skilled birth attendants, a clean blood supply and a clean water supply, appropriate antibiotics, and the introduction of a minimum age of 18 years for marriage, are all measures that could benefit both mothers and their children. Most importantly, if the international community wishes to effectively reduce the tragic rates of maternal mortality, respect for and promotion of the right to health and of access to medications must not

only be spoken about, but also be put into action, by States as well as by non-governmental organizations and by civil society.

Mr. President,

Policies aimed at combating Maternal Mortality and Child Mortality need to strike a delicate balance between the rights of mother and those of the child, both of whom are rights bearers, the first of which is the right to life. The maternity clinics and hospitals promoted by the Catholic Church do exactly that: they save the lives both of mothers and of child, born and yet-to-be-born.

Thank you, Mr. President.

NOTES

1. [1] According to a study recently published in the medical journal, The Lancet, (Vol.375, Issue 9726, pp.1609-1623, 8 May 2010) there are approximately 350,000 maternal deaths *per annum* worldwide; WHO and UNICEF estimate 500,000 such deaths each year. The difference is attributed to diverse approaches to statistical modeling.

STATEMENT AT THE 48TH SERIES OF MEETINGS OF THE WORLD INTELLECTUAL PROPERTY ORGANIZATION GENERAL ASSEMBLIES

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

21 September 2010

(Selected Excerpts)

Mr. President,

The Delegation of the Holy See greatly appreciates that the focus of attention of this High Level Segment of the 48th Series of Meetings of the WIPO's General Assemblies is directed to the critical issues of innovation, growth and development: enhanced creativity opens new concrete options for all.

The *raison d'être* of the protection system of intellectual property is the promotion of literary, scientific or artistic production and, generally, of inventive activity for the sake of the "common good". Thus protection officially attests the right of the author or inventor to recognition of the ownership of his work and to a degree of economic reward. At the same time it serves the cultural and material progress of society as a whole. According to article 27 of the Universal Declaration of Human Rights, "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author". In the end, intellectual property protection recognizes the dignity of man and his work that becomes an expression of, and a contribution to, the growth of the individual personality and to the common good.

[…]

Mr. President,

These few observations want to underline the conviction that the main goal of the international community in developing a fair regime of intellectual property rights should aim toward the good of all, the pursuit of more equitable international relations, especially with regard to poorer and more vulnerable people. Of this goal we are reminded by Pope Benedict's latest Encyclical Letter: "…in the context of immaterial or cultural causes of development and underdevelopment, we find these same patterns of responsibility reproduced. On the part of rich countries there is excessive zeal for protecting knowledge through an unduly rigid assertion of the

right to intellectual property, especially in the field of health care. At the same time, in some poor countries, cultural models and social norms of behaviour persist which hinder the process of development." [1]

NOTES

1. [1] Pope Benedict XVI, Encyclical Letter *Caritas in Veritate*, § 22.

MESSAGE TO THE PARTICIPANTS AT THE 25TH INTERNATIONAL CONFERENCE ORGANIZED BY THE PONTIFICAL COUNCIL FOR HEALTH CARE WORKERS

POPE BENEDICT XVI

15 November 2010

(Selected Excerpts)

Health is a precious good for the person and the community to be promoted, preserved and protected, dedicating the necessary means, resources and energy in order that more and more people may benefit from it.

Unfortunately the fact that still today many of the world's populations have no access to the resources they need to satisfy their basic needs, particularly with regard to health care, is still a problem. It is necessary to work with greater commitment at all levels to ensure that the right to health care is rendered effective by furthering access to basic health care. In our day on the one hand we are witnessing an attention to health that borders on pharmacological, medical and surgical consumerism, almost a cult of the body, and on the other, the difficulty of millions of people in achieving a basic standard of subsistence and in obtaining the indispensable medicines for treatment.

In the health-care sector too, which is an integral part of everyone's life and of the common good, it is important to establish a real distributive justice which, on the basis of objective needs, guarantees adequate care to all. Consequently, if it is not to become inhuman, the world of health care cannot disregard the moral rules that must govern it.

[…]

To bend down, like the Good Samaritan, over the wounded man left by the roadside is to fulfil that "greater justice" which Jesus asks of his disciples and practised in his life, because the fulfilment of the Law is love. The Christian community, in following in the Lord's footsteps, has complied with his mandate to go out into the world "to teach and to heal the sick" and, down the centuries, "has felt strongly that service to the sick and suffering is an integral part of her mission" [1] to bear witness to integral salvation, which is health of soul and body.

The pilgrim People of God on the tortuous paths of history, joins forces with many other men and women of good will in order to give a truly

human face to health-care systems. Justice in health care must be among the priorities on the agenda of Governments and International Institutions.

NOTES

1. [1] Pope John Paul II, *Motu Proprio Dolentium Hominum*, 11 February 1985, 1.

STATEMENT AT THE 65TH WORLD HEALTH ASSEMBLY

ARCHBISHOP ZYGMUNT ZIMOWSKI, PRESIDENT OF THE PONTIFICAL COUNCIL FOR THE PASTORAL CARE OF HEALTH CARE WORKERS

21 May 2012

Madame President,

My delegation, in conjunction with other delegations, wishes to reaffirm the Resolution on Sustainable health financing structures and universal coverage (WHA64.9), which among others urges member States to aim for affordable universal coverage and access for all citizens on the basis of equity and solidarity. As Pope Benedict XVI emphasizes, "in the health-care sector too, which is an integral part of everyone's life and of the common good, it is important to establish a real distributive justice which, on the basis of objective needs, guarantees adequate care to all. Consequently, if it is not to become inhuman, the world of health care cannot disregard the moral rules that must govern it." [1]

The goal of the International Community is to enable everyone to access health services without running the risk of financial hardship in doing so (WHA58.33). Despite the progress made in some countries, we are still a long way from this target. There is need therefore for greater commitment at all levels in order to ensure that the right to health care is rendered effective by furthering access to basic health care. In this regard, the Holy See delegation supports the integration of universal coverage in high-level meetings related to health or social development, as well as its inclusion as a priority in the global development agenda.

At the recent Forum on Universal Health Coverage held in Mexico City, on 2 April, 2012, it was noted that more countries, especially those with emerging economies, are moving towards universal coverage, and this is very encouraging. The results obtained in these countries are not simply a fruit of financial resources; it has been observed that good policies that promote equity have guaranteed better health for a greater number of citizens in these countries. Therefore my delegation strongly believes that in the endeavor to promote universal coverage, fundamental values such as equity, human rights and social justice need to become explicit policy objectives.

Secondly, Mme. President, it has been shown by both low and middle-income countries that progress towards universal coverage is not the prerogative of high-income countries. Nevertheless, most low-income countries need the support of the international community, especially of high-income countries and other development partners, in order to

overcome the funding shortfalls in health. The Holy See delegation therefore wishes to reiterate the call for greater global solidarity and commitment in development assistance for health. Evoking the words of the Holy Father, "more economically developed nations should do all they can to allocate larger portions of their gross domestic product to development aid, thus respecting the obligations that the international community has undertaken in this regard." [2]

Lastly, at the level of each single nation, the progress towards universal coverage cannot be the effort of the state machinery alone. It requires support from the civil society and communities, whose contribution to health service delivery is fundamental. In this regard States should, "in accordance with the principle of subsidiarity, generously acknowledge and support initiatives arising from the different social forces and combine spontaneity with closeness to those in need." [3] Faith-based organizations and Church-sponsored healthcare institutions, inspired by Charity, are part of those living forces in the healthcare field.

With over 120,000 social and healthcare institutions worldwide, [4] the Catholic Church is in many developing countries, one of the key partners of the State in healthcare delivery, providing services in remote areas to rural low-income populations, enabling them to access services that would otherwise be out of their reach. The efforts and contribution of such organizations and institutions towards universal access, merit the recognition and support of both the State and the International Community, without obliging them to participate in activities they find morally abhorrent. Thus Pope Benedict XVI asks "international agencies to acknowledge them and to offer them assistance, respecting their specific character and acting in a spirit of collaboration." [5]

Thank you, Mme. President, and God bless you all.

NOTES

1. [1] Pope Benedict XVI, Message to Participants in the 25th International Conference Organized by the Pontifical Council for Health Care Workers, 15 November 2010, Vatican City.
2. [2] Pope Benedict XVI, Encyclical Letter *Caritas in Veritate*, n. 60.
3. [3] Pope Benedict XVI, Encyclical Letter *Deus Caritas Est*, n. 28b.
4. [4] *Secretaria Status*, Statistical Year Book of the Church 2009, Libreria Editrice Vaticana, Vatican City 2009, pp. 355-365.
5. [5] Pope Benedict XVI, Post-Synodal Apostolic Exhortation *Africae Munus*, n. 73.

STATEMENT AT THE 22ND SESSION OF THE HUMAN RIGHTS COUNCIL

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

7 March 2013

Mr. President,

My Delegation welcomes the focus on the Child's Right to Health during this Annual Discussion. Allow me to call special attention to the situation of children living with HIV or with HIV/TB co-infection – a topic that could have received more extensive consideration in the Report of the High Commissioner in preparation for this important discussion.

Despite evidence that treatment is very successful in children living with HIV, even in resource-limited settings, there remain significant obstacles to expanding access for children living with HIV to such life-saving and life-enhancing treatment. In fact, only 28% of children living in low- and middle-income countries in need of highly active anti-retroviral treatment, or HAART, are currently able to benefit from such medications, compared with 50% of adults living with HIV who have access to ART. [1] As a result, 30 children under 15 years of age living with HIV die every hour. [2] For children living with both HIV and tuberculosis (TB), the situation is even worse; despite the fact that TB remains the main cause of death among children with AIDS, pediatric drug formulations are not available to treat HIV/TB co-infection in children.

One major barrier to treating children with HIV is the difficulty of detecting the infection in babies younger than 18 months. In high-income countries, children can be diagnosed accurately within 48 hours of birth. However, the specialized and sophisticated tests that permit such diagnosis among infants are not commonly available in low-income countries because they require expensive laboratory equipment and trained staff. Moreover, scale-up of testing programs for children requires investment in training and technical assistance for health care providers, improvement of laboratory capacity and facilities, and referral networks and community mobilization.

We know, of course, that 90% of HIV infection among children is transmitted from a mother who is living with the virus to her child while still in the womb, during the birth process, or during breastfeeding. Even though interventions are available to prevent the transmission of HIV from

mother to child, approximately 330,000 children were newly infected with HIV during 2011[3], mainly through mother-to-child transmission. If access to special programs to prevent mother-to-child transmission through early diagnosis of the mothers and through provision of anti-retroviral treatment to such mothers immediately upon diagnosis were increased, the number of children newly infected with HIV would soon decrease. Moreover, the immediate initiation of HAART among children born to HIV-positive mothers would delay the onset of HIV-related illnesses among such children.

Without adequate care and treatment, up to one third of all children born with HIV die before their first birthday, and half of them will die before they are two years old. Yet children treated with HAART, must take three or more different anti-retroviral drugs several times a day in order to avoid developing resistance to a single drug, and therefore to prevent the further progression of HIV disease. These medicines must be formulated differently than those for adults, and in a way that takes into consideration the climatic conditions in the areas in which they will be distributed and used. It also should be noted that, in many low-income settings, clean drinking water, adequate nutrition, and a continuous supply of electricity are not always available and can therefore further jeopardize the quality of treatment that a child can access. Indeed, an insufficient variety of formulations of antiretroviral medicines are available for specific use among children, "largely because the HIV medicine market for children was judged too small to warrant investments in such research" [4].

Mr. President, the above-mentioned barriers thwart the ability of the child to enjoy and exercise his or her right to the highest attainable standard of physical and mental health, recognized, inter alia, in the Convention on the Rights to the Child. My delegation speaks her not merely in an abstract or legalistic manner but on the basis of information and lived experience reported by Catholic Church-related organizations engaged in promoting and protecting the child's right to health in every part of the world. A recent study conducted by the Catholic HIV/AIDS Network, an informal network of Catholic Church-related organizations engaged in providing financial and technical assistance support to HIV programs in developing countries reports significant engagement by such programs in efforts to eliminate mother-to-child transmission of the virus, to promote comprehensive and early diagnosis and treatment of those children who have been infected, and to confront the social stigma and ignorance that often obstructs the effective and efficient implementation of such programs. This report was discussed in a parallel event, held on 6 March 2013, in conjunction with the 22nd Session of this Council.

In an appeal on World AIDS Day 2012, Pope Benedict XVI noted with much urgency: "HIV/AIDS particularly affects the poorest regions of the world, where there is very limited access to effective medicines. My

thoughts turn in particular to the large number of children who contract the virus from their mothers each year, despite the treatments which exist to prevent its transmission. I encourage the many initiatives that, within the scope of the ecclesial mission, have been taken in order to eradicate this scourge." [5]

Mr. President, my Delegation sincerely hopes that this Council itself will appeal to the Member States of the United Nations to invest funds and collaborate closely with pharmaceutical companies and research institutes in order to preserve and advance the life and dignity of children living with HIV or with HIV/TB co-infection by providing them with available, affordable, and accessible diagnostic tools and medications and thereby assuring their full enjoyment of the right to health.

Notes

1. [1] UNAIDS, Report on the Global AIDS Epidemic, December 2012
2. [2] UNAIDS Report, Together We Will End AIDS, July 2012
3. [3] *Ibid.*
4. [4] Paediatric HIV: From a Human Rights Lens, *Caritas Internationalis* HAART for Children Newsletter, Issue 2, June 2012, Interview with Professor Daniel Tarantola.
5. [5] http://www.vatican.va/holy_father/benedict_xvi/audiences/2012/documents/hf_ben-xvi_aud_20121128_en.html

STATEMENT AT THE 23RD SESSION OF THE HUMAN RIGHTS COUNCIL

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

27 May 2013

Mr. President,

The Delegation of the Holy See has carefully reviewed the Report on Access to Medicines. While the Special Rapporteur maintains that "Full realization of access to medicines requires the fulfillment of key elements of availability, accessibility, acceptability and quality," my Delegation found that the Report gave insufficient attention to certain factors cited as "key elements" by the Special Rapporteur.

With regard to accessibility, my Delegation believes that a comprehensive analysis of this crucial topic must reach beyond legal frameworks to include an examination of the social and political realities that deprive millions of people from enjoyment of the highest attainable standard of physical and mental health because of the obstacles that they place on access to medicines.

Article 25 of the Universal Declaration on Human Rights clearly adopted such a comprehensive perspective when it declared: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."

Thus the Holy See Delegation found that the Report paid insufficient attention to basic needs of individuals and families, at all stages of the life cycle from conception to natural death. Such challenges often block access to medicines as much as, if not more than, the various legal factors that occupied the main focus of the Report. Effective reversal of such obstacles requires an integral human development approach that promotes just legal frameworks as well as international solidarity, not only among States, but also among and between all peoples.

Thus the Holy See noted, with alarm, "the difficulties millions of people face as they seek to obtain minimal subsistence and the medicines they need to cure themselves" and called for "establishing true distributive justice which guarantees everyone adequate care on the basis of objective needs."[1]

The Report made frequent references to the obligation of States to set the conditions for access to medicine. While governmental fulfillment of such responsibility is a clear prerequisite, the strong engagement of nongovernmental and religious organizations in providing both medicines and a wide range of treatment and preventive measures to ensure the full enjoyment of the right to health also should have been acknowledged.

From its contacts down to the grass-root level with 5,305 hospitals and 18,179 clinics [2] inspired and organized under Catholic Church auspices throughout the world, the Holy See is well aware that these institutions serve the poorest sectors of society, many of whom live in rural and isolated areas or in conflict zones, where governmental health systems often do not reach. This fact has been confirmed by professional mapping exercises, with support and collaboration of the World Health Organization, which reported that "between 30 and 70 per cent of the health infrastructure in Africa is currently owned by faith-based organizations."[3]

Mr. President, optimal facilitation of access to medicine is a complex endeavor and deserves comprehensive analysis and acknowledgement of all factors contributing to its promotion, rather than a more restricted analysis of legal, economic, and political frameworks.

Thank you, Mr. President.

Notes

1. [1] Pope Benedict XVI, 25th International Conference of the Pontifical Council for Health Pastoral Care, 15 November 2010.
2. [2] Catholic Church Statistics, Agenzia Fides, Vatican City, 21 October 2012.
3. [3] Dr. Kevin De Cock (then-Director of HIV/AIDS Services, World Health Organization), Faith based organizations play major role in fighting HIV/AIDS – UN study, 9 February 2007.

APOSTOLIC EXHORTATION EVANGELII GAUDIUM

POPE FRANCIS

24 November 2013

(Selected Excerpt)

52. In our time humanity is experiencing a turning-point in its history, as we can see from the advances being made in so many fields. We can only praise the steps being taken to improve people's welfare in areas such as health care, education and communications. At the same time we have to remember that the majority of our contemporaries are barely living from day to day, with dire consequences. A number of diseases are spreading. The hearts of many people are gripped by fear and desperation, even in the so-called rich countries. The joy of living frequently fades, lack of respect for others and violence are on the rise, and inequality is increasingly evident. It is a struggle to live and, often, to live with precious little dignity. This epochal change has been set in motion by the enormous qualitative, quantitative, rapid and cumulative advances occuring in the sciences and in technology, and by their instant application in different areas of nature and of life. We are in an age of knowledge and information, which has led to new and often anonymous kinds of power.

ADDRESS TO PARTICIPANTS IN THE CONFERENCE OF THE ITALIAN SOCIETY OF SURGICAL ONCOLOGY

POPE FRANCIS

12 April 2014

Dear Brothers and Sisters,

I welcome all of you who are taking part in the Conference of the Italian Society of Surgical Oncology, organized by the Sapienza University of Rome and Sant'Andrea Hospital. In welcoming you, I call to mind all the men and women under your care, and I pray for them.

Scientific research has increased the possibilities for prevention and care; it has discovered therapies to treat a wide variety of diseases. You have also worked for this most worthy commitment: to respond to the needs and hopes of the sick throughout the world.

But in order to talk about total health, it is necessary not to lose sight of the fact that the human person, created in the image and likeness of God, is a unity of body and spirit. The Greeks were more precise: body, soul and spirit. The human person is unity. These two elements may be distinguished but not separated, because the person is one. Thus also illness, the experience of pain and suffering, involves not only the physical dimension, but man in his totality. That is why there is need for integral treatment, which considers the person as a whole and joins medical care — "technical" care — to human, psychological and social support, for the physician has to care for all aspects: the human body in its psychological, social and spiritual dimensions, as well as the spiritual accompaniment and support for the sick person's family. It is, therefore, imperative that healthcare workers be those who are "led by an integrally human view of illness and who as a result are able to effect a fully human approach to the sick person who is suffering" [1]. Fraternal sharing with the sick opens us up to the true beauty of human life, which also includes its fragility, thus enabling us to recognize the dignity and value of every human being, in whatever situation they may find themselves, from conception to death.

Dear friends, tomorrow is the start of Holy Week, which culminates in the Triduum of the Passion, death and Resurrection of Jesus. Here, human suffering is completely taken on and redeemed by God. By God-Love. Only Christ gives meaning to the scandal of innocent suffering. Many times, the agonizing question of Dostoyevsky comes to the heart: why do children suffer? Only Christ can give meaning to this "scandal". You can always look to Him, crucified and Risen, in carrying out your daily work. And at the foot of the Cross of Jesus, we also meet the Sorrowful Mother. She is the Mother of all humanity, and she is always close to her sick and

ailing children. If our faith waivers, hers does not. May Mary always sustain you and your commitment to research and action in your work. And I pray, I ask the Lord to bless all of you.

Thank you.

NOTES

1. [1] Pope John Paul II, *Motu Proprio Dolentium Hominum*, 11 February 1985.

STATEMENT AT THE 2015 SOCIAL FORUM OF THE HUMAN RIGHTS COUNCIL

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

18 February 2015

Mr. Chairman,

The Delegation of the Holy See acknowledges the responsibility of States to ensure that medicines are available, financially affordable, and physically accessible on a basis of non-discrimination to everyone and appreciates the decision of the Human Rights Council to dedicate this annual session of the Social Forum to this urgent issue. With regard to the availability of medicines, we take special note that "… scientific research has multiplied the possibilities of prevention and healing" and "has allowed for the discovery of therapies that are indicated in caring for a variety of pathologies." This represents "a highly valuable commitment that aims to respond to the expectations and the hopes of many ill people across the world". [1]

On the other hand, from the perspective of the Catholic Church's experience in caring for the sick in more than 5,000 hospitals and 18,000 dispensaries in every region of the world, my delegation has called attention to the fact that States, in particular, and the international community, as a whole, have not fulfilled their responsibility to make medicines and diagnostic tools affordable and accessible to the poorest and most marginalized populations in low-income countries and even in certain areas and among certain groups of people in high-and middle-income countries. A major stumbling block in providing such access is found in restrictive applications and interpretations of intellectual property rights by many in the pharmaceutical industry.

Mr. Chairman,

Application of the intellectual property instruments, as it currently prevails in many parts of the world, interferes with the right to health in two ways. First of all, some pharmaceutical companies assert a claim to unrealistic profit and cost recovery margins even though most governments and individual buyers from developing countries do not have the financial capacity to purchase these products at such high cost. This system can lead to total disregard for those who cannot afford the price of certain medical products and allow an imbalanced free trade system, and thus constitute a virtual monopoly.[2]

The second obstacle relates to research and development (R&D) in order to develop new and more effective medicines and other vital medical products, including diagnostic tools to facilitate early identification and treatment of certain life-threatening illnesses. The system, in fact, does not operate as an incentive to research on so-called "no market" or "low return on investment" treatments, such as those for neglected tropical diseases, rare diseases, or even for those illnesses that have higher prevalence among low-income people, or in economically-deprived regions, including HIV, tuberculosis, malaria, hepatitis and Ebola Virus Disease, which most recently has been ravaging coastal West Africa. It is most regrettable, therefore, that, due to an excessive focus on profit, we witness a preference within much of the pharmaceutical industry to orient research toward health issues that have greater market potential in wealthier industrialized countries.

One group particularly deprived of access to medicines is that of children. Many essential medicines have not been developed in appropriate formulations or dosages specific to paediatric use. Thus, families and health care workers often are forced to engage in a "guessing game" on how best to divide adult-size pills for use with children. This situation can result in the tragic loss of life or continued chronic illness among needy children. While some progress to address this problem has been made in recent years, especially in relation to children living with HIV, many more challenges must be addressed in order to ensure access to medicines that are prepared in "child sized", fixed dose combinations, of acceptable taste and form, and easy to administer to infants and very young children.

Mr. Chairman,

While fully respecting the right to private intellectual property, the Holy See urges a creative and innovative approach, with full use of the flexibilities allowed under the Trade Related Intellectual Property instruments, so that the right to health for all people without any form of discrimination can be fully guaranteed and implemented. We are convinced, therefore, that concern for the protection of intellectual property rights, while legitimate in itself, must be seen within the wider perspective of promoting the common good, building global solidarity and prioritizing the life and dignity of the world's most vulnerable people, many of whom bear an inequitable burden of both communicable and non-communicable diseases.

NOTES

1. [1] Pope Francis, Address to the Participants to the Conference on Oncological Surgery, Vatican City, 12 April 2014.

2. [2] http://www.vatican.va/roman_curia/secretariat_state/documents/rc_seg-st_doc_20010620_wto_en.html

STATEMENT AT THE 68TH WORLD HEALTH ASSEMBLY

ARCHBISHOP ZYGMUNT ZIMOWSKI, PRESIDENT OF THE PONTIFICAL COUNCIL FOR THE PASTORAL CARE OF HEALTH CARE WORKERS

20 May 2015

Mr. President,

The Holy See delegation wishes to note the importance and the timeliness of the theme for the general discussion. The recent Ebola outbreak was a human and public health tragedy, which, among others, showed that the need to build resilient health systems cannot be over emphasized, as they are essential for the provision of universal health coverage and for a prompt response to outbreaks of disease.

There is an established awareness that the smooth and effective operation of health systems is critical to achieving both national and international health goals. [1] Unfortunately, most low income countries, which are still afflicted by infectious disease and epidemics, have very poor health systems that need urgent intervention, if they are to respond to the health needs of the whole population.

In fact, many health centers are unable to provide safely the services needed, as they lack staff, medicines, equipment and health information. This is aggravated by the chronic low public expenditure on health. We therefore need to re-prioritize investment in healthcare for the good of public health. This requires long-term commitment from national governments and international donors to support resilient health systems and to ensure universal coverage of health services, thus strengthening the capacity of national health systems to deliver equitable and quality health-care services, and also stepping up their ability to respond to outbreaks and to improve community ownership and participation.

This means short and long-term investment in a number of key elements of the health system; particularly, improved primary health care, an adequate number of trained health workers, availability of medicine, appropriate infrastructure, update statistical data, sufficient public financing, public-private partnership and scaling up the number of well-equipped health posts and district hospitals. It is also a challenge to donors to make a shift from short-term program funding to long-term comprehensive health service financing.

The recent report on Global evidence on inequities in rural health protection, by the International Labor Office, revealed that more than half of the population in rural areas worldwide do not have access to basic healthcare, with many of them at risk of impoverishment or deepened

poverty due to out of pocket payment for services. [2] This is clear evidence that, in 2015, we are still a long way from universal coverage. For various reasons, there are strong inequalities in access to healthcare between the rural and urban areas, with the latter often more advantaged than the former which are most deprived. Embracing the recommendation of the report, my delegation wishes to note the urgent need to address this rural urban divide in the post-2015 Development Agenda, bearing in mind that "human life is always sacred and always has 'quality'. (…) There is no human life qualitatively more significant than another, only by virtue of resources, rights, greater social and economic opportunities." [3] This means addressing the needs of the disadvantaged, marginalized and vulnerable rural populations. As Pope Francis reminds us "persons and peoples ask for justice to be put into practice: not only in a legal sense, but also in terms of contribution and distribution. Therefore, development plans and the work of international organizations must take into consideration the wish, so frequent among ordinary people, for respect for fundamental human rights and, in this case, the right to social protection and health." [4]

In relation to this, the Holy See delegation wishes to emphasize the role of public-private partnership in promoting universal coverage, especially in many low-income countries where primary healthcare services are accessed by a majority of the population in the rural and hard to reach areas, mainly from private not-for profit health centers and hospitals, managed by the Church and other faith based institutions. In many countries, the Catholic Church is privileged to be one of the primary partners of the State in providing much needed health care services to populations in remote areas, through its over 110,000 health and social-welfare institutions around the world.[5] It is therefore important to offer them the necessary collaboration and support so as to enable them to bring the services close and to render them accessible to poor people in particular.[6] Indeed, in many low-income countries, the contribution of civil society and communities to health services delivery is fundamental.

Finally, Mr. President, while remembering the many victims of the Ebola virus in Guinea, Liberia and Sierra Leone, as well as the many dedicated healthcare workers, both from public and private Church owned health institutions, who lost their lives while assisting those affected, and aware of the impact of the outbreak on the already fragile health systems of the affected countries, whose capacity to provide essential health services has been greatly compromised, my delegation welcomes the recommendations of the Resolution on Ebola (EBSS3.R1) and supports its review and approval by this august assembly (WHA 68).

May I wish all the distinguished delegates a fruitful discussion and deliberation during this Assembly.

Thank you, Mr. President.

Notes

1. [1] A64/13 Health System Strengthening: Current Trends and Challenges.

2. [2] International Labor Organization (ILO), Global Evidence on Inequities in Rural Health Protection: New Data on Rural Deficits in Health Coverage for 174 Countries, 2015, pp. 6-12.

3. [3] Pope Francis, Address to participants in the commemorative Conference of the Italian Catholic Physicians' Association on the occasion of its 70th anniversary of foundation, 15 November 2014.

4. [4] Pope Francis, Address to FAO Nutrition Conference, 21 November 2014, 2.

5. [5] The Catholic Church has a total of 116,185 health and social-welfare institutions world-wide, of which 5,034 hospitals, 16,627 dispensaries, 611 leprosaria, 15,518 homes for the aged, chronically ill, invalids and disabled, 9,770 orphanages, 3,896 special centers for social re-education and other social-welfare institutions. Cf. *Secretaria Status*, Statistical Yearbook of the Church 2013, Libreria Editrice Vaticana, 2013, pp. 355-365.

6. [6] Pope Benedict XVI, Encyclical Letter *Deus Caritas est*, 25 December 2005, 28b.

ENCYCLICAL LETTER LAUDATO SI'

POPE FRANCIS

24 May 2015

(Selected Excerpts)

102. Humanity has entered a new era in which our technical prowess has brought us to a crossroads. We are the beneficiaries of two centuries of enormous waves of change: steam engines, railways, the telegraph, electricity, automobiles, aeroplanes, chemical industries, modern medicine, information technology and, more recently, the digital revolution, robotics, biotechnologies and nanotechnologies. It is right to rejoice in these advances and to be excited by the immense possibilities which they continue to open up before us, for "science and technology are wonderful products of a God-given human creativity". [81] The modification of nature for useful purposes has distinguished the human family from the beginning; technology itself "expresses the inner tension that impels man gradually to overcome material limitations". [82] Technology has remedied countless evils which used to harm and limit human beings. How can we not feel gratitude and appreciation for this progress, especially in the fields of medicine, engineering and communications? How could we not acknowledge the work of many scientists and engineers who have provided alternatives to make development sustainable?

103. Technoscience, when well directed, can produce important means of improving the quality of human life.

[…]

104. Yet it must also be recognized that nuclear energy, biotechnology, information technology, knowledge of our DNA, and many other abilities which we have acquired, have given us tremendous power. More precisely, they have given those with the knowledge, and especially the economic resources to use them, an impressive dominance over the whole of humanity and the entire world.

[…]

109. The technocratic paradigm also tends to dominate economic and political life. The economy accepts every advance in technology with a view to profit, without concern for its potentially negative impact on human beings.

Notes

1. [81] Pope John Paul II, Address to Scientists and Representatives of the United Nations University, 3: AAS 73 (1981), 422.

2. [82] Pope Benedict XVI, Encyclical Letter *Caritas in Veritate*, 69: AAS 101 (2009), 702.

STATEMENT AT THE WORLD TRADE ORGANIZATION - TRADE RELATED INTELLECTUAL PROPERTY RIGHTS COUNCIL

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

10 June 2015

(Selected Excerpts)

Mr. President,

I join previous speakers to congratulate you on your election. The World Health Organization (WHO) estimates that about one-third of the population lacks regular access to essential medicines and vaccines. It believes that 10 million lives could be saved annually if such resources were more readily available.

The Least Developed Countries (LDCs), as the poorest and weakest segment of the international community, are most vulnerable. The classification of LDCs is contingent on a number of key human development indicators, including levels of poverty, literacy and infant mortality.

[…]

As underlined in the Istanbul Program of Action, LDCs are the most "off-track" in the achievement of the internationally agreed development goals. Their productive capacity is limited, and they have severe infrastructure deficits. [1] In 2011, of the 34 million people living with HIV worldwide, some 9.7 million lived in LDCs. Of these, 4.6 million were in need of antiretroviral treatment; however only 2.5 million had received it. [2] Up to one-half of those deprived of treatment were expected to die within 24 months. [3] In the 49 countries designated as LDCs by the United Nations, non-communicable diseases as well are rising much faster than in higher income countries.

Mr. President,

Some LDCs have used the transition period as a major selling point for attracting investment in their local pharmaceutical industry. [4] However, some LDCs have provided patent protection for medicines despite the availability of the transition period or have signed free trade and investment agreements that may contain IP provisions curtailing any benefits arising from the transition period. In this context, the report observed that the

transition period in itself, though important, will not be sufficient to attract generic companies to invest in local pharmaceutical production. [5] However, the transition period is intended to provide LDCs with the necessary policy space to take measures that would facilitate the growth of industrial capacity in desired sectors without being impeded by the existence of patents, which could hinder the development of the local industry.

Since 2000, there has been a noticeable decline in the number of new HIV infections in LDCs since 2000, as in the developing world as a whole, reflecting improvements in early diagnosis, access to treatment, nutrition, and responsible behaviour change. However, despite such improvements, the goal of universal access to anti-retroviral treatment is far from achieved and requires continuing investment and both health and community system strengthening. Moreover, the deficiencies of health systems in LDCs have been sharply highlighted during 2014 and 2015, in conjunction with the significant outbreak of the Ebola Virus Disease in Coastal West Africa. Such health emergencies could jeopardize, or even reverse, the achievements of several LDCs in terms of human and economic development.

We have before us a critical opportunity to help LDCs to reach health and sustainable development goals and the failure to do so could put millions of lives at risk. Access to adequate healthcare, including affordable medicines, remains a key challenge in most LDCs. The current flexible intellectual property arrangements for LDCs are a crucial tool for improving health. In fact, the flexibility agreed in TRIPS Article 66.1 has been accepted in recognition of the economic, financial, and administrative constraints preventing LDCs from immediate observance of all the obligations set out in the TRIPS Agreement. The general transition period may be useful in supporting the development of a strong chemical industry that could gradually move toward to production of API (Active Pharmaceutical Ingredient). Long-term sustainability of the local pharmaceutical industry would require the development of the internal capacity to manufacture generic formulations thus reducing dependency and the high import costs for obtaining APIs. In particular, there is a need to develop a second line HIV treatment which, a present, is more than double the price of the first line regime. Moreover, the costs for a third line HIV treatment could be as much as 15 times the price of first line treatment. Clearly, in this context, the establishment of a pharmaceutical industry is particularly important.

Mr. President,

As clearly stated by the TRIPs Agreement, a well-designed intellectual property system "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, in a manner conducive to social and economic welfare, and to a balance of rights and obligations" [6].

In conclusion, Mr. President, the Holy See Delegation hopes that a sense of common responsibility, as shown in the decision adopted, will bring us all to recommend to the General Council a waiver for LDCs from obligations under Articles 70.8 and 70.9 of TRIPS for as long as they remain LDCs.

Thank you, Mr. President.

NOTES

1. [1] Istanbul Plan of Action (par.4) doc. A/CONF.219/3.
2. [2] TRIPS transition period extensions for least-developed countries, UNDP and UNAIDS Issues Brief, 13 February 2013.
3. [3] Mr. Michel Sidibé, UNAIDS Executive Director, Report to 31st UNAIDS Programme Coordinating Board, December 2012.
4. [4] UNCTAD (2011), Investment in Pharmaceutical Production in the Least Developed Countries: A Guide for Policymakers and Investment Promotion Agencies (UNCTAD Secretariat, Geneva, New York), pp. 40-42.
5. [5] *Ibid.*
6. [6] Article 7 TRIPs Agreement.

STATEMENT AT THE WORLD TRADE ORGANIZATION – TRADE RELATED INTELLECTUAL PROPERTY RIGHTS COUNCIL

ARCHBISHOP SILVANO M. TOMASI, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

6 November 2015

(Selected Excerpt)

Access to affordable pharmaceutical products is a prerequisite for LDCs to deal with the numerous public health challenges that they face. LDCs are home to some of the world's most vulnerable people and bear considerable health burdens. They face growing burdens of neglected, infectious, and chronic non-communicable diseases. UNAIDS reported in its 2015 Gap Report that three out of five people living with HIV, and in need of antiretroviral therapy, still do not have access to such life-saving and life-prolonging medicines. Many of these people live in LDCs, and their numbers will increase dramatically if such countries are deprived of the price flexibilities from which they previously have benefited. Our engagement and our work should continue to be inspired by Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health in recognition of the gravity of the public health problems afflicting LDCs and their acknowledged right to maximum flexibility to take steps to ensure access to medicines for all. They disproportionately suffer health risks associated with poverty such as malnutrition, unsafe water and poor sanitation.

In his recent address to the Congress of the United States of America, Pope Francis appealed, "I know that you share my conviction that much more still needs to be done, and that in times of crisis and economic hardship a spirit of global solidarity must not be lost. At the same time I would encourage you to keep in mind all those people around us who are trapped in a cycle of poverty. They too need to be given hope. The fight against poverty and hunger must be fought constantly and on many fronts, especially in its causes." The extension of the transition period, therefore, is critical to enable LDCs to be able to import affordable generic medicines as well as to strengthen local production capacity.

As already stated by my Delegation, a time-limited transition period creates an uncertain environment for the producers of affordable medicines, procurement agencies, and donors, as well as for LDC governments, all of

which rely on the specific pharmaceutical transition period to produce and import affordable medicines. This, in turn, jeopardizes the health situation of the people and communities within LDCs, and results in especially adverse consequences for the scaling up of HIV treatment. However, the decision that the obligations of LDC Members - under paragraph 8 and 9 of Article 70 - shall be waived with respect to pharmaceutical products until 1 January 2033, represent a significant step forward.

In conclusion:

With deep interest in addressing these pressing public health needs, securing the ability to progressively realize the right to health, and ensuring continuous access to more affordable medicines of assured quality, the Delegation of the Holy See hopes that the consensus reached on the proposal of extension represents an important sign by the World Trade Organization, especially in anticipation of the next Ministerial Conference in Nairobi. The Holy See Delegation remains confident that a sense of common responsibility, as shown in the decision adopted, will bring us all to support such an extension as an accelerated step toward the human and economic progress of LDCs.

Thank you, Mr. President.

ADDRESS TO THE PARTICIPANTS OF THE INTERNATIONAL CONFERENCE ON THE PROGRESS OF REGENERATIVE MEDICINE

POPE FRANCIS

29 April 2016

Dear Friends,

I am pleased to welcome all of you. I thank Cardinal Gianfranco Ravasi for his words and, above all, for having organized this meeting on the challenging problem of rare diseases within today's social and cultural context. During your discussions, you have offered your professionalism and high-level expertise in the area of researching new treatments. At the same time, you have not ignored ethical, anthropological, social and cultural questions, as well as the complex problem of access to care for those afflicted by rare conditions. These patients are often not given sufficient attention, because investing in them is not expected to produce substantial economic returns. In my ministry I frequently meet people affected by so called "rare" diseases. These illnesses affect millions of people throughout the world, and cause suffering and anxiety for all those who care for them, starting with family members.

Your meeting takes on greater significance in the Extraordinary Jubilee Year of Mercy; mercy is "the fundamental law that dwells in the heart of every person who looks sincerely into the eyes of his brothers and sisters on the path of life" [1]. Your work is a sign of hope, as it brings together people and institutions from diverse cultures, societies and religions, all united in their deep concern for the sick.

I wish to reflect, albeit briefly, on three aspects of the commitment of the Pontifical Council for Culture and institutions working with it: the Vatican Science and Faith Foundation–STOQ, the Stem for Life Foundation, and many others who are cooperating in this cultural initiative.

The first is "increasing sensitivity". It is fundamentally important that we promote greater empathy in society, and not remain indifferent to our neighbour's cry for help, including when he or she is suffering from a rare disease. We know that we cannot always find fast cures to complex illnesses, but we can be prompt in caring for these persons, who often feel abandoned and ignored. We should be sensitive towards all, regardless of religious belief, social standing or culture.

The second aspect that guides your efforts is "research", seen in two inseparable actions: education and genuine scientific study. Today more than ever we see the urgent need for an education that not only develops students' intellectual abilities, but also ensures integral human formation and

a professionalism of the highest degree. From this pedagogical perspective, it is necessary in medical and life sciences to offer interdisciplinary courses which provide ample room for a human formation supported by ethical criteria. Research, whether in academia or industry, requires unwavering attention to moral issues if it is to be an instrument which safeguards human life and the dignity of the person. Formation and research, therefore, aspire to serve higher values, such as solidarity, generosity, magnanimity, sharing of knowledge, respect for human life, and fraternal and selfless love.

The third aspect I wish to mention is "ensuring access to care". In my Apostolic Exhortation Evangelii Gaudium I highlighted the value of human progress today, citing "areas such as health care, education and communications".[2] I also strongly emphasized, however, the need to oppose "an economy of exclusion and inequality" [3] that victimizes people when the mechanism of profit prevails over the value of human life. This is why the globalization of indifference must be countered by the globalization of empathy. We are called to make known throughout the world the issue of rare diseases, to invest in appropriate education, to increase funds for research, and to promote necessary legislation as well as an economic paradigm shift. In this way, the centrality of the human person will be rediscovered. Thanks to coordinated efforts at various levels and in different sectors, it is becoming possible not only to find solutions to the sufferings which afflict our sick brothers and sisters, but also to secure access to care for them.

I encourage you to nurture these values which are already a part of your academic and cultural programme, begun some years ago. So too I urge you to continue to integrate more people and institutions throughout the world into your work. During this Jubilee Year, may you be capable and generous co-operators with the Father's mercy. I accompany you and bless you on this journey; and I ask you, please, pray for me.

Thank you.

NOTES

1. [1] Pope Francis, Papal Bull *Misericordiae Vultus*, 11 April 2015, 2.
2. [2] Pope Francis, Apostolic Exhortation *Evangelii Gaudium*, 24 November 2013, 52.
3. [3] *Ibid.*, 53

ADDRESS TO THE COLLEGE FOR ASPIRING AND MISSIONARY DOCTORS "DOCTORS WITH AFRICA - CUAMM"

POPE FRANCIS

7 May 2016

(Selected Excerpt)

Health, indeed, is not a consumer good, but a universal right which means that access to healthcare services cannot be a privilege.

Healthcare, even basic treatment, is in fact denied — denied! — in various parts of the world and in many regions of Africa. It is not regarded as a universal right, but rather still a privilege for the few, those who can afford it. Accessibility to healthcare services, to treatment and medicine is still a mirage. The poorest are unable to pay and are excluded from hospital services, even from the most essential and basic. This shows how important your generous work is in support of an extensive network of services, designed to meet the needs of the populations.

STATEMENT AT THE HIGH - LEVEL MEETING ON HIV/ AIDS

ARCHBISHOP BERNARDITO AUZA, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS IN NEW YORK

10 June 2016

Mr. President,

After years of shocking narratives on the loss of health and life among men, women and children living with HIV, my delegation is pleased with the progress detailed in the Secretary General's Report "On the Fast-Track to End the AIDS Epidemic." It is indeed heartening to set strategic goals and benchmarks with a view to ending this disease, and to do so within the more comprehensive framework of the 2030 Agenda for Sustainable Development.

My delegation, however, urges the international community to pay equal attention to the cautionary note raised in the same Report, namely, that "AIDS is far from over […] despite remarkable progress," and "if we accept the status quo unchanged, the epidemic will rebound in several low- and middle-income countries."

In this regard, Catholic-inspired organizations often report the persistent obstacles posed by lack of access to early diagnosis and treatment; by lack of appropriate, affordable, and accessible "child-friendly" formulations and dosages of medications for pediatric use; by changes in funding priorities imposed by donor governments and agencies resulting in disruptions of services for those who do not live in the so-called HIV "hot spots"; by frequent stock-outs of medicines and diagnostic equipment and supplies; by interruptions of treatment, especially of women and young people who are subjected to stigma, discrimination and physical and emotional abuse as a result of their HIV status.

While global goals and targets will be essentially moving forward, they must be anchored in reality, integrating the very real concerns that respective countries have in considering the holistic well-being of their people. Discrimination and stigmatization can never be an excuse to exclude or leave anyone behind. Every effort must be made to distinguish between policies that discriminate and stigmatize and those that are put in place to discourage risk-taking behaviors and encourage responsible and healthy relationships, especially among youth. While access to prevention, treatment and health care services must be guaranteed to all, they will never be enough by themselves to end HIV transmission and AIDS. We must continue to address their root causes and promote healthy lifestyles.

Mr. President,

The obstacles to eradicating the spread of HIV/AIDS give ample evidence of the fact that in different parts of the world, especially in many regions of Africa, health care is still a privilege of the few who can afford it. As Pope Francis has said, access to health care, treatment, and medicines remains a dream for too many. Health-related issues, such as HIV/AIDS and related infections, require urgent political attention, above and beyond all other commercial or political interests. The international community must and the will, the technical expertise, the resources and the methods that provide access to diagnosis and treatment for all, and not simply for a privileged few, for "there is no human life that is more sacred than another, as there is no human life that is qualitatively more significant than another." [1]

Presently, as many as fifty percent of HIV-positive children die before their second birthday, because they do not have access to the necessary diagnosis, treatment and medication. In fact, the majority of HIV-positive children are not diagnosed until they are four years of age.

Taking up these concerns, the Holy See recently convened two meetings in the Vatican with the

executive-level leaders of companies that manufacture pharmaceuticals and diagnostic equipment, in order to plan a timelier and more appropriate response to children living with HIV and tuberculosis. These business leaders, together with representatives of specialized multilateral organizations, governments, religious and other non-governmental organizations, agreed that providing affordable, appropriate, and accessible HIV medicines and diagnostic tools for pediatric use everywhere is an urgent global goal, thus committing themselves to overcoming the obstacles and accelerating access to diagnosis, treatment and medication for children living with HIV/AIDS.

The Holy See and all the institutions of the Catholic Church are motivated more than ever to consider the plight of children living with HIV. Together let us muster the will, continue to sharpen the technical expertise already available and the resources necessary to provide access to diagnosis, care and treatment, not only for a privileged few, but for all.

Thank you, Mr. President.

Notes

1. [1] Pope Francis, Address to the International Federation of Catholic Medical Associations, 20 September 2013.

STATEMENT AT THE 34TH SESSION OF THE HUMAN RIGHTS COUNCIL

ARCHBISHOP IVAN JURKOVIČ, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

10 March 2017

Mr. President,

With regard to the right of everyone to enjoy the highest attainable standard of physical and mental health, my Delegation wishes to raise additional concerns regarding the need for effective action in order to guarantee universal access to medicines, vaccines, diagnostics and medical devices. Working for a just distribution of the fruits of the earth and of human labour is not mere philanthropy. This is a moral obligation.

In relation to pursuing of the double goals of access to medicines and necessary medical innovation, policy coherence is fundamental for effective, sustainable and equitable progress towards universal health coverage and improved health outcomes for all. The adoption of the Sustainable Development Goals (SDGs) created an enabling framework for progress toward the achievement of both access and innovation. SDG 3, in particular, includes the targets to support "the research and development of vaccines and medicine for the communicable and non-communicable diseases that primarily affect developing countries" and to provide "access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on TRIPs Agreement [Agreement on Trade-Related Aspects of Intellectual Property Rights] and Public Health".

In this sense, the Holy See appreciates the entry into force, last January, of the amendment to the TRIPs Agreement. The amendment provides a secure and legal pathway to access affordable medicines and helps the most vulnerable access treatments that meet their needs, including those related to HIV, tuberculosis, malaria, as well as other epidemics.

Access to affordable medicines no longer represents a challenge only for the Least Developed and other developing countries; it has also become an increasingly urgent issue for higher-income countries as well. States find themselves unable to combat antimicrobial resistance. Moreover, developing countries are confronted with a serious lack of new medicines, especially as public health budgets have been constrained worldwide.

Mr. President,

As we all are aware, health is a fundamental human right, essential for the exercise of many other rights, and necessary for living a life in dignity.

Therefore, the Catholic Church provides a major contribution to health care in all parts of the world – through local churches, religious institutions and private initiatives, which act on their own responsibility and with respect of the law of each country. These include the sustenance of 5,158 hospitals, 16,523 dispensaries and clinics, 612 leprosaria, and 15,679 homes for the elderly, the chronically ill, or disabled people. With firsthand information coming from these facilities in some of the poorest, isolated, and marginalized communities, my Delegation is obliged to report that the rights detailed in the international instruments and in the SDGs already mentioned are far from being realized.

Mr. President,

Pope Francis decries the selfishness and short-term thinking that sabotage progress on saving the environment, on peace building, and on public health crises as well. He insists on dialogue "as the only way to confront the problems of our world and to seek solutions that are truly effective". [1] Authentic dialogue is honest and transparent. It does not permit the interests of individual countries, or specific interest groups, to dominate discussions. "Science and technology are not neutral". [2] It is our moral obligation to seek, fight and build a better future that we are expected to deliver for our future generations. "There is also the fact that people no longer seem to believe in a happy future; they no longer have blind trust in a better tomorrow based on the present state of the world and our technical abilities. There is a growing awareness that scientific and technological progress cannot be equated with the progress of humanity and history, a growing sense that the way to a better future lies elsewhere". [3]

In order to promote human dignity and to adopt policies rooted in a human rights approach, we need to confront and remove barriers, such as monopolies and oligopolies, lack of access and affordability and, in particular, both overwhelming and unacceptable human greed. If we fully intend to build a better world and future for the generations that will come after us, we must remedy and correct the misalignments and policy incoherence between the intellectual property rights of inventors, innovators or manufacturers and the human rights of human persons. As such, trade could be considered in the context of public health and access to technologies and thus be closely linked to both the fundamental human rights to health and to life. All our efforts must be directed to ensure human dignity, quality of health and life and to the building of a better world for the generations to come.

Thank you, Mr. President.

NOTES

1. [1] Pope Francis, Address to Participants in the Meeting Sponsored by the "Foundation for Sustainable Development" on "Environment Justice and Climate Change", 11 September 2015.
2. [2] Pope Francis, Encyclical Letter *Laudato Si'*, 24 May 2015, 114.
3. [3] *Ibid.*, n. 113.

STATEMENT AT THE 70TH WORLD HEALTH ASSEMBLY

ARCHBISHOP IVAN JURKOVIČ, PERMANENT OBSERVER OF THE HOLY SEE TO THE UNITED NATIONS AND OTHER INTERNATIONAL ORGANIZATIONS IN GENEVA

23 May 2017

Mr. President,

The Holy See delegation recognizes that health promotion is a fundamental aspect of advancing the 2030 Agenda for Sustainable Development, and is also a necessary component for socio-economic stability. It has been duly noted that "weak health systems remain an obstacle in many countries, resulting in deficiencies in coverage for even the most basic health services."[1] The current and emerging global health challenges call for better health systems that are capable of delivering effective and affordable interventions for prevention and treatment to all, especially those in greatest need, those in extreme poverty and the most disadvantaged in our societies, including migrants and refugees, who represent a vexing sign of our times. This is in line with the pledge that "no one will be left behind." [2]

As Pope Francis observed, "the simplest and best measure and indicator for the implementation of the new Agenda for development will be effective, practical and immediate access, on the part of all, to essential material and spiritual goods." [3] Strong and resilient health systems are indeed critical for the achievement of the set goals and targets for health, which above all aim at ensuring healthy lives and promoting well-being for all at every age. [4]

National efforts to build better health systems will certainly require continued technical guidance from the World Health Organisation, as well as support from development partners in order to overcome the funding shortfalls in health. In addition, besides strong and accountable infrastructures, health systems need to keep the human person and his/her physical, emotional and spiritual needs at the centre of the care they provide, in full respect for the sacredness of human life in all its stages and the dignity of every person. [5]

Mr. President, as States embark on planning, investing and implementing measures for the development of quality infrastructure and the creation of resilient health systems, it is important that central governments do not focus only on systems that are directly coordinated and operated by state institutions, but that they have an inclusive approach that embraces all major stake-holders, especially religious organizations whose contribution to health service delivery is fundamental.[6] In fact in many countries, religious organization and other faith based institutions assume significant

responsibility for health systems and thus should be included in the formulation of policies related to health systems and should be given access to adequate resources in order to assure the strength and capacity of such undertakings in the religious and non-governmental sectors.

Lastly, Mr. President, a well-functioning health system ought to have among other things a reliable supply of medicinesand technologies. However, the situation on the ground, as it emerges from the Report of the Secretariat on the progress in the implementation of the 2030 Agenda for Sustainable Development, with regard to access to selected essential medicines, calls for resolute action from the international community. It is recorded that median availability of selected essential medicines is only 56% in the public sector of lower-middle-income countries. Moreover, "innovation for new products remains focused away from the health needs of those living in developing countries… and as little as 1% of all funding for health research and development is allocated to diseases that predominantly affect developing countries."[7] We need to forge partnerships that will help to align health research and development with global health demands and needs, in order to ensure increased access to essential drugs for all. As Pope Francis has affirmed: "health, indeed, is not a consumer good, but a universal right which means that access to healthcare services cannot be a privilege."[8] In this regard, the new Dicastery for the Promotion of Integral Human Development has planned an International Conference around the theme "Addressing Global Health Disparities", which will take place in the Vatican, from 16 to 18 November 2017. You are all most welcome to participate.

Thank you, Mr. President

NOTES

1. [1] World Health Organization (WHO), Progress in implementation of the 2030 Agenda for Sustainable Development, Report by Secretariat, A70/35, 3.
2. [2] United Nations General Assembly resolution 70/1 of September 2015, entitled Transforming our world: the 2030 Agenda for Sustainable Development, preamble para.2
3. [3] Pope Francis, Address during the Meeting with Members of the United Nations General Assembly, 25 September 2015.
4. [4] SDG, 3.
5. [5] United Nations General Assembly, Letter dated 25 September 2016 from the Permanent Observer of the Holy See to the United Nations addressed to the Secretary-General, A/71/1430, 17-19.
6. [6] At present the Catholic Church has over 116,000 social and healthcare institutions world-wide. Cf. Statistical Year Book of the Church 2015, Libreria Editrice Vaticana, Vatican City 2016, pp. 355-365.
7. [7] World Health Organization (WHO), Progress in implementation of the 2030 Agenda for Sustainable Development, Report by Secretariat, A70/35, 28.
8. [8] Pope Francis, Address to Doctors with Africa- CUAMM, 7 May 2016.

MESSAGE TO THE PRESIDENT OF THE PONTIFICAL ACADEMY FOR LIFE ON THE OCCASION OF THE EUROPEAN REGIONAL MEETING OF THE 'WORLD MEDICAL ASSOCIATION' ON 'END OF LIFE' ISSUES

POPE FRANCIS

16 November 2017

(Selected Excerpts)

The growing therapeutic capabilities of medical science have made it possible to eliminate many diseases, to improve health and to prolong people's life span. While these developments have proved quite positive, it has also become possible nowadays to extend life by means that were inconceivable in the past. Surgery and other medical interventions have become ever more effective, but they are not always beneficial: they can sustain, or even replace, failing vital functions, but that is not the same as promoting health.

[…]

It should also be noted that these processes of evaluation are conditioned by the growing gap in healthcare possibilities resulting from the combination of technical and scientific capability and economic interests. Increasingly sophisticated and costly treatments are available to ever more limited and privileged segments of the population, and this raises questions about the sustainability of healthcare delivery and about what might be called a systemic tendency toward growing inequality in health care. This tendency is clearly visible at a global level, particularly when different continents are compared. But it is also present within the more wealthy countries, where access to healthcare risks being more dependent on individuals' economic resources than on their actual need for treatment.

MESSAGE TO THE PARTICIPANTS IN THE 32ND INTERNATIONAL CONFERENCE ON THE THEME: 'ADDRESSING GLOBAL HEALTH INEQUALITIES'

POPE FRANCIS

18 November 2017

(Selected Excerpt)

Last year's Conference took note of encouraging data on the average life expectancy and on the global fight against pathologies, while at the same time pointing out the widening gap between the richer and poorer countries with regard to access to medical products and health-care treatment. Consequently, it was decided to address the specific issue of inequalities and the social, economic, environmental and cultural factors underlying them. The Church cannot remain indifferent to this issue. Conscious of her mission at the service of human beings created in the image of God, she is bound to promote their dignity and fundamental rights.

To this end, the New Charter for Health Care Workers states that "the fundamental right to the preservation of health pertains to the value of justice, whereby there are no distinctions between peoples and ethnic groups, taking into account their objective living situations and stages of development, in pursuing the common good, which is at the same time the good of all and of each individual" [1]. The Church proposed that the right to health care and the right to justice ought to be reconciled by ensuring a fair distribution of healthcare facilities and financial resources, in accordance with the principles of solidarity and subsidiarity. As the Charter notes, "those responsible for healthcare activities must also allow themselves to be uniquely and forcefully challenged by the awareness that 'while the poor of the world continue knocking on the doors of the rich, the world of affluence runs the risk of no longer hearing those knocks, on account of a conscience that can no longer distinguish what is human'" [2].

I am pleased to learn that the Conference has drafted a project aimed at concretely addressing these challenges, namely, the establishment of an operational platform of sharing and cooperation between Catholic health care institutions in different geographical and social settings. I willingly encourage those engaged in this project to persevere in this endeavour, with God's help. Healthcare workers and their professional associations in particular are called to this task, since they are committed to raising awareness among institutions, welfare agencies and the healthcare industry as a whole, for the sake of ensuring that every individual actually benefits from the right to health care. Clearly, this depends not only on healthcare

services, but also on complex economic, social, cultural and decision-making factors. In effect, "the need to resolve the structural causes of poverty cannot be delayed, not only for the pragmatic reason of its urgency for the good of society, but because society needs to be cured of a sickness which is weakening and frustrating it, and which can only lead to new crises. Welfare projects, which meet certain urgent needs, should be considered merely temporary responses. 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." [3] I would like to focus on one aspect that is fundamental, especially for those who serve the Lord by caring for the health of their brothers and sisters. While a well-structured organization is essential for providing necessary services and the best possible attention to human needs, healthcare workers should also be attuned to the importance of listening, accompanying and supporting the persons for whom they care.

In the parable of the Good Samaritan, Jesus shows us the practical approach required in caring for our suffering neighbour. First, the Samaritan "sees". He notices and "is moved with compassion" at the sight of a person left stripped and wounded along the way. This compassion is much more than mere pity or sorrow; it shows a readiness to become personally involved in the other's situation. Even if we can never equal God's own compassion, which fills and renews the heart by its presence, nonetheless we can imitate that compassion by "drawing near", "binding wounds", "lifting up" and "caring for" our neighbour [4].

A healthcare organization that is efficient and capable of addressing inequalities cannot forget that its *raison d'être*, which is compassion: the compassion of doctors, nurses, support staff, volunteers and all those who are thus able to minimize the pain associated with loneliness and anxiety.

Compassion is also a privileged way to promote justice, since empathizing with the others allows us not only to understand their struggles, difficulties and fears, but also to discover, in the frailness of every human being, his or her unique worth and dignity. Indeed, human dignity is the basis of justice, while the recognition of every person's inestimable worth is the force that impels us to work, with enthusiasm and self-sacrifice, to overcome all disparities.

Finally, I would like to address the representatives of the several pharmaceutical companies who have been invited to Rome to address the issue of access to antiretroviral therapies by paediatric patients. I would like to offer for your consideration a passage of the New Charter for Healthcare Workers. It states: Although it cannot be denied that the scientific knowledge and research of pharmaceutical companies have their own laws by which they must abide – for example, the protection of intellectual property and

a fair profit to support innovation – ways must be found to combine these adequately with the right of access to basic or necessary treatments, or both, especially in underdeveloped countries, and above all in the cases of so-called rare and neglected diseases, which are accompanied by the notion of orphan drugs. Health care strategies aimed at pursuing justice and the common good must be economically and ethically sustainable. Indeed, while they must safeguard the sustainability both of research and of health care systems, at the same time they ought to make available essential drugs in adequate quantities, in usable forms of guaranteed quality, along with correct information, and at costs that are affordable by individuals and communities" [5].

I thank all of you for the generous commitment with which you exercise your valued mission. I give you my Apostolic Blessing, and I ask you to continue to remember me in your prayers.

NOTES

1. [1] New Charter for Health Care Workers, n. 141.
2. [2] *Ibid.* n. 91; Pope Benedict XVI, Encyclical Letter *Caritas in Veritate*, 29 June 2009, 75.
3. [3] Pope Francis, Apostolic Exhortation *Evangelii Gaudium*, 24 November 2013, 202.
4. [4] Lk 10:33-34.
5. [5] *Ibid.* n. 92

ADDRESS TO THE MEMBERS OF THE DIPLOMATIC CORPS ACCREDITED TO THE HOLY SEE FOR THE TRADITIONAL EXCHANGE OF NEW YEAR GREETINGS

POPE FRANCIS

8 January 2018

(Selected Excerpt)

Defending the right to life and physical integrity also means safeguarding the right to health on the part of individuals and their families. Today this right has assumed implications beyond the original intentions of the Universal Declaration of Human Rights, which sought to affirm the right of every individual to receive medical care and necessary social services. [10] In this regard, it is my hope that efforts will be made within the appropriate international forums to facilitate, in the first place, ready access to medical care and treatment on the part of all. It is important to join forces in order to implement policies that ensure, at affordable costs, the provision of medicines essential for the survival of those in need, without neglecting the area of research and the development of treatments that, albeit not financially profitable, are essential for saving human lives.

Notes

1. [10] Universal Declaration of Human Rights, art. 25

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The right to the highest attainable standard of physical and mental health is a basic human right.

In the last decades, despite formal recognition of the right to health, its full enjoyment remains, for millions of people around the world, an elusive goal, due to obstacles in access to high quality, accessible, affordable, and acceptable life-saving medicines. Among the challenges experienced by many countries, there is a predominant emphasis on profitability of medicines and diagnostic tools, resulting in prohibitive price structures. This is the case for many people living with HIV and for millions of people to continue to be newly infected by this illness. Even though there has been much progress with the development of antiretroviral medicines for adults, children living with HIV have not been accorded priority attention in this field. These children are part of our future; they experience much suffering during their brief lives. Without access to early diagnosis and antiretroviral treatment, more than one-third of them die before their first birthday, and one-half die before their second birthday.

International efforts to address these serious challenges already have been undertaken by the Holy See, in collaboration with UNAIDS, PEPFAR, WHO, *Caritas Internationalis*, WCC-EAA, EGPAF, governments, private industry engaged in developing and producing pharmaceuticals and diagnostic tools, and faith-based organizations providing such services or engaged in advocacy related to pediatric HIV. Some of these projects are presented and explained in this publication.

Without continued, timely, effective and cooperative actions, HIV will continue to claim the lives of too many children and adolescents. There is an urgent need to implement attainable and measurable milestones in the efforts to end HIV among children by 2020 in order to "leave no child living with HIV behind". The collaboration between international organizations, governments, the private sector, non-governmental organizations and faith-based organizations is the key to close the gap between good intentions and the reality on the field.

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