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# Symposium: Clinical Trials and Access to Essential Medicines in African Countries

## Access to Essential Medicines in African Countries: An Introduction

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The concept of a human right to health was first recognized internationally by the World Health Organization in 1946 when it declared that “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.”<sup>1</sup> Since that time, the right has become encoded and entrenched in both conventional and customary international law.

Article 25 of the Universal Declaration of Human Rights (1948) recognizes the right to health as part of an adequate standard of living closely linked with other economic and social rights such as “food, clothing, housing and medical care and necessary social services.”<sup>2</sup>

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1. Economic and Social Council, Constitution Adopted by the United States of America and Other Governments respecting a World Health Organization 62 Stat. 2679, 14 U.N.T.S. 185 (June 21, 1948) (establishing the World Health Organization, originally signed 22 July 1946).

2. Universal Declaration of Human Rights, G.A. Res. 217 A (III), U.N. GAOR, 3d Sess.,

Today, the *locus classicus* of the right in international law is Article 12 of the International Covenant on Economic, Social and Cultural Rights (1976) which provides that States Parties recognize “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” and that steps are to be taken in order to realize the right in the areas of (a) reduction of the still-birth rate and infant mortality; (b) improvement of environmental and industrial hygiene; (c) prevention, treatment and control of diseases; and (d) creation of conditions assuring to all medical service and attention in the event of sickness.<sup>3</sup> Various other international and regional human rights instruments have similar provisions.<sup>4</sup>

It was within the context of tackling the global HIV/AIDS crisis in the 1990s that the first practical and theoretical linkages started to be made between the fields of health and human rights. At a normative level, a key breakthrough occurred in 2000 when the UN Committee on Economic, Social and Cultural Rights issued General Comment 14 on the right to health which had the effect of providing authoritative guidance on the scope and content of the right as well as ushering in a new era of work. The focus of the General Comment is on the interrelated and essential elements of availability (sufficient quantity); accessibility (physical, economic and non-discrimination); acceptability (being respectful of medical ethics and being culturally appropriate); and quality (scientifically and medically appropriate). The committee further sought to give legal content to the obligations assumed by States (1) to respect (all persons and without interference to traditional care); (2) to protect (with legislative and other measures and include no restrictions to access); and (3) to fulfill (with positive measures in national, political, legal, and policy systems) the right to health.

Since the early 2000s, numerous UN and regional human rights reports have explored how to operationalize the right to health according to these criteria. This has required translating legal standards into the design and functioning of entire health systems so as to ensure not

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1st plen. mtg., U.N. Doc. A/810 (Dec. 12, 1948), art. 25.

3. G.A. Res. 2200 (XXI) A, annex, International Covenant on Economic, Social and Cultural Rights, art. 12 (Dec. 16, 1966).

4. European Social Charter art. 11, *opened for signature* Oct. 18, 1961, E.T.S. No. 035 (entered into force Feb. 26, 1965); Organization of American States [OAS] Res. XXX, American Declaration of the Rights and Duties of Man, art. 11 (May 2, 1948); Org. of African Unity [OAU], African Charter on Human and Peoples' Rights art. 16, June 17, 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 ILM. 58 (1982); G.A. Res. 44/25, Convention on the Rights of the Child, art. 23–4 (Nov. 20, 1989); G.A. Res. 34/180, Convention on the Elimination of Discrimination Against Women, art. 12 (Dec. 18, 1979).

merely the identification of violations *ex ante* but the upfront promotion and protection of the right. The key elements in this normative development of the right can be traced through the reports of the successive UN Special Rapporteurs on the right to health and, in particular, the widely regarded reports of Paul Hunt written between 2002–2008. Three elements, in particular, are discernable.

First, a concern not only with outcomes (such as provision of essential medicines and safe drinking water) but also with process (e.g., transparency, participation, and non-discrimination). Second, the realization that the health of individuals, communities and populations requires more than medical care but also a focus on the underlying determinants of health such as access to safe water, adequate sanitation, an adequate supply of food and housing, healthy environmental conditions, and health-related education. And third, the proposition that the right gives rise to legally binding obligations on States, especially the obligation to ensure that its health system includes certain features and measures such as a comprehensive national plan and a minimum basket of health-related services and facilities.<sup>5</sup>

The key question addressed in this Symposium<sup>6</sup> is how exactly access to essential medicines is recognized and operationalized in both theory and practice as part of the human right to health, and what barriers exist—historical, political, legal and socioeconomic—to the realization of this right in the specific context of states in southern Africa. In particular, how might international legal regimes, in the areas of trade and intellectual property, pose obstacles to access to essential medicines in African countries.<sup>7</sup>

The genesis of the Symposium lies in a remarkable collaboration that has developed between Chancellor College Faculty of Law in Zomba, Malawi and the University of Maryland Frances King Carey School of Law in Baltimore, Maryland, United States which began in 2010 when the Global Health Interprofessional Council (GHIC) at the University of Maryland first sent a multidisciplinary team of faculty

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5. For a comprehensive discussion of the right-to-health approach to strengthening health systems, see Gunilla Backman, Paul Hunt et al., *Health Systems and the Right to Health: An Assessment of 194 Countries*, 372 LANCET 2047 (2008).

6. The Symposium on Clinical Trials and Access to Essential Medicines in African Countries was held at the University of Maryland Frances King Carey School of Law on October 29–30, 2015.

7. Other topics addressed at the Symposium included the law and ethics of clinical trials and the obligations owed to host communities by clinical researchers and sponsors. These papers are published in a parallel symposium issue of the *Journal of Health Care Law and Policy*, volume 19 (2016).

and students to Malawi to study the health and legal rights of orphans and vulnerable children. Since then, successive visits of students and faculty have been made and, in 2013, the International & Comparative Law and Law & Health Care Programs at Maryland Law School teamed up to organize a series of lectures and a workshop at Chancellor College on the right to health and HIV/AIDS, as well as to discuss the HIV/AIDS legal clinics at the two schools.<sup>8</sup>

The articles published following this Symposium reflect the unique and interdisciplinary nature of this collaboration. The first article by Lucie White, *Getting Real About Essential Medicines: “The Last Kilometer,”*<sup>9</sup> squarely addresses the question of what it means to realize the human right to essential medicines. White begins with the hypothetical story of A, an eighteen-year-old girl in a West African nation, who develops a form of mental illness. Her point is that the vantage point from which to evaluate the right to essential medicines must be “where the people who need the drug actually stand.”<sup>10</sup> Realization of the right, in other words, must be assessed from the perspective of the rights holders’ themselves, and this requires a systemic perspective on “the *institutions and systems* that failed to deliver the medicine that ‘last kilometer’ to the people who need them.”<sup>11</sup>

White seeks to reframe the right to essential medicines as a “call for pragmatic action” that “addresses the treatment challenge from the bottom up and top down, so as to connect people with what they need to maintain wellbeing, even while sick, not through drugs alone, but through *drugs within systems of care.*”<sup>12</sup> In doing so, she challenges four aspects of the contemporary debate. First, the concept of essential medicines “since its origins has been constrained within a formalistic frame.”<sup>13</sup> Second, the “dominant frame for understanding human rights has been similarly formalistic” and thus any hoped-for convergence between rights doctrine and access to essential medicine policy has

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8. Further exchange visits were organized in 2015 in relation to the Access to Justice clinic at the Maryland Law School and spanned issues of criminal justice reform, effective assistance of counsel, and bail.

9. Lucie White, *Getting Real About Essential Medicines: “The Last Kilometer,”* 31 MD. J. INT’L L. 79 (2016).

10. *Id.* at 81.

11. White here cites Paul Farmer’s notion of “structural violence” describing the social arrangements embedded in forms of political and economic organization that cause injury to people. See Paul Farmer, *Structural Violence and Clinical Medicine*, 3 PLOS MED. 1686 (2006).

12. White, *supra* note 9, at 81.

13. *Id.* at 87.

been undermined.<sup>14</sup> Third, the movement for HIV/AIDS treatment, in effect, reframed the right to essential medicines from “a formalistic conception into a call for social movement and pragmatic action for change”<sup>15</sup> (as reflected, for example, in the landmark decision of the South African Constitutional Court in *Minister of Health v. TAC*).<sup>16</sup> And finally, a “public health movement that embeds within it the right to essential medicines can transform the demand for ‘access to essential medicines’ into a call—and a movement—for holistic systems of care.”<sup>17</sup>

The second article by Danwood Chirwa, *Access to Medicines and Health Care in Sub-Saharan Africa: A Historical Perspective*,<sup>18</sup> discusses a vital and usually ignored dimension of the challenge of improving access to essential medicines and medical care in African states: an historical account of the problem and the need to understand the “historical genesis and context” of these challenges. Chirwa addresses five broad periods in his analysis of the nature of health care systems in Africa: first, the pre-colonial period and the ways in which approaches to health were “intricately linked to African communitarian philosophy and beliefs”;<sup>19</sup> second, the simultaneously “modernizing” and “marginalizing” impact of Christian missionaries during the period of colonialism in the late nineteenth century; third, the legal, political and economic changes effected by African nationalists in the post-independence period which both sought to extend medical services to rural areas while leaving the colonial health system in place and ultimately resulted in “an uneasy relationship between traditional medicine and African customs and traditions, on the one hand, and western medicine and the received law, on the other”;<sup>20</sup> fourth, the negative economic impact of the implementation by African governments of structural adjustment programs in the third and fourth decades following independence; and finally, the generally positive effects on health policy of the far-reaching democratization and constitutional reforms of the 1990s, especially regarding the acceptance of economic, social and cultural rights.

The third article by Lisa Forman, *The Inadequate Global Policy*

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14. *Id.*

15. *Id.*

16. (2002) (5) SA 721 (CC).

17. White, *supra* note 9, at 87.

18. Danwood Chirwa, *Access to Medicines and Health Care in Sub-Saharan Africa: A Historical Perspective*, 31 MD. J. INT’L L. 21 (2016).

19. *Id.* at 23.

20. *Id.* at 29.

*Response to Trade-Related Intellectual Property Rights: Impact on Access to Medicines in Low- and Middle-Income Countries*,<sup>21</sup> shifts focus to the question of how trade and intellectual property rules and regimes themselves may operate in international law to derogate the rights to health and life protected in international and regional human rights treaties. Forman analyzes, in particular, the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement)<sup>22</sup> and the increasing use by states of bilateral and free trade agreements (FTAs). The inaccessibility of essential medicines in low- and middle-income countries under the strictures of these regimes suggests that exiting global policy initiatives have failed and that "bolder measures" are needed if the drug gap is to be remediated. For Forman, this must take the form not merely of TRIPS flexibilities (which "turn the fundamental human right to health and affordable medicines into a rigidly restricted exception to a property right")<sup>23</sup> but actual suspension of the application of trade-related intellectual property rights to essential drugs for affected countries in southern Africa. If this is to occur, the impetus must come from social actors and movements.

The final article by Chikosa Banda, *Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern Africa Development Community Region*,<sup>24</sup> continues the focus on the 1994 TRIPS Agreement and the significant barriers this regime poses to access to essential medicines in developing countries. Banda explores in depth the various flexibilities, transition periods, waivers and exemptions potentially available to "least-developed countries" in terms of TRIPS compliance. He suggests that these flexibilities do offer countries in the southern African region "some policy space to facilitate the development of local production capacity" and that this can be "done through the creation of legal environments that permit the copying and imitation of technologies."<sup>25</sup>

Most discussions and reforms to date, however, have focused on

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21. Lisa Forman, *The Inadequate Global Policy Response to Trade-Related Intellectual Property Rights: Impact on Access to Medicines in Low- and Middle-Income Countries*, 31 MD. J. INT'L L. 8 (2016).

22. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

23. *Id.* at 19.

24. Chikosa Banda, *Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern Africa Development Community Region*, 31 MD. J. INT'L L. 44 (2016).

25. *Id.* at 49.

facilitating the importation of essential medicines from countries such as India, rather than on spurring local and regional innovation and production of pharmaceuticals. Banda's thesis is that importation of generic, essential medicines is at best a short- and medium-term solution and that countries in the region must move towards local production in order to achieve a sustainable long-term solution. While the structural and fiscal challenges to pharmaceutical innovation and access are "multiple and multifaceted," and while much "policy incoherence" remains in and between national laws, countries in the region are "increasingly becoming aware of the need to find sustainable solutions to the problem of how to access pharmaceutical products" and this realization is slowly leading to patent law reforms aimed at domesticating TRIPS flexibilities and harnessing of economies of scale in order to stimulate local and regional production.<sup>26</sup>

These are vastly complex and difficult questions and, as the articles in the Symposium so vividly illustrate, the struggle to realize the right of access to essential medicines in African countries is, in many respects, just beginning. Two strong themes, in particular, emerge: first, that much reigning neoliberal orthodoxy in the field of health and human rights needs urgently to be rethought and political space opened up to reconnect issues of poverty and human rights as matters of justice (not merely policy); and second, that gross violations of the right to health require us to look beyond immediate local and national contexts and to examine more critically the interconnected history, political economy and powerful transnational institutions that continue to shape the health-related laws and policies in post-colonial African states.

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26. *Id.* at 53–55, 73.