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Moral, ethical and human rights arguments for using experimental and clinically unproven drugs to combat the Ebola Virus Disease

Summary

This article discusses and considers the arguments in favour of using clinically unproven medicine in the fight against terminal diseases, with specific reference to the Ebola Virus Disease (EVD) in Africa. In particular, this proposition is supported from a moral, ethical and human rights-based approach. To this end, two philosophical foundations are considered, namely the utilitarian theory of morality and the rights-based approach. Furthermore, emphasis is placed on the role of African leadership in putting in place best and co-ordinated measures to combat EVD. An analysis of the use of clinically untested or unproven drugs is articulated by analysing the famous American case of *Abigail Alliance for Better Access to Developmental Drugs.* From a utilitarian perspective, access to unproven drugs may only be morally and ethically justified if it will positively combat EVD. In terms of the rights-based approach, access must be in the public interest and should not violate the rights of other persons. After considering scholarship that argues for and against the creation of a constitutionally guaranteed right of access to unproven drugs, it is concluded that a delicate balancing of all relevant issues is not as easy as it appears. Nevertheless, the article recommends that African governments leverage the 2014 statement by the WHO that it is ethical to use untested drugs subject to meeting certain conditions in their efforts to combat EVD.

1.   Introduction

1.1   Background and historical context

The Ebola Virus Disease (EVD) resurfaced in West Africa, with rising fatalities reported in the Democratic Republic of Congo (DRC) during 2018. The outbreak was the ninth of its kind since EVD first appeared in 1976. It is argued that "the issue of access for terminally ill patients to Phase I drugs is as much a moral, legal

and political issue today as it was 20 years ago".[1] As mentioned, the first outbreak of EVD in the DRC (at the time known as Zaire) is reported to have occurred in 1976. The disease then resurfaced in December 2013, with Guinea as the epicentre of the outbreak. The World Health Organization (WHO) was notified of the outbreak on 23 March 2014. On 8 August 2014, the WHO issued a public declaration that EVD is a "public health emergency of international concern"[2] and that its rampage in West Africa made it one of the world's catastrophic clinical diseases. Feldman observed the alarming numbers of EVD infections and reported that the subsequent deaths indicated the inability or the limitation of "public health systems to respond to rare, highly virulent communicable diseases".[3]

On 11 August 2014, the WHO set up an Advisory Group on the Ebola Virus Disease Response (WHO Ebola Advisory Group) consisting of individuals from different disciplines and backgrounds with varied expertise, including ethics, epidemiology, disease control, EVD treatment and care, as well as human rights. The Advisory Group had to, among others, investigate and advise on the ethical implications of the use of untested medical interventions such as medicines, vaccines and passive immunotherapy to treat EVD patients. It concluded that it was ethically and morally correct to administer unproven interventions during outbreaks such as the EVD epidemic in Guinea. However, certain conditions for doing so were set. These included that the process must be transparent as far as possible and that it should specifically address a host of ethical issues such as freedom of choice, care, confidentiality, informed consent, respect for, and preservation of patient dignity, and due consideration of the interests of the communities affected by the disease. At issue at the time was the use of ZMapp on human beings,[4] an experimental Ebola treatment drug that was not tested for human safety or effectiveness. It was reported that primates survived after taking ZMapp 24 to 48 hours after infection.[5] Furthermore, the use of ZMapp could still be beneficial if administered 4 to 5 days after infection.[6]

The EVD outbreak spawned a race by pharmaceutical companies and countries to develop appropriate medical intervention. For instance, TKM-Ebola, an experimental antiviral drug for EVD developed by Tekmira Pharmaceuticals Corp and now known as Arbutus Biopharma, had already begun human clinical trials. According to Schmidt and Chang, Phase I of the clinical trial began in January 2014 with the aim of assessing its safety and efficacy, tolerability and pharmacokinetics in respect of adult human

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1   Schuklenk & Lowry 2009:19.
2   WHO 2014:1.
3   Schuklenk & Lowry 2009:19.
4   ZMapp was administered in its clinically unapproved state to two American medical workers, Dr Kent Brantly and Nancy Writebol, who had contracted EVD in Liberia. Both individuals were reported to have recovered. See, in general, Chiappelli *et al* 2015:28.
5   Sullivan *et al* 2000:605-609.
6   Goodman 2014:1087.

subjects.[7] It was also reported at the time that a Chinese pharmaceutical company and a former military scientific unit (Sihuan Pharmaceutical Holdings Group Ltd and the Academy of Military Medical Sciences, respectively) sought to obtain permission from the China Food and Drug Administration to use the drug JK-05 for use in combating EVD.[8]

WHO Ebola Response Teams were set up in different parts of West Africa as part of the initiative to control the EVD outbreak. For instance, such a response team was set up in North Kivu, a province in north-eastern DRC that was experiencing a rapid spread of the disease.[9] Results of a study conducted by the team, based on data from activities of the teams in Guinea, Liberia, Nigeria, and Sierra Leone, painted a grim picture of a region in dire need of help.[10] In my view, these results were instrumental in opening the debate as to access to experimental and clinically unproven drugs in certain cases. According to this study:

> The majority of patients are 15 to 44 years of age (49.9% male), and we estimate that the case fatality rate is 70.8% (95% confidence interval [CI], 69 to 73) among persons with known clinical outcome of infection. The course of infection, including signs and symptoms, incubation period (11.4 days), and serial interval (15.3 days), is similar to that reported in previous outbreaks of EVD. On the basis of the initial periods of exponential growth, the estimated basic reproduction numbers (R0) are 1.71 (95% CI, 1.44 to 2.01) for Guinea, 1.83 (95% CI, 1.72 to 1.94) for Liberia, and 2.02 (95% CI, 1.79 to 2.26) for Sierra Leone. The estimated current reproduction numbers (R) are 1.81 (95% CI, 1.60 to 2.03) for Guinea, 1.51 (95% CI, 1.41 to 1.60) for Liberia, and 1.38 (95% CI, 1.27 to 1.51) for Sierra Leone; the corresponding doubling times are 15.7 days (95% CI, 12.9 to 20.3) for Guinea, 23.6 days (95% CI, 20.2 to 28.2) for Liberia, and 30.2 days (95% CI, 23.6 to 42.3) for Sierra Leone. Assuming no change in the control measures for this epidemic, by 2 November 2014, the cumulative reported numbers of confirmed and probable cases are predicted to be 5740 in Guinea, 9890 in Liberia, and 5000 in Sierra Leone, exceeding 20,000 in total.[11]

1.2 Scope of the article

This article considers arguments for and against the use of clinically unproven medicine in the fight against terminal diseases, with specific

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7   Schmidt & Chang "Looking beyond ebola: Validated RNAi delivery platform and proprietary pipeline", http://www.investorvillage.com/uploads/86439/files/TKM-2014-08-18_Leerink.pdf (accessed on 20 August 2014).
8   See Huang 2017:1-7.
9   See, in general, Branswell, https://www.statnews.com/2018/10/23/ebola-response-teams-struggling-vaccine-tracking/ (accessed on 5 February 2019).
10   For more information on the study, including methods of data collection and country results, see, in general, WHO Response Team 2014. This study is a result of authorship and contribution of over 30 members of the WHO Ebola Response Team.
11   WHO Response Team 2014:1481.

reference to the EVD. Advocacy for the granting of access to clinically unproven drugs or experimental drugs based on moral, ethical and human rights to health remains, in my view, a consistently topical issue that must be conclusively addressed.[12]

In light of disturbingly large numbers of EVD fatalities noted in 1.1 above, a need exists for a critical reflection on the moral, ethical and human rights-based approach (HRBA) regarding access to unproven drugs in the treatment of EVD patients. I am mindful that further issues that must be taken into account are varied and include, for example, and given the particular nature of the EVD:

• Would it be possible to meet the conditions set by the WHO Advisory Group in practice?

• What lessons can Africa and West Africa, in particular, learn from the United States regarding access to essential unproven drugs to combat EVD and other debilitating diseases and epidemics?

Some of these issues may be understood in the context of the famous American litigation by the *Abigail Alliance for Better Access to Developmental Drugs* (*Abigail Alliance*), which involved numerous cases.[13] These cases changed how the world viewed debates on access to medicine and issues of responsible clinical practice. Malinowski views it as having spurred legislative changes in this area of the law in the United States.[14] It all started with the plight of a 21-year-old young lady, Abigail, who suffered from head and neck cancer. Abigail's attempts to obtain permission from the Food and Drug Administration (FDA) to use an experimental new drug (Erbitux), which was not approved by the FDA, were unsuccessful.[15] After her death, her father, Frank Burroughs, formed the Abigail Alliance for Better Access to Developmental Drugs ("Abigail Alliance")[16] in 2001 to

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12 To some, the debate on the access to untested drugs may be perceived as a moot point – at least in the American context – in light of the 30 May 2018 signing into law by United States President Donald Trump of the *Right to Try Act* (H.R.5247), which is a federal law allowing access to unproven medicine and therapies outside the existing United States Food and Drug Administration (FDA) clinical trials framework.

13 See *Abigail Alliance for Better Access to Development Drugs* (*Abigail I*) v. *McClellan*, No. 03-1601 (RMU), 2004 WL 3777340, (D.D.C. Aug. 30, 2004); *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach (Abigail II*), 445 F.3d 470 (D.C. Cir. 2006), panel rehearing denied, November 21, 2006; *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach (Abigail Alliance III)*, 495 F.3d 695, 697. (*D.C. Cir. 2007*); *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach (Abigail IV), 128 S. Ct. 1069 (2008*).

14 See Malinowski 2014:630, arguing that the *Abigail* litigation "has and presumably will continue to inspire legislative proposals", such as the 2005 *Access, Compassion, Care, and Ethics for Seriously Ill Patients Act* introduced in the United States Senate in 2005.

15 See Ott 2008:822.

16 Abigail Alliance for Better Access to Developmental Drugs is an advocacy group of terminally ill patients and their supporters who have sought to

champion the cause of terminally ill patients who are in desperate need of access to experimental drugs.

Before proceeding further, it is necessary to remark on the relevance of the *Abigail* cases in the African context.

2.   Justification for the relevance of the *Abigail Alliance for Better Access to Developmental Drugs* cases in the African context

The question is: How relevant and important is the *Abigail* line of cases for the African context? The South African constitutional provision on the right to public healthcare, for example, contextualises arguments for the consideration of the *Abigail* cases and the importance of the discourses around it for the African context. *The South African Constitution* of 1996 does not provide for the issue of the right of access to an experimental or clinically unproven drug. Yet, sec. 27(1)(a) of the *Constitution* guarantees "everyone" the right to have access, *inter alia*, to "health care services". Sec. 27(2) further obliges the state to "take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation" of this right as well as the other rights covered in sec. 27.

Although the meaning and significance of sec. 27(1)(a) was considered in the case of *Minister of Health v Treatment Action Campaign*[17] (hereafter "the *TAC* case"), no single case has yet addressed – or imported into the purview of sec. 27 – the right to access experimental or clinically unproven drugs. It is submitted, however, that a flexible approach must be adopted towards understanding sec. 27(1)(a) of the *Constitution*. This view is based in part on the following. First, there is no evidence that the drafters of the *Constitution* did not anticipate the debate on sec. 27(1)(a) covering unproven medicines and medical treatments, and there is no express exclusion of the same from the ambit of the provision. There is, therefore, no direct or indirect engagement with the issue as to how clinically unproven drugs could enhance and promote the right to healthcare services.

Secondly, in my view, sec. 27(2) provides a window of opportunity for clinically unproven drugs to be considered as part of the "other measures" that may be necessary to advance the right of access to healthcare services.

Lastly, the understanding of the normative content of the public health rights in South Africa (and Africa) must be treated as an evolving content. In this regard, it is perhaps of importance to note that it is clear from the wording of sec. 27 that its drafters avoided treating healthcare in a narrow

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advance the notion that individuals should have a right to obtain drugs that are in a clinical trial phase before the FDA has given the manufacturer permission to market the drug in the United States. See Korvatis 2006:157-158, reporting that the mission of Abigail Alliance is "[t]o help cancer patients and others with life threatening illnesses".

17   *Minister of Health v Treatment Action Campaign* 2002 (5) SA 721 (CC).

sense "just medicines or clinics".[18] Hence, it was linked to other important rights, including those related to housing and nutrition, and other incidental social and environmental factors.[19] Although it dealt primarily with the implementation of measures necessary for the prevention of mother-to-child transmission of HIV, the *TAC* case, for example, was also litigated on the backdrop of concerns of the safety of antiretroviral drugs. In this case, the Constitutional Court upheld the High Court order to make Nevirapine available to all HIV-positive pregnant women, thus granting the petition of the Treatment Action Campaign (TAC), which had argued that refusing pregnant mothers access to Nevirapine violated the right to healthcare services protected under secs 27(1) and 28(1)*(c)* of the *Constitution*. According to the Court, the government was wrong to severely restrict access to antiretroviral medicine that was effective in reducing the risk of mother-to-child HIV transmission.

Others may argue that in arriving at this decision, the court in the *TAC* case was convinced that the "safety and efficacy of nevirapine … have been established and the drug is being provided by government itself to mothers and babies at the pilot sites in every province."[20] However, it must not be discounted that what also informed the decision of both courts was the high prevalence of HIV/AIDS and the increasing number of AIDS orphans.[21] Subsequently, in November 2003, the State announced its approval of *South Africa's Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment* intended to provide ARV treatment to up to 1.5 million people by 2008. This plan took cognisance of the claims by civil society that access to treatment is a human right. Another important observation is that, in the case of *Purohit and Moore v The Gambia,*[22] *(Purohit)*, the African Commission on Human and Peoples' Rights held that states parties have an obligation to ensure that healthcare facilities and commodities, including medicines, are made available to citizens.[23] It is, therefore, argued that providing access to unproven drugs to avert national disasters and pandemics such as EVD may be justified under the need for the State to discharge its constitutional obligations regarding the right to health, and relevant continental and international requirements to provide access to public healthcare and facilities.

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18   See sec. 27. A background to health law and human rights in South Africa. Health and Democracy, http://www.section27.org.za/wp-content/uploads/2010/04/Chapter1.pdf, at 9. In this instance, sec. 27 refers to a public interest law centre or organisation that takes its name from sec. 27 of the *Constitution of the Republic of South Africa* of 1996. Sec. 27 as an organisation "seeks to achieve substantive equality and social justice in South Africa".

19   See sec. 27. A background to health law and human rights in South Africa. Health and Democracy, http://www.section27.org.za/wp-content/uploads/2010/04/Chapter1.pdf:7-8.

20   See *Minister of Health v Treatment Action Campaign*:par. 72.

21   To date, EVD has claimed many lives and created many orphans in Africa.

22   *Purohit and Moore v The Gambia (Purohit), Communication* 241/ 2001 (2003) AHRLR 96 (ACHPR 2003).

23   *Purohit and Moore v The Gambia (Purohit), Communication*:paras. 80-81.

Furthermore, healthcare rights are espoused in a number of international and regional human rights instruments. These include, for example, the Universal Declaration of Human Rights (UDHR);[24] the International Covenant on Economic, Social and Cultural Rights (ICESCR);[25] the Convention on the Elimination of all forms of Discrimination Against Women (CEDAW);[26] the Convention on the Rights of the Child (CRC);[27] the African Charter on Human and Peoples' Rights (African Charter);[28] the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa,[29] and the African Charter on the Rights and Welfare of the Child (African Children's Charter).[30]

Even though the *Abigail* cases did not set an international precedent for justifiability of access to unproven drugs, they highlight how healthcare rights can be promoted and advanced in an innovative fashion. Even at its trial stage, for instance, ZMapp proved its efficacy in arresting EVD on the two American medical workers. Surely, its efficacy in reducing the spread of EVD in Africa should not be discounted merely because it is still on trial stage. African states must be proactive if EVD is to be controlled. To this end, the *TAC* case provides a good example of the pro-active implementation of public health rights when the court rejected the *amici* argument for it to draw a distinction between a minimum core content of the right to healthcare and the obligations imposed on the state in terms of sec. 27(2) of the *Constitution*, which could have meant that the TAC's case could fail. In my view, the *TAC* and *Purohit* cases are, with the necessary qualifications, instructive in considering the debate of access to unproven drugs to deal with the problem of EVD in Africa.[31]

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24   See the Universal Declaration of Human Rights (UDHR):art. 25.
25   See the International Covenant on Economic, Social and Cultural Rights (ICESCR):art. 12.
26   See the Convention on the Elimination of all Forms of Discrimination Against Women (CEDAW):art. 14(2)(b).
27   See the Convention on the Rights of the Child (CRC):arts. 3(3) and 24.
28   See the African Charter on Human and Peoples' Rights (African Charter):art. 4.
29   See the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa:art. 4(h).
30   See the African Charter on the Rights and Welfare of the Child (African Children's Charter):art. 14.
31   In South Africa, for example, there are already unregulated and untested medicines on the market over which the government of South Africa, through its Medicines Regulatory Affairs Cluster of the Department of Health, and the Medicines Control Council have failed to exercise regulatory oversights. Some are marketed as medical devices and not as medicines. See *Omegalabs (Pty) Ltd v Medicines Control Council and Others* (32570/2015) [2016] ZAGPPHC 1157 (7 December 2016).

3. Insights from the United States on access to unproven drugs: Overview of the *Abigail* cases

3.1 General

The Supreme Court of Florida, in the case of *In re Guardianship of Estelle M. Browning,*[32] stated that an adult person of sound mind has "the fundamental right to the sole control of his or her person",[33] including the "constitutional right to choose or refuse medical treatment, and that right extends to all relevant decisions concerning one's health".[34] The decision, though it dealt with the question of foregoing medical intervention, is one of the many that generated a sound jurisprudence in the United States dealing with rights to health. The issue, in this case, was whether the patient's wish not to be on life support should be respected.[35] The patient, an 89-year-old Mrs Browning, had earlier signed a living will stating her preference not to be placed on any life-support machines.[36] But the State of Florida refused to honour that wish. It was argued that the individual's wishes regarding medical treatment should be respected and be free of government intrusion, except where there is a compelling and overriding government interest. The trial court "entered an order denying the petition to terminate".[37] The Court held that the evidence concerning Mrs Browning was "limited and troubling" for the court to rule in her favour. Also, that her condition was not "terminal" for the purposes of the relevant State of Florida statute that created the right to refuse life-prolonging medical interventions.[38] However, the District Court did not agree with the trial court and proceeded to state that an individual has "the right to reject life-prolonging or life-sustaining procedures".[39] The Court also emphasised that the state can "override the individual's self-determination if the individual's decision is outweighed by various state interests",[40] including the protection of third parties and the preservation of medical integrity and ethics. The District Court also buttressed as an established rule that "an incompetent adult patient has the same constitutional right to refuse medical treatment as a competent patient".[41] The District Court ruling was taken on review before the Florida Supreme Court.[42] The Supreme Court affirmed the decision of the district court and answered in the affirmative the question as to whether the guardian of a patient who is incompetent but not in a permanent vegetative state and who suffers

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32 *In re Guardianship of Estelle M. Browning* (*Browning I*) 543 So.2d 258, 275 (Fla. 2d DCA 1989). See, in general, Calder 1992:291.
33 *Browning I:8.*
34 *Browning I:261.*
35 *Browning I:11.*
36 *Browning I:262.*
37 *Browning I:263.*
38 *Browning I:264.*
39 *Browning I:265.*
40 *Browning I:265.*
41 *Browning I:267.*
42 In Re *Guardianship of Estelle M. Browning (Browning II)*, 568 So. 2d 4 (Fla. 1990).

from an incurable, but not terminal condition, may exercise the patient's right of self-determination to forego sustenance provided artificially by a nasogastric tube?[43] Not only did the Court re-iterate its previous holding that "competent and incompetent persons have the right to determine for themselves the course of their medical treatment",[44] it also further ruled that "without prior judicial approval, a surrogate or proxy, as provided here, may exercise the constitutional right of privacy for one who has become incompetent and who, while competent, expressed his or her wishes orally or in writing".[45]

Although an equivalent contestation was rejected by the Court in case of the living will of Mrs Browning, it is my argument, in the context of access to untested drugs, that a voluntary individual's wish to tilt the scale in favour of the argument that an adequately informed patient with a sound mind should be free to choose whether or not to use an experimental or clinically unproven drug, which s/he believes to be capable of curing his/her infirmity and/or elongating his/her life, should be granted.

At the centre of *Abigail Alliance for Better Access to Developmental Drugs v Andrew Von Eschenbach (Abigail Alliance II)*[46] was a request that the Commissioner of Food and Drugs amend 21, Code of Federal Regulation (CFR) § 312 to allow the use of unapproved drugs outside of clinical investigation following a petition by the Washington Legal Foundation (WLF) on behalf of itself and the Abigail Alliance.[47] The DC Circuit Court ruled in favour of access to drugs that the FDA had not approved, but that had successfully completed Phase I testing as a constitutional right of terminally ill patients.[48] Notable is that the court emphasised, as the basis of its ruling, that the Due Process Clause of the United States Constitution protects the right of terminally ill patients to make informed decisions to access potentially life-sustaining drugs in cases where there are no alternative FDA-approved treatment options.[49] The fundamental principle at play, according to the majority ruling, was the right to make a decision

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43   *Browning II*:17.
44   *Browning II*:17.
45   *Browning II*:17. This latter part of the ruling was rejected by Overton J, at 17, who in his part dissent, expressed concern that, without judicial involvement, financially interested surrogate decision-makers would abuse their position and terminate life early in order to gain financially.
46   *Abigail II*, 445 F.3d 470 (D.C. Cir. 2006).
47   In particular, the WLF and the Abigail Alliance petitioned for "the creation of a new Food and Drug Administration policy to grant Initial Approval for promising drugs, biologics, and devices ("drugs") intended to treat life-threatening diseases with unmet needs. The Initial Approval authority would become the first tier of a three-tiered approval system consisting of Initial Approval (Tier 1), Accelerated Approval (Tier 2) and Full Approval (Tier 3) designed to provide reasonable treatment options to all Americans. Tiers 2 and 3 are already in place. The petition also seeks regulatory changes to permit expanded availability of developmental life-saving drugs.
48   *Abigail II*:486. For insightful discussion of the Court's decision, see Hill 2007:277-345; Leonard 2009:269-279. See also articles cited in fn. 81.
49   *Abigail II*:484.

about one's life without any government interference and the respect to be accorded to an individual's choice to voluntarily assume any known or unknown risk that could potentially save or prolong life.[50]

The notion of self-preservation played a key role in the court's decision.[51] In reaching its decision, the court also had to address the government's argument that the FDA's long-standing history of drug regulation renders moot arguments of access without government intervention. In counter-argument, the court stated that the account of American history, legal traditions, and practices show hardly any denial or blockage of access to new drugs by the government. The court noted that the FDA came into existence only in 1906, and that it began to regulate drug safety and efficacy in 1938 and 1962, respectively.[52] It was also noted by the Court in *Abigail II* that access to unproven drugs has been an issue before the courts in the United States even before the FDA regulation came into existence during the time of the Colonies such the Colony of Virginia that "passed an act in 1736 that addressed the dispensing of more drugs than was 'necessary or useful' because that practice had become 'dangerous and intolerable'".[53] Controlled access was also dealt with the Territory of Orleans (Louisiana), South Carolina, Georgia and Alabama, for example.[54] So was the early existence of control and intervention by the Federal Government itself.[55] The Court in *Abigail II* then remanded the case to the District Court to determine if the FDA's policy restricting the use of experimental drugs was justified having due regard to compelling government interest.[56]

The matter was later taken on appeal to the *en banc* panel of judges in the Court of Appeals for the District of Columbia in *Abigail III*.[57] In reversing the ruling of the three judges and re-instating the original decision of the district court, the *en banc* panel in *Abigail III* held that there was no constitutional right of terminally ill patients to unapproved drugs; neither did the due process of the Fifth Amendment justify the use of new investigational drugs.[58] In what was seemingly a direct contradiction of the DC Circuit Court's ruling in 2006, the *en banc* Court of Appeals observed that the Abigail Alliance failed to provide tangible evidence that there was "a right to procure and use experimental drugs that is deeply rooted in [America's] history and traditions."[59]

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50   *Abigail II*:484.
51   *Abigail II*:484 and 486. See also Ozmun 2007:231, fn. 16.
52   *Abigail II*:481-483.
53   *Abigail III*, 495 F.3d 695, 697 (D.C. Cir. 2007):704.
54   *Abigail III*:704.
55   *Abigail III*:704 and 705.
56   *Abigail II*:486.
57   *Abigail III*, 495 F.3d 695 (D.C. Cir. 2007).
58   *Abigail III*:697 and 711. See also Ozmun 2008:227. See Madara 2009:555, who argues that the "en banc decision placed great emphasis on a lack of history and tradition for unfettered access to experimental drugs. However, the court deftly avoided a thorough discussion of the major federal legislation."
59   *Abigail III*:711.

In addition, the court in *Abigail III* rejected arguments that the doctrine of necessity, the right to self-defence, and the misdemeanour of intentional interference with rescue has established a self-preservation right based on which terminally ill patients can claim rights of access to experimental drugs.[60] The court defended the FDA's policy of restricting access to experimental drugs by stating that "[t]he FDA's policy of limiting access to investigational drugs was rationally related to the legitimate state interest of protecting patients from potentially unsafe drugs with unknown therapeutic effects".[61] Interestingly, Judge Rogers who was joined by Chief Judge Ginsburg in dissent, castigated the majority decision as reflecting "a flawed conception of the right claimed by the Abigail Alliance for Better Access to Developmental Drugs and a stunning misunderstanding of the stakes."[62] Judge Rogers pointed to the existence of grounds for the maintenance or possible upholding of such a right. In particular, Judge Rogers maintained that the common law doctrine of necessity supports assertion for the right to life-saving drugs, even if untested.[63] Implicit in her dissent is that Judge Rogers based her arguments on the utility of the untested drugs.[64] The Abigail Alliance was not satisfied with the ruling of the Appeals Court and filed a petition for *writ of certiorari* in the Supreme Court of the United States, which was denied.[65]

An appeal against *Abigail II* to the United States Supreme Court was denied in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach* (*Abigail IV*).[66] The Supreme Court declined to hear the appeal, thus leaving standing the ruling in *Abigail II* that there is no rights of access to untested drugs without proven therapeutic benefit.[67]

3.2   Responses to the outcomes of the *Abigail* saga

The Court of Appeals decision engendered different views, some of which directly supported the position of the Abigail Alliance. According to Jacobson and Parmet, for example, the ruling upholding the constitutional right to unproven medicines, which was later vacated by the full DC Circuit Court of Appeals, had the potential to "… reshape the regulation and sale of pharmaceuticals and, perhaps, encourage increased use of unregulated drugs ... threatening the ability of the FDA to protect public health. … Such a ruling would open the door to the romance of the latest

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60   *Abigail III*:706. See Ott 2008:834-838, discussing the common law defence of necessity and the attempt by the Abigail Alliance to apply necessity in such a way as to introduce a new defence of medical self-defence.

61   *Abigail III*:706.

62   *Abigail III*:714.

63   This was in direct contradiction of the reasons tendered by the majority and in support of the arguments by the Abigail Alliance.

64   *Abigail III*:714-715, 718.

65   See, in general, *Abigail III*.

66   *Abigail IV*, 128 S. Ct. 1069 (2008).

67   See, in general, Sha & Zettler 2010.

new untested treatment."[68] Ott criticises the Abigail Alliance argument as "tongue-in-cheek",[69] observing that the Alliance had at best been myopic in its attempts to gain access to unproven medicines. Furthermore, Ott argues that Abigail Alliance ignores the fact that everyone is "free to make decisions regarding his or her body",[70] provided that such a decision does not affect others. Benioff observed that the right to experimental and unproven drugs was nearly elevated to a constitutional right but was "snuffed out,"[71] to the surprise of some commentators.[72] Koraris acknowledged that the issue of access to untested experimental drugs is worthy of consideration, but it may not be advanced as a constitutional right because "the Constitution may be the improper venue for such a policy debate".[73] While making some concessions which acknowledge that there is a challenge that merits further or future consideration, some commentators hail the *en banc Abigail* ruling as the right decision for human rights jurisprudence. Leonard, for instance, stated that, in declining to recognise a constitutional right to access to unproven drugs, the Court "… restored the world of fundamental rights jurisprudence as we knew it … Sound policymaking in this area requires consideration of the interests of not only tragically, terminally ill patients today but also the public and all patients tomorrow.".[74]

A different and scathing view has been expressed, with the court seen as having over-emphasised the word "unsafe", that the decision was "a concatenation of a legal decision and a factual decision: it presumes a legal interpretation of the word 'safe' that sets a scientific standard and a factual finding that post-Phase 1 drugs do not meet this standard".[75] The court was criticised for failing to separately evaluate the legal and scientific findings on which its substantive due process analysis was based, in order to allow judicial review of the different findings. Furthermore, the court failed in its duty to thoroughly interrogate the FDA's assertions, but was ready to dismiss the Abigail Alliance's position in an approach of "extreme deference",[76] which failed to take into account other federal legislation and the advancements in clinical trial processes that consider safety and efficacy a priority.[77] Chin argues that the decision was incorrect, because it failed to recognise a limited right of access to experimental drugs based on the facts presented.[78] According to him, the court erroneously applied

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68   Jacobson & Parmet 2007:205.
69   Ott 2008:843.
70   Ott 2008:843.
71   Menikoff 2008:1045.
72   See Hill 2007:314, stating that the panel decision in *Abigail* "surprised many commentators".
73   Korvatis 2006:168.
74   Leonard 2009:2071.
75   See Anonymous 2008:689.
76   See Anonymous 2008:689.
77   See, in general, the thought-provoking arguments in Madara 2009:556, 579.
78   Chin 2008:1792.

the restrictive "Glucksberg test",[79] the application of which discourages the creation of new fundamental rights.[80]

Writing on the need to seek a balance between individual autonomy and social control of medical interventions, Epstein noted the following:

> The defensive use of personal autonomy allows individuals to refuse medical treatment that others may have concluded, even rightly, would work for their own benefit. At the same time, the offensive use of autonomy – namely the right to accept treatment with consent – has been widely rejected today, especially in connection with the use of drugs. No individual today can demand whatever medical treatment he or she wishes to receive.[81]

Epstein strongly advocated for the critical decision on the utilisation of medical intervention to be left to private organisations taking into account the risk of delays if the matter is left in the hands of the State.[82] In advocating for the tampering with, or curtailment of what he calls the "*permititis*"[83] power of the State, Epstein argues that "[t]he FDA's permit power is an open wound in the body politic. *Permititis* cannot be controlled; it should be eliminated."[84] Hall disagrees with Epstein, arguing against *permititis* as dangerous and "fraught with peril"[85] in that it seeks to displace "the FDA in assessing all available evidence about a particular therapy and making efficacy determinations".[86] In Hall's words, "Epstein has raised the right question, but delivered the wrong answer".[87] What is clearly demonstrated is that the issues involved are not easily reconcilable. One may argue that it is through a social contract that the State was bestowed with making final decisions about medical interventions, particularly if they are unproven. However, Epstein argues that "[s]ound social policy places a heavy burden on any government exercise of its permit power that has such a stark impact on the lives of ordinary citizens, without their consent, and often over their protest".[88]

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79   Ensuing from the case of *Washington v. Glucksberg*, 521 U.S. 702, 719 (1997). For more on Glucksberg test, see Hawkins 2006:413.
80   Chin 2008:796.
81   Epstein 2009:1. See also Epstein 2008:566-580.
82   Epstein 2009:41.
83   Epstein 2009:5 coined the term "*permititis*" to mean "the ability of government agencies to block voluntary personal decisions which should be presumptively regarded as a danger to be avoided rather than as a progressive development worthy of social support backed by public funds".
84   Epstein 2009:41.
85   Hall 2010:72.
86   Hall 2010:72.
87   Hall 2010:84.
88   Epstein 2009:5. On the legal aspects of using untested drugs, see, in general, Donovan 2010:31.

4. Making a case for the use of untested drugs in Africa

A number of reasons or grounds may be proffered in support of justifying access to clinically untested drugs in Africa to help fight EVD. These will now be considered.

4.1 Compassionate, ethical and moral grounds: Utilitarian use approach

> The idea that the way to save lives is through unapproved drugs offers the illusion of choice and the reality of false hope — not an acceptable basis for public policy.[89]

> This is the cruel and dark reality that faces many terminally ill cancer patients, their families, and their friends. They are left out in the cold to watch people die, knowing that there is a drug …[90]

The above opposing excerpts question the desirability or otherwise of a utilitarian approach to access to untested drugs, and bring to light concerns and considerations that cannot be ignored. Utilitarianism, sometimes referred to as consequentialism, in a medical context, poses the question: If you had scenarios to make a choice, which of the two choices is likely to produce the greatest beneficial results?[91] Thus, in terms of utilitarianism, where a difficult choice has to be made, one should assess and weigh the potential benefits and harms to arrive at a balanced judgment on the proportionality of the good that would follow a given choice.[92] In the words of Smith: "[t]he greater the amounts of benefit for a given amount of potential or actual harm then the more likely it is that the action can be justified. Put another way, the greater the amount of potential harm for a given benefit the less likely it is that the action can be justified." [93]

The gist, in this instance, from a perspective of consequentialist ethics is that the rightness or wrongness of an (in)action is judged by "the goodness, or badness of the results that flow from it, not from any inherent qualities".[94] Simply, consequentialist ethics pose that "… the morality of any action is to be assessed by the consequences of that action".[95] The utilitarian approach simply argues that an action or measure is good if the results thereof benefit the greatest number of people.[96]

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89   Jacobson & Parmet 2007:208.
90   Do Coito 2008:347.
91   For more on what utilitarianism is, see, in general, Quinton 1989.
92   Smith 2004:3.
93   See, in general, Smith 2004:3-15.
94   Quinton 1989:1.
95   Smith 2004:3.
96   See Yunker 1986:57-79.

The question to be asked is whether the potential harm posed by the use of untested medicine outweighs the harm caused by EVD in light of the fatalities indicated in the introduction to this article. Put differently, is there any moral, ethical and/or humanitarian indictment for the use or non-use of untested medical intervention to combat the EVD? As indicated earlier, the Advisory Group recommended to the WHO that it would not be ethically questionable to administer unproven EVD medicine in light of the devastating spread of the outbreak in West Africa. By recommending access to unproven medicines, the Advisory Group moved closer to echoing the World Medical Association's (WMA) Declaration of Helsinki,[97] which allowed recourse to unproven interventions in clinical practice.[98]

For the sake of completeness, I should also attempt to answer in brief the question posed in the introduction to this article as to whether it is possible to meet the ethical and moral conditions set by the WHO Advisory Group in practice. There have been divergent views on the ethical and moral correctness of the use of unproven medical interventions on human beings. Although appreciative of the possible benefits of ZMapp in the treatment of EVD, Goodman cautions against the misleading, even harmful medical outcomes of the use of unproven drugs without proper and adequate clinical trials to determine their effectiveness and efficacy.[99] Goodman's view is similar to that expressed by Sha, who argues for very limited access due to "the considerable uncertainty about the safety and efficacy of unapproved drugs".[100] In support of this position, Sha provides the example of the health risks associated with the use of clinically unproven treatment of breast cancer.[101]

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97   World Medical Association (WMA)'s Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects was adopted by the 18th WMA General Assembly, Helsinki, Finland, in June 1964. It underwent a series of amendments, the latest of which at the 64th WMA General Assembly, Fortaleza, Brazil, in October 2013. The Declaration of Helsinki (Document 17.C) is an official policy document of the WMA, the global representative body for physicians. It was first adopted in 1964 (Helsinki, Finland) and revised in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset-West, South Africa) and 2000 (Edinburgh, Scotland). For the full text of the WMA Declaration of Helsinki see, http://web.up.ac.za/sitefiles/file/45/2875/Declaration%20of%20Helsinki_Fortaleza_Brazil%202013.pdf (accessed on 15 October 2014).

98   The Helsinki Declaration has since been rejected by the FDA. Sec. 37 of the Declaration of Helsinki, aptly titled *Unproven interventions in clinical practice*, states: "In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if, in the physician's judgement, it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available."

99   Goodman 2014:1088.

100   Sha & Zettler 2010:178.

101   Sha & Zettler 2010:179.

Taking a rather ambivalent position, Krech and Kieny question several issues, including the delay it took the global health intervention role players to develop EVD interventions, arguing that the disease until now "has received little attention because it was affecting mostly poor people in poor countries".[102] Krech and Kieny also highlight the ethical dilemma of the use of ZMapp, noting the immorality of not immediately using ZMapp treatment *en masse* when too many people are losing their lives to EVD. Krech and Kieny do, however, ponder on the need to hold back the use of ZMapp, since its safety and efficacy in human beings have not been tested and/or conclusively proven.[103] They are concerned with the protection of EVD patients from further harm, due to the administration of untested ZMapp when used outside the controlled environment of clinical investigation, even if it is for compassionate reasons.[104]

The concerns addressed above cannot be dismissed as being without merit. It is for this reason that the WHO Advisory Group imposed strict conditions for using unproven drugs, which, in my view, can be met, if only in part. The conditions are: care, informed consent, freedom of choice, confidentiality, respect for the patients, preservation of patients' dignity, and giving due consideration to the interests of the communities involved.

The requirement of consent and choice may appear as not being difficult to meet. The two American EVD patients who were treated with ZMapp, for example, consented to receive this treatment with the full knowledge that it had never been tested on human beings.[105] It would seem that they made a choice for the benefit of the preservation of their lives. Could it, therefore, be argued that consent would be a complete defence for medical practitioners, should a patient in similar circumstances choose and consent to being treated with unproven drugs with negative results or harm ensuing? I am tempted to answer in the affirmative, because the personal autonomy of choice[106] and consent of the patient may have made

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102 Krech & Kieny 2014:622.

103 Krech & Kieny 2014:622.

104 Compassionate use of unproven drugs is a standard in terms of the FDA legislation. Secs. 312.34(a) and (b) define the conditions for access to unapproved new drugs outside a clinical investigation – commonly known as "compassionate use". The regulation uses the term "treatment use" rather than "compassionate use".

105 This experimental treatment was arranged privately by Samaritan's Purse, the private humanitarian organisation that employed one of the Americans who contracted the virus in Liberia. On 28 August 2014, the National Institute of Health (NIH) announced that initial human testing of an investigational vaccine to prevent EVD will be conducted by the National Institute of Allergy and Infectious Diseases (NIAID). Part of the clinical trial was to evaluate the safety and efficacy of the vaccine and its ability to generate an immune system response in healthy adults.

106 The question as to whether personal autonomy to seek medical attention is interpreted defensively or offensively is   important to the convergence of social and legal aspects of the utilisation of unproven medical intervention.

it possible to claim *volenti non fit injuria.*[107] However, the defence may be less difficult to maintain because at the heart of *volenti non fit injuria* should be confirmation of reasonable knowledge of all risks involved.[108] Simply put, "[t]he consenting person must have full knowledge of the nature and extent of the risk of possible prejudice".[109] Until such time as there is a completed human clinical trial of the safety of EVD drugs, one cannot argue that the risk was reasonably known to EVD patients.[110] Thus, the issue of informed consent is very important in the administration of untested drugs, particularly at clinical trial level.[111] An important observation by Ochs is that the vulnerability of pharmaceutical companies to informed consent litigation has a chilling effect, and the companies may be reluctant to provide access to experimental drugs to EVD patients, for example, who are not part of clinical trials.[112] In my view, informed consent may not be said to be fully achieved even for persons involved in clinical trials, because, at the time of such, all potential side effects of the drug are not known.

What may prove difficult (or rather challenging) to meet is the requirement of giving due consideration to the interests of the communities involved. This requirement is akin to the requirement of public interest. In my view, the requirement also speaks particularly to rule-utilitarianism, in terms of which access to medicine must have much broader social efficacy than an act of utility would to an individual. Considered in totality, the conditionalities present an internal contradiction challenge in the form of

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107   The gist of *volenti non fit injuria* is that he who voluntarily assumes risk cannot later claim to have been harmed. For a critical appraisal of *volenti non fit injuria*, see Flemming 1952:141-169, who at the time also fiercely advocated for the abolition of the principle, particularly as far as it relates to implied assumption of risk.

108   See Flemming 1952:143. Others may argue that the discussion of *volenti non fit injuria*, in the context of the two American patients who were treated with ZMapp, is not appropriate or convincing enough, because they were health workers and not in the same position as most of the victims in Africa who had no knowledge of the safety and efficacy of ZMapp.

109   Ahmed 2014:91.

110   Oduwole *et al* 2016:5 make the following thought-provoking and important observation with regard to consent: "It may also be argued that testing the unregistered drugs on Africans, outside a clinical trial, may be seen as a discriminatory and an unfair deal. This is particularly so given the vulnerability of the population most involved in EVD. If the side effects of such drugs are harmful, then the mistrust of developing countries about developed countries may worsen, as they will be seen as unfairly experimenting on a vulnerable population. Further, the question of informed consent and autonomy comes to the open as there is mandatory treatment of victims in EVD epidemic. How do we handle inform consent and could there have been consent at all in the state of emergency as the outbreak of EVD presented? The principle of autonomy may be threatened as EVD patients may find it difficult to process information because of their state of health. They may be desperate to receive treatment or may even be scared of what the treatment entails."

111   For more on informed consent and ethics, see, in general, Corrigan 2003:768-792; Weijer 2000:344-361.

112   Ochs 2009:582-583.

having to weigh the individual against the societal or community interests. Important to note also is the compassionate-use-approach argument for using unproven medicines during EVD epidemics, with which I agree. Oduwole *et al* give as an example the European Regulation 726/2004/EC, which allows compassionate or expanded use programmes for clinically unproven medicinal products for "patients with severe diseases who have no other treatments available to them".[113] Likewise, the FDA permits the use of untested drugs on compassionate grounds.[114] It is submitted that African countries do have a moral and ethical obligation to consider controlled access to unproven EVD medicines on compassionate grounds.

4.2 A human rights-based approach: Is it possible and desirable?

What does the human rights-based approach (HRBA) entail and how does or would it apply to the public health and/or medical law context regarding access to unproven medicine? Equally important to consider are the following questions: Is there in reality a so-called human right to unproven medicine or to unproven medical interventions? Can one, in the wake of the rampant EVD outbreak with its devastating impact, claim access to a legal right, constitutional or otherwise, to unproven drugs or unproven medical interventions?

HRBA is a conceptual framework that is normatively based on international human rights standards, generally used towards enhancing the promotion and protection of human rights. As noted by Gruskin *et al*, HRBA "requires adoption of an approach explicitly shaped by human rights principles".[115] In answering the question as to what a HRBA to health is, London refers to work done for the Network on Equity in Health in Southern Africa (EQUINET), which identified four approaches to using human rights to promote health equity. Included among these approaches is holding government accountable for public health issues.[116] Generally, a HRBA places corresponding duties and obligations on the state to make the enjoyment of the right to public healthcare possible. Health policy-making and decision-making, such as a decision whether or not to allow access to unproven drugs, must, according to a HRBA, be guided by human rights standards and principles. The ultimate goal must be to further advance the realisation of the right to health and other health-related human rights as contained in international and national human rights laws. Therefore,

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113 Oduwole *et al* 2016:7.
114 Oduwole *et al* 2016:7.
115 See Gruskin *et al* 2010:134, stating that "[g]lobal attention to RBAs came to the fore in 1997 when Kofi Annan, then UN Secretary General, called for the UN to integrate human rights into all of its work. Only in 2003 did the UN develop a unified definition of an RBA, the 'Common Understanding on a Human Rights-Based Approach to Development Cooperation'. This 'Common Understanding' calls for human rights principles to guide 'all phases of the programming process' of all UN agencies."
116 London 2008:70.

as an approach in this article, HRBA identifies EVD victims as holders of the rights to healthcare and serves as a justification for them to argue for entitlements towards measures that will alleviate their suffering.

Art. 25(1) of the Universal Declaration of Human Rights (UDHR) reads: "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 ...".

Several resolutions of the United Nations have since been adopted that give effect to the UDHR. Resolution 12/24 of the Human Rights Council (HRC), for example, recognises that "access to medicine is one of the fundamental elements in achieving progressively the full realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[117] The right to health has been codified under Art. 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The ICESCR requires states to recognise "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[118] Access to essential medicine is considered "a sub-component of the broader right to adequate health".[119] Art. 16(2) of the African Charter on Human and Peoples' Rights (hereafter "African Charter") enjoins states parties to "take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick".[120]

Admittedly, the UDHR and related regional instruments do not address the rights to unproven medicines. It is my view that it was not the intention of the drafters of the UDHR, the African Charter, and other international and regional health-related provisions to absolutely exclude any consideration of unproven drugs as part of a state's accountability obligations when an epidemic strikes. It is further my contention that, when the WHO Advisory Group concluded that it was ethically and morally correct to administer unproven interventions during cases of outbreaks, such a decision took into consideration the internationally recognised right to health and the right to life of EVD patients. Art. 4 of the African Charter provides that "[h]uman beings are inviolable. Every human being shall be entitled to

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117　*Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development* A/HRC/RES/12/24 12 October 2009:par. 1.

118　International Covenant on Economic, Social, and Cultural Rights, art. 12, Dec. 16, 1966, 993 U.N.T.S. 3:art.12.

119　Smita 2011:7, fn. 16, citing U.N. Special Rapporteur on the Right of Everyone to the Highest Attainable Standard of Physical and Mental Health, Addendum: Mission to the World Trade Organization, ¶ 18, U.N. Doc. E/CM.4/2004/49/Add.1 (Mar. 1, 2004) (asserting that the right to health encompasses "access to essential medicines").

120　African Charter on Human and Peoples' Rights (Banjul Charter), adopted 27 June 1981 OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982) and entered into force on 21 October 1986. See Mbazira 2006:358-381, indicating that some of the Charter's provisions 'mirror' those of the CESCR. See also Duroyaje 2013:393-418, discussing the African Charter.

respect for his life and the integrity of his person. No one may be arbitrarily deprived of this right."

The importance of the reference to this provision lies in the fact that, in the case of *Sudan Human Rights Organisation & Another v Sudan*,[121] the African Commission on Human and Peoples' Rights (hereafter "the African Commission") interpreted the right to life with reference to the right to health. In this case, the African Commission held that the right to life in art. 4 of the African Charter was central to the existence of all other rights. The African Commission then stated that the right to life deserves a broad interpretation, which includes states parties being obligated to "take positive and proactive steps to protect citizens from outbreaks of infectious diseases".[122] Therefore, states parties must be pro-active and diligent in addressing the EVD epidemic, which includes allowing controlled access to unproven drugs.

Human rights standards and principles such as accountability are built into the HRBA by requiring the state to be accountable by ensuring that the right to health is not compromised and thus by putting EVD redress mechanisms in place. Moreover, the outbreak of an epidemic such as EVD does not only implicate the rights to health; it also implicates a range of other human rights, including freedom from arbitrary detention and freedom of movement resulting from quarantines.[123] Therefore, it can be argued that a range of international, regional and national human rights instruments including, but not limited to Art. 25 of the UDHR, Resolution 12/24 of the Human Rights Council (HRC), Art. 4 of the African Charter, Art. 12 of the ICESCR – as purposively interpreted and applied – support a position that patients with life-threatening and otherwise untreatable diseases may have some recourse to gain access to unproven or experimental medical treatment on the basis of the human rights to physical and mental health. Simply put, HRBA justifies granting access to, and use of experimental and/or clinically unproven EVD drugs.[124]

Permit me to take a step back by stating that the *Abigail* cases and the debates that followed them are enlightening with regard to the question as to whether HRBA can be relied on to enable access to unproven drugs for treating EVD. I agree in part that one should not readily agree with the *Abigail II* and *Abigail III* decisions and overly dismissive of the Abigail Alliance's arguments for a right to experimental drugs without engaging with substantive reasons. The utilitarian approach would require a well-considered decision before denying access to new experimental drugs as a right, particularly in the wake of the catastrophic nature of EVD.[125]

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121 *Sudan Human Rights Organisation & Another v Sudan* (2009) AHRLR 153 (ACHPR 2009):par. 146.
122 See Oduwole & Akintayo 2017:2002-2001.
123 See, in general, Pearson 2018:201-222.
124 For an enlightening discussion on the rights-based approach, including the criticism she levelled against the utilitarian theory, see Thomson 1985:1395-1415.
125 See, in general, the thought-provoking arguments by Madara 2009:535.

5. Conclusion and recommendations

The issue of access to unproven drugs has been the subject of well-engaged academic debates based on wide-ranging perspectives.[126] Discourses on access to unproven drugs as the issue played itself out in *Abigail Alliance Litigation*, had, in my view, a nuanced demonstration of the many and differing advances that African governments can make in addressing health challenges posed by EVD at both policy and health-system levels. The question posed is: What can we learn from the EVD crisis and the uncertainties on how nations should proceed to combat the disease? The lesson learnt – or at least to be learned – is that well-functioning and properly regulated healthcare systems are important to combat and control disease outbreaks. Nations must do everything necessary to strengthen healthcare systems, and to assist in developing and capacitating the healthcare systems of those countries that are battling to contain EVD.[127] In the Millennium Declaration,[128] Heads of States acknowledged and conceded that they are collectively responsible "to uphold the principles of human dignity, equality and equity at the global level …, especially the most vulnerable …".[129] At the time, the responsibility in question was best to be discharged by reaching the target of public health under Millennium Development Goal (MDG) 8, read in the context of the general limitations of these goals.[130] The Heads of States stated that primary healthcare itself has not been met satisfactorily.[131] This is the kind of leadership that should have been exercised by the global community since the first outbreak of EVD.[132]

There are clearly ethical and legal dilemmas regarding efforts made and measures introduced to combat EVD. In addition to its debilitating impact, as discussed by the WHO, EVD is a public health challenge and a humanitarian crisis which has left the global community at sixes and sevens, pondering on whether to allow access to medical interventions such as ZMapp and TKM-Ebola. The risk of the catastrophe that will befall Africa and the world, in general, if the disease remains uncontrolled, calls for

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126 See, in particular, the following illuminating academic publications: Chin 2008:1971-2000; Ozmun 2008:227-241; Do Coito 2008:1045-1075; Goodman 2008:107-141; Madara 2009:535-580; Shah & Zettler 2010:135-196; Jacobson & Parmet 2007:205-208; Ott 2008:821-857; Ochs 2009:559-609; Malinowski 2014:615-660; Korvatis 2006:59-168; Leonard 2009:269-279.

127 See, in general, Gostin & Archer 2007:526.

128 For more on the Millennium Development Goals (MDGs), see, in general, Center for Conflict Resolution. 2013.

129 U.N. Millennium Declaration, http://www.ohchr.org/english/law/millennium. htm (accessed on 4 September 2007).

130 See, in general, Fehling *et al* 2013:1109-1122.

131 See Adeleye & Ofili 2010:1-6.

132 Unfortunately, world leaders failed to live up to the responsibility. See Gostin & Friedman "Ebola: A crisis in global health leadership" 2014, O'Neill Institute Papers. Paper 71, http://scholarship.law.georgetown.edu/ois_papers/71 (accessed on 12 June 2017), arguing that there is a lack of global health leadership at the core of the present Ebola crisis in West Africa.

the positive consideration of allowing access to untested drugs. However, the possible consequences of the utilisation of untested drugs also have to be taken into account. Clearly, the issue requires a delicate balance and full appreciation of the outcomes and all possible ramifications. Developments in respect of EVD treatment have also seen unfortunate divisions based on nationalities and country of origin. For instance, the quarantine measures introduced in countries such as the United States appeared to be targeting Africans or people who have come from the African continent. This is unethical and discriminatory. Cases reported included, for example, that Harvard Vanguard Medical Center in Braintree, Massachusetts, was evacuated on suspicion that a man who had just returned from Africa may be carrying EVD when there was no reason to believe that he contracted EVD; that an American nurse sent home a patient complaining of minor fever and abdominal pain after returning from visiting family in Africa. The patient reportedly had to sit at home to self-medicate; was subsequently admitted to hospital for suspected EVD, and later died in isolation.[133]

The argument for the recognition of an individual's *human right* to access to untested drugs is an interesting one. Who can argue against the estimated 70 per cent of the EVD fatality rate (and still counting), and predictions of probable cases in excess of 20.000 in total if not treated successfully?[134] EVD is clearly a public health threat for Africa.[135] But, I do not necessarily agree with, or support the proposition that there must be a blanket constitutional or human right of access to untested drugs. Admittedly, sound and convincing arguments were made for such a right following the *Abigail* cases. In my view, and given the EVD crisis, some form of regime must be established making access to untested drugs possible *in exceptional circumstances*. The EVD crisis in West Africa is, in my view, such an exceptional circumstance. In the case of EVD, the ethical dimensions of administering unproven drugs are clearly important compared to the classic textbook determinations of the morality or determinants of moral attitudes,[136] which, in my view, precludes the use of unproven drugs to saving lives and easing people's pain and suffering.

African governments or regional formations must work towards drug-distribution and drug-use laws and/or policies designed to provide a proper response to epidemics such as the EVD in line with international law. In particular, these instruments must explicitly address access to clinically untested or unapproved drugs. The 1981 African Charter on Human and

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133 See Collman *et al* "America on edge over Ebola fears: Patient who sparked Boston hospital evacuation does NOT have deadly virus – while LAX plane put on lockdown when passenger became sick", *Mail Online* 12 October 2014, http://www.dailymail.co.uk/news/article-2790233/ebola-alert-boston-hospital-evacuated-patient-recently-traveled-west-africa-begins-virus-like-symptoms.html#ixzz3Jga22788 (accessed on 21 September 2014).

134 WHO Ebola Response Team 2014:1.

135 See Baize *et al* 2014:1418.

136 On determinants of moral attitudes, see, in general, Woodrum 1988:553-573.

Peoples' Rights (also known as the Banjul Charter) which has been ratified by all African countries with the exception of South Sudan, places health rights obligations on its parties. Art. 16 of the Charter, in particular, states that "[e]very individual shall have the right to enjoy the best attainable state of physical and mental health" and further obligates states parties to protect the dignity inherent in human beings by, among others, "taking all the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick". Surely, it is an indictment on the continent that diseases such as EVD kill thousands of African people without, in the specific case of EVD, states parties achieving any point of arresting it for almost half a century. The human rights-based intervention in this regard calls for a different approach, which, in my view, may necessitate allowing access to effective yet clinically unproven drugs while at the same time addressing some of the health-related international obligations such as the Sustainable Development Goals (SGDs). The SDGs owe their genesis to the launching of the global consultation for the SGDs in 2012 by the United Nations (UN), and the subsequent agreement on 17 SDGs in 2015 by the UN General Assembly.[137] SDG 3, for example, requires states parties to promote access to health services and health rights across the African continent.[138] SGDs are, in essence, an advanced continuation of the Millennium Development Goals[139] (MDGs). In light of both SGD 3 and MDG 8, it is my view that the target of public health within the context of its general limitations, particularly the emphasis on primary healthcare, have not been met satisfactorily. Indeed, the absence of a pronounced statement on access to life-saving medicines by African countries or regional formations is deafening in its silence.

The African Union must take the initiative of exploiting the 2014 statement by the WHO that it is ethical to use untested drugs subject to meeting certain conditions. This may be achieved through numerous measures, including collaborative efforts.[140] In fact this kind of leadership should have been exercised by the global community since the first outbreak of EVD in 1970.[141] Controlling the spread of EVD and other infectious diseases such as SARS, tuberculosis, malaria, hepatitis, HIV and Zika remains a test African countries must pass to determine their success in respect of the SDGs. As Raviglionea and Maherb correctly posit, achieving this "calls for a shift from individual disease control strategies … to a more coherent and global public health approach that also reflects the key feature of the SDGs that development sectors are integrated and indivisible."[142]

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137 Marmot & Bell 2018:1. For more on sustainable development goals, see also Nunes *et al* 2016:1-12.
138 See Morton *et al* 2017:81-90.
139 For more on the Millennium Development Goals (MDGs), see, in general, Center for Conflict Resolution 2013.
140 See Adeleye & Ofili 2010:1-6.
141 Unfortunately, African and world leaders failed to live up to the responsibility. See Gostin & Friedman 2014, arguing that the core of the Ebola crisis in West Africa is a lack of global health leadership.
142 See Raviglionea & Maherb 2017:142.

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