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## Medicines that Kill

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 Professor Mary Dillard  
 Health and Sickness in Africa  
 15 November 2011

Medicines that Kill:

“At least 200,000 lives could be saved in Africa every year if there were not [sic] fake medicines”

Tanzania Daily News, 31 March 2010<sup>1</sup>

Counterfeit drugs are a growing threat to public health care systems around the world, particularly to those in the developing world. African countries, in recent years, have fallen victim to this trade. Many African public healthcare systems already struggle to cope with the strain that diseases like malaria, tuberculosis and HIV/ AIDS place on them.<sup>2</sup> Therefore, the effects of counterfeit drugs are adversely felt and exceptionally hard to deal with. Nigeria, once a haven for these drugs, has had great success in combating the issue. Many attribute Nigeria’s success to the efforts of Dora Akunyili<sup>3,4</sup>, the head of the National Agency for Food and Drug Administration and Control (NAFDAC). Nigeria’s success in eradicating counterfeit drugs from their pharmaceutical market gives many other African countries hope, and something to aspire to. Countries like Kenya and Tanzania, which have only recently begun to tackle the counterfeit trade, stand to learn a great deal from Nigeria’s example. If other countries in Africa do not follow in Nigeria’s footsteps and work towards better

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<sup>1</sup> "allAfrica.com: Tanzania: Fake Medicines Are Sold in Country." *allAfrica.com: Home*. Tanzania Daily News, 31 Mar. 2010. Web. 14 Dec. 2011.

<<http://allafrica.com/stories/201004020870.html>>.

<sup>2</sup> Ambali, A, J Mugabe, and C Mutero. 2009. "Science, Technology and Innovation for Public Health in Africa ( Overview)." *www.nepadst.org*. New Partnership for Africa’s Development (NEPAD), n.d. Web. 11 Dec. 2011. <New Partnership for Africa’s Development (NEPAD)>.

<sup>3</sup> Bate, Roger. 2008. *Making a killing: the deadly implications of the counterfeit drug trade*. Washington, D.C.: AEI Press; p.20

<sup>4</sup> Dora Nkem Akunyili "the iron lady" b. July 14, 1954, is a Nigerian internationally renowned pharmacist and the former Director General of NAFDAC (National Agency for Food and Drug Administration and Control). She is the current Minister of Information and Communications.

drug regulation and legislation, then many African nations are greatly in danger of undoing the efforts of African healthcare workers who have laboured tirelessly to improve the healthcare systems for decades.

With this in mind, it becomes increasingly evident why the issue of counterfeit drugs in Africa needs to be addressed. This paper will attempt to evaluate the extent of the counterfeit drug trade in Africa and what aspects of it are particularly unique. Based on this, an analysis of why Africa is particularly susceptible; particular attention will be paid to the prevalence of the problem in Nigeria, Kenya and Tanzania, and their efforts to combat the issue. Will counterfeit drugs succeed in further suppressing the African healthcare system, or will Africans rise to the challenge and overcome this illegal and deadly trade?

Nigeria is an example of a country that has been very successful at combating the issue, whereas Kenya and Tanzania are countries that are at the elementary stages of dealing with it. The experiences of these countries, Dora Akunyili and the World Health Organizations guidelines for combating this issue will then hopefully allow for a conclusion to be reached on the methods that have worked best in dealing with drug counterfeiting in Africa. In addition, the role of technology, and particularly the role of text messaging in drug certification as a possible solution to the problem, will be evaluated. Finally, an evaluation of the possible future outcomes of the situation in Africa will then be made based on expert opinion and facts on the ground.

### The Importance of Defining the Counterfeit Drug:

There is no universally accepted term for what constitutes a counterfeit drug; definitions vary from country to country. In most cases, the definition that the World Health Organization (WHO) offers is the most widely accepted one.

The WHO defines a counterfeit drug as:

A counterfeit medicine is one, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.<sup>5</sup>

The definition offered by the WHO allows for some form of uniformity among nations. Nonetheless, the fact that there is no internationally agreed upon definition makes it difficult to adequately tackle the issue. How can a substance be eradicated when there is no agreement as to what that substance is? Most countries take the definition offered by the WHO and adapt it for local use. Unfortunately, some countries, like Kenya, do this by redefining the definition of counterfeit drugs to include generics.<sup>6</sup> Organizations, like Regional Network for Equity in Health in East and Southern Africa (EQUINET), feel that this is a dangerous adaptation to make, because for many Africans generic drugs make treatment not only affordable, but also possible. By including generic drugs in their definition of counterfeit drugs, countries like Kenya risk alienating many Africans from medical treatment.

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<sup>5</sup> World Health Organization. "Counterfeit Medicines." World Health Organization. [www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/index1.html](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html) (accessed December 12, 2011).

<sup>6</sup> CEHRUD (2010) Anti-counterfeiting laws and access to essential medicines in East and Southern Africa EQUINET, CEHRUD, TARSC Policy brief 22, EQUINET, Harare

Furthermore, while it may be true that some of the counterfeit drugs in circulation in the continent are of generic branding, that does not mean that all generic drugs are counterfeited. Generic drugs are not, by definition, counterfeited drugs. They are simply the unbranded versions of medications that have had their patents expire.<sup>7</sup> Concerned about the inclusion of generic drugs by some African nations, who have started their own initiatives to combat drug counterfeiting, in their definition a group, has spurred a group of African legislators band together in response. Using working policies drafted by regional and governmental bodies throughout East Africa these legislators aim to use these policies as a basis of establishing a robust legal framework that tackles the issue without including generic drugs.<sup>8</sup> They hope that a shared definition, which excludes generic drugs, but imposes strict penalties on drug counterfeiters, will allow African policy makers and healthcare workers to “understand the true extent of the problem at global level”<sup>9</sup>, thereby, allowing them to better combat the issue within the continent.

### When Did Drug Counterfeiting Start and What are the Facts on the Ground like Today?

Data on when counterfeited drugs first appeared on the continent is scarce. However, if we use Nigeria as an indicator, we can trace the appearance

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<sup>7</sup> World Health Organization. "Multisource (generic) Pharmaceutical Products: Guidelines on Registration Requirements to Establish Interchangeability." (World Health Organization International. [www.who.int/medicines/services/expertcommittees/pharmprep/QAS04\\_093Rev4\\_final.pdf](http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS04_093Rev4_final.pdf) (accessed December 12, 2011).

<sup>8</sup> CEHRUD (2010) Anti-counterfeiting laws and access to essential medicines in East and Southern Africa EQUINET, CEHRUD, TARSC Policy brief 22, EQUINET, Harare

<sup>9</sup> World Health Organization. "Counterfeit Medicines." World Health Organization. [www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/index1.html](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html) (accessed December 12, 2011).

of counterfeit drugs on the continent back to 1968, which is when counterfeit drugs first started to appear in Nigeria, according to Dora Akunyili.<sup>10</sup> The first incident of mass casualties resulting from large-scale use of counterfeit drugs occurred in Niger in 1995, when Nigeria unknowingly donated compromised meningitis vaccines to Niger<sup>11</sup>. The 88,000 donated meningitis vaccines had been counterfeited.<sup>12</sup> The inoculation of more than 50,000 people with the vaccine resulted in the deaths of 2,500 people. Unfortunately, apart from this particular incident, there are no mishaps or indicators to suggest the prevalence of counterfeit drugs in Nigeria and its neighboring countries at the time.

Information on the occurrence of counterfeit drugs within the region and the wider continent between 1968 to the early the 2000s is almost nonexistent. By 2002 statistics on the prevalence of counterfeit drugs in Nigeria became available, although there were many discrepancies on what the exact statistics were. Most of the values obtained were guestimates as Nigerian officials did not have the means, such as adequate manpower and management, to provide accurate values. Nigerian officials predicted that counterfeit drugs accounted for 40% of the pharmaceutical market, whereas some studies suggest that as much as 85% of the drugs in circulation in Nigeria were counterfeit.<sup>13</sup>

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<sup>10</sup> Raufu , Abiodun. 2006. "Nigeria Leads Fight Against "Killer" Counterfeit Drugs." World Health Organization. [www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/index1.html](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html) (accessed December 11, 2011).

<sup>11</sup> Raufu , Abiodun. 2006. "Nigeria Leads Fight Against "Killer" Counterfeit Drugs ." World Health Organization . [www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/index1.html](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html) (accessed December 11, 2011).

<sup>12</sup> Ibid

<sup>13</sup> Bate, Roger. 2008. Making a killing: the deadly implications of the counterfeit drug trade. Washington, D.C.: AEI Press; 46

Subsequently, in response to these staggering numbers, Nigeria took great strides to combat the issue. As of 2006, counterfeit drugs only make up 16% of the drugs in circulation in Nigeria<sup>14</sup>. Meanwhile, in the rest of Africa the situation has been worsening, and counterfeit drugs have become an increasing threat. Recent studies show that counterfeit drugs are in greater circulation in the region than in Nigeria. In a study conducted in 2010, across 17 different Sub-Saharan African countries, it was found that a median of 20% of the people interviewed said that they or someone in their household had fallen victim to counterfeit drugs.<sup>15</sup> The results that the survey yielded showed vast polarizations in the percentage of occurrence. In Sierra Leone, for instance, 43% of the drugs in the market are counterfeited. On the other hand, in South Africa 3% of the drugs in circulation are counterfeited.

### What Makes Many African Countries Susceptible to Counterfeiting?

South Africa's low prevalence rate is not indicative of the situation in the continent. Few countries in the continent are lucky enough to have such low numbers. The reasons for large disparities between countries like South Africa and Sierra Leone are a product of differences in the strength of their healthcare systems and regulatory bodies. It is regulation that determines how susceptible a country is to penetration of counterfeit drugs into its pharmaceutical market. A country like South Africa, which has a one of the best health care systems on the

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<sup>14</sup> Bate, Roger. 2008. Making a killing: the deadly implications of the counterfeit drug trade. Washington, D.C.: AEI Press;47

<sup>15</sup> Ogisi, Mitchell. "EBSCOhost: Fake Medicine Common in Many Sub-Saharan African Countries ." EBSCO Publishing Service Selection Page. <http://web.ebscohost.com/ehost/detail?sid=b1785ae3-05e7-4e98-a0e6-2b8ecf7b5a9d%40sessionmgr11&vid=1&hid=19&bdata=jnNpdGU9ZWwhvc3QtbGl2ZQ%3d%3d#db=buh&AN=66669810> (accessed December 12, 2011).

African continent, is not very likely to have counterfeit drugs in high circulation.<sup>16</sup> Meanwhile, other African countries, with less capable regulatory bodies, are far more susceptible to the uninterrupted distribution of the counterfeit drugs in their pharmaceutical market. Poor regulatory bodies, coupled with the prevalence of diseases like malaria, tuberculosis and AIDS, and an inability to afford expensive medications, means that for the many Africans who do suffer from these diseases, they may not always be able to afford the necessary treatment. Few Africans have the luxury of buying the most trusted brands –which are much harder to counterfeit – but instead they buy the cheapest option that is available to them.

The cheapest option is more likely to be counterfeited, because in many counterfeit drugs the active ingredients are replaced by smaller quantities than the required amount, or in some cases they are replaced with chalk. As a result, drug counterfeiters can afford to sell these drugs at much lower costs. They sell them at prices that appeal to the unsuspecting African patient, whilst still being able to make a profit. These drugs are often sold in non-regulated outlets or in some cases open markets. When Dora Akunyili first assumed her role as the head of Nigeria's NAFDAC, more than half of the drugs in open markets in Nigeria, like Kano market, were counterfeited<sup>17</sup>. When she shut down the Kano<sup>18</sup>

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<sup>16</sup> "Healthcare in South Africa." International Expatriate (Expat) Health Insurance, Global Medical Healthcare - Allianz Worldwide Care. <http://www.allianzworldwidecare.com/healthcare-in-south-africa> (accessed December 14, 2011).

<sup>17</sup> *Bad Medicine*. DVD. Directed by Karen O'Connor. London: British Broadcasting Corporation, 2005.

<sup>18</sup> This is significant because Kano has historically been one of the largest markets in Africa.

market, and her agents began to confiscate the drugs, and found that the drugs in Kano market were worth £140,000 (about \$ 218,858 as of 12<sup>th</sup> March 2012) <sup>19</sup>.

It is not just patients who venture into these markets in search for cheap drugs. In July 2003, the International Children's Heart Foundation set up base at the Enugu Teaching Hospital in Nigeria, to perform heart surgeries on ten children. During one of the surgeries complications arose, and the child was injected with adrenaline to remedy the situation. The child did not respond, her heart failed and she died. Four other children died that day. The adrenaline that was used had been counterfeited. The hospital had purchased the drug and various other hospital supplies from an open market in the area.<sup>20</sup> What this incident illustrates is that even at the hospital level, drug regulation in some African countries is lax. NAFDAC eventually reprimanded the hospital and confiscated the fake adrenaline and other counterfeited products. Yet, in spite of this, the hospital still maintains, "there is no proof to link the deaths of the patients with the drugs used."<sup>21</sup> If healthcare institutions do not take responsibility and do not tighten their drug regulations then African healthcare institutions will continue to be susceptible to the threat of counterfeited drugs. Nigeria's case proves that better regulation will indeed reduce the circulation of counterfeit drugs; the prevalence of counterfeit drugs in Nigeria only began to decrease after Dora Akunyili put numerous reforms in place. <sup>22</sup>

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<sup>19</sup> Frenkiel, Olenka. "One Woman's War with Fake Drugs." BBC NEWS. [http://news.bbc.co.uk/2/hi/programmes/this\\_world/4656627.stm](http://news.bbc.co.uk/2/hi/programmes/this_world/4656627.stm) (accessed December 10, 2011)

<sup>20</sup> Ibid

<sup>21</sup> Ibid

<sup>22</sup> Raufu, Abiodun. "Bulletin of the World Health Organization." World Health Organization. <http://www.who.int/bulletin/volumes/84/9/06-020906/en/> (accessed December 12, 2011).

Some might argue that African illiteracy makes Africans susceptible to the threat of counterfeited drugs. It is certainly a logical conclusion to reach; however, it is an incorrect one. Literacy might aid the ordinary African to infer whether or not a product has bypassed its expiration date. Nevertheless, most counterfeiters are very good at what they do, and know better than to make their products so easily detected. In cases where expired drugs are used, counterfeiters often re-label or repackage the drugs to mask their expiration date. Regulatory officials seem to agree that it is almost impossible to tell whether a drug has been counterfeited without a lab test.<sup>23</sup> It is for this reason that literacy can do little to protect patients from falling victim to the use of counterfeit drugs.

To further the argument, the correlation between literacy and exposure to counterfeit drugs in Nigeria, Tanzania and Kenya would suggest that literacy plays no significant role in protecting individuals; the literacy rates in Nigeria, Tanzania and Kenya are 60%, 73% and 87% respectively.<sup>24</sup> In Tanzania, where drug regulation and literacy rates are both mediocre the number of people who had been affected or had a member of their household affected by counterfeit drugs stands at 24%. However, in Kenya where regulation is poor and literacy is high, the percentage of counterfeit drugs in the market is 25%. Meanwhile, in

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<sup>23</sup> Gibson, Hannah. "A dangerous case of mistaken identity: Counterfeit medicines in West Africa." Consultancy Africa Intelligence - Assist | Inform | Empower. [http://www.consultancyafrica.com/index.php?option=com\\_content&view=article&id=460:a-dangerous-case-of-mistaken-identity-counterfeit-medicines-in-west-africa&catid=60:conflict-terrorism-discussion-papers&Itemid=265](http://www.consultancyafrica.com/index.php?option=com_content&view=article&id=460:a-dangerous-case-of-mistaken-identity-counterfeit-medicines-in-west-africa&catid=60:conflict-terrorism-discussion-papers&Itemid=265) (accessed December 14, 2011).

<sup>24</sup> "UNICEF - Information by country." UNICEF - UNICEF Home. <http://www.unicef.org/infobycountry/> (accessed December 12, 2011).

Nigeria, where regulation is comparatively much stricter, but literacy is comparatively lower, the percentage of people that have been exposed to counterfeited drugs is 20%.<sup>25</sup> These numbers illustrate that literacy does little to help individuals living in these countries to distinguish between the genuine and counterfeited versions of the drugs. Therefore, there it may be said that there is no correlation between literacy and high prevalence rates of drug counterfeiting. Higher literacy rates will not eradicate counterfeit drugs in Africa, but better drug regulation will. Tanzania and Kenya may have surpassed Nigeria in an effort to improve literacy rates, but Nigeria has surpassed them in its effort to eradicate counterfeit drugs. Both countries could learn a great deal from Nigeria, and Akunyili's efforts to eradicate drug counterfeiting.

#### What Can Other African Policy Makers Learn From Dora Akunyili?

Dora Akunyili, a former professor of pharmacology<sup>26</sup>, became the Director General of NAFDAC in 2001 and has held that post ever since.<sup>27</sup> Her first order of business was to fire her most corrupt officers. She changed the staff who were already working there and hired "a new team of female inspectors and pharmacists (she believes most men are too easily tempted by bribes) and

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<sup>25</sup> Ogisi, Mitchell. "Fake Medicine Common in Many Sub-Saharan African Countries." Gallup.Com - Daily News, Polls, Public Opinion on Government, Politics, Economics, Management. <http://www.gallup.com/poll/149942/fake-medicine-common-sub-saharan-african-countries.aspx> (accessed December 13, 2011).

<sup>26</sup> Raufu, Abiodun. 2006. "Nigeria Leads Fight Against "Killer" Counterfeit Drugs ." World Health Organization . [www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/index1.html](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html) (accessed December 11, 2011).

<sup>27</sup> Larkin, Marilyn. "ScienceDirect - The Lancet Infectious Diseases : Dora Akunyili: battling against counterfeit drugs." ScienceDirect - Home . <http://www.sciencedirect.com/science/article/pii/S1473309906705758> (accessed December 14, 2011).

started to prosecute importers of fake drugs".<sup>28</sup> To boost morale amongst the workers she gave them incentives like trips abroad, better facilities and better working conditions.<sup>29</sup> The corruption that had taken place, preceding Akunyili's arrival undoubtedly accounted, to certain extent, for why there were so many counterfeit drugs in circulation. Through the elimination of "systems in which informal payments can be easily made in order to pass counterfeits through bureaucratic barriers",<sup>30</sup> Akunyili could focus more of her efforts on investigating possible counterfeiters instead of her own personnel, thus vastly improving the efficiency of NAFDAC.

Next, Akunyili created a campaign against drug counterfeiting. A series of public service announcements and infomercials were released to inform Nigerians of the threat that counterfeit drugs posed to their health. These infomercials not only alerted Nigerians to the issue, but they armored Nigerians with the knowledge they needed to be able to undertake the necessary precautions and alerted them to the signs they should look out for when purchasing medications.<sup>31</sup> Television commercials were not the only form of media used, as not all Nigerians have access to television. Radio services and newspapers were utilized as well. Newspapers were to publish a regularly

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<sup>28</sup> Frenkiel , Olenka . "One Woman's War with Fake Drugs." BBC NEWS. [http://news.bbc.co.uk/2/hi/programmes/this\\_world/4656627.stm](http://news.bbc.co.uk/2/hi/programmes/this_world/4656627.stm) (accessed December 10, 2011)

<sup>29</sup> Raufu , Abiodun. 2006. "Nigeria Leads Fight Against "Killer" Counterfeit Drugs ." World Health Organization . [www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/index1.html](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html) (accessed December 11, 2011).

<sup>30</sup> Fenoff, Roy S., and Jeremy M. Wilson. "Africa's Counterfeit Pharmaceutical Epidemic: The Road Ahead." *Anti Counterfeiting And Product Protection Programme*. University of Michigan, 1 Oct. 2009. Web. 7 Nov. 2011. <<http://a-capp.msu.edu/sites/default/files/publications/Africa%20Pharma%20Paper.pdf>>.

<sup>31</sup> *Bad Medicine*. DVD. Directed by Karen O'Connor. London: British Broadcasting Corporation, 2005.

updated list of the drugs that had been counterfeited recently. As a result of **efforts** to raise public awareness of the issue, today 83% of the population is aware of the presence of counterfeit drugs in their country, compared to the 66% of Tanzanians and 63% of Kenyans that are aware of the problem.<sup>32</sup>

Once Akunyili had settled the Nigerian aspect of the trade, she looked abroad and followed the counterfeit trail to India and China, which was a very important step as it had implications for the rest of Africa. African governments looking to clamp down on counterfeit drug entry into their country could use her findings in their own countries. She made it her business to engage with drug regulators in India in an effort to get them to stop exporting “bad medicines” into Nigeria. Akunyili observed that drug regulations on drugs meant for internal use in India were much stricter than for drugs that were to be exported to countries like Nigeria. Angered by the lax regulation standards for exported drugs, Akunyili made calls for laws to be put in place to ensure that the stricter regulation be enforced for drugs exported out of India. Drug regulators in India agreed with Akunyili, and promised to make the necessary changes to the legislation. After sometime, she saw that no such changes were being made to the legislation, and so Akunyili took matters into her own hands. In the NAFDAC labs, tests were carried out on drugs imported from India and China. Companies, whose products were found to have been counterfeited consistently, were black listed. Akunyili was able to black list and eventually ban 19 drugs manufactured

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<sup>32</sup> Ogisi, Mitchell. " Fake Medicine Common in Many Sub-Saharan African Countries ." Gallup.Com - Daily News, Polls, Public Opinion on Government, Politics, Economics, Management . <http://www.gallup.com/poll/149942/fake-medicine-common-sub-saharan-african-countries.aspx> (accessed December 13, 2011).

in India. More importantly, Akunyili tightened Nigerian customs on drug imports coming from abroad.<sup>33</sup>

Her crusade to eradicate counterfeit drugs in Nigeria did not go unnoticed. Drug counterfeiters were so angered by her actions that on March 7<sup>th</sup>, 2004 they set fire to NAFDAC laboratories and offices<sup>34</sup>. Later, they made an attempt on her life, which she survived without injury. She has also angered pharmaceutical companies by calling for them to take action and to work together with governments to help eradicate the problem. Companies, like Pfizer, whose drugs have been imitated by counterfeiters, are hesitant to respond, because they do not want their name associated with the counterfeiting. It reflects badly on them, and could affect their business. Their shareholders might switch to companies with better reputations and they might have to do massive recalls in cases where counterfeited versions of their products have resulted in mass casualties.<sup>35</sup>

Akunyili has a vision and she is adamant that she will see it through. She asserts, "We are not there yet. Even 1% fake drugs is not good enough, because every life is important".<sup>36</sup> It is this vision and fearlessness that Tanzanian and Kenyan policy makers could learn a great deal from. Tanzania, like Nigeria, has a Food and Drug regulatory body. The Tanzania Food and Drug Authority (TFDA)

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<sup>33</sup> *Bad Medicine*. DVD. Directed by Karen O'Connor. London: British Broadcasting Corporation, 2005.

<sup>34</sup> Akunyili, Dora. "Akunyili." Farmaceuter utan Gränser Sverige. [www.fug.se/ovrigt/Akunyili.pdf](http://www.fug.se/ovrigt/Akunyili.pdf) (accessed December 14, 2011).

<sup>35</sup> *Ibid*

<sup>36</sup> Raufu, Abiodun. 2006. "Nigeria Leads Fight Against "Killer" Counterfeit Drugs ." World Health Organization . [www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/index1.html](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index1.html) (accessed December 11, 2011).

was established in 2003<sup>37</sup>, thus making it a decade younger than NAFDAC, which was established in 1993.<sup>38</sup> It has had less time than its Nigerian counterpart, but it is definitely making great progress. Through the course of the year 2009 the World Health Organization in conjunction with TFDA worked towards the improvement of drug regulation and on training 20 TFDA drug inspectors on detection, identification and investigation of counterfeit medicines.<sup>39</sup> Still, as the journalist Songa Wa Songa stated, “authorities would need to do extra homework to win the war”<sup>40</sup>. There is a great deal of room for improvement; in order to combat the issue, Tanzanian authorities need to first establish what the exact extent of the problem is. Currently, Tanzanian authorities are only able to make speculations about the market worth of counterfeit drugs in the market, but they suspect that “racketeers could be walking away with billions of shillings at the expense the public's wellbeing”. As recently as October 1<sup>st</sup>, 2011, the TFDA has conducted sting operations. Nevertheless, as Mr. Songa points out, “such sporadic raids have not deterred dealers”.<sup>41</sup> Tanzania must tighten its customs and borders, especially when its neighbors are struggling to get a hold of the counterfeit trade in their own countries.

Kenya, a neighbor of Tanzania, is only now beginning to take a more active role in combatting the issue of counterfeit drugs within its borders. The

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<sup>37</sup> [http://www.afro.who.int/en/downloads/doc\\_details/2783-united-republic-of-tanzania-country-pharmaceutical-profile-and-npo.html?tmpl=component](http://www.afro.who.int/en/downloads/doc_details/2783-united-republic-of-tanzania-country-pharmaceutical-profile-and-npo.html?tmpl=component)

<sup>38</sup> NAFDAC. "NAFDAC Organisation." NAFDAC.

[http://www.nafdac.gov.ng/index.php?option=com\\_content&view=article&id=46:nafdac-organisation](http://www.nafdac.gov.ng/index.php?option=com_content&view=article&id=46:nafdac-organisation) (accessed December 13, 2011).

<sup>39</sup> [http://www.afro.who.int/en/downloads/doc\\_details/2783-united-republic-of-tanzania-country-pharmaceutical-profile-and-npo.html?tmpl=component](http://www.afro.who.int/en/downloads/doc_details/2783-united-republic-of-tanzania-country-pharmaceutical-profile-and-npo.html?tmpl=component)

<sup>40</sup> Ibid

<sup>41</sup> Wa Songa, Songa. "allAfrica.com: Tanzania: Fake Drugs Nightmare." allAfrica.com: Home. <http://allafrica.com/stories/201110090045.html> (accessed December 13, 2011).

regulatory board in Kenya, the Pharmacy and Poisons Board, was established early in 1957, and become recognized as a corporate body in 1993.<sup>42</sup> It is as old as NAFDAC; yet, it seems to have done much less in comparison. Granted, the prevalence of counterfeit drugs did not reach as high a percentage as that of Nigeria, but today, Nigeria has surpassed Kenya in its attempt to eradicate counterfeit drugs within its borders. In present day Nigeria, somewhere between 16%-20% of the drugs in its market are counterfeited, whereas in Kenya as much as an estimated 30% of the drugs in circulation are counterfeited<sup>43</sup>. The Kenyan government and the Kenyan Pharmacy and Poisons Board are still grappling with the issue. In September 2011 it was discovered that at least 16,340 batches of the counterfeit Anti-Retroviral drugs were released into the pharmaceutical market. According to a reporter:

The ARVs were found to be falsified versions of a World Health Organization (WHO)-certified generic drug purchased through a distributor endorsed by the Kenya Pharmacy and Poisons Board (KPPB), the country's drug regulatory authority.<sup>44</sup>

Occurrences such as these indicate that the Kenyan regulatory body should enforce stricter customs on drug imports. In addition, they should carry out more frequent inspections, and not rely so much on external organizations, like the World Health Organization to ensure the safety of the drugs they import. The World Health Organization has set up a body to monitor and prevent drug counterfeiting around the world. The International Medical Products Anti-

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<sup>42</sup> "Pharmacy & Poisons Board | About Pharmacy and Poisons Board." Pharmacy & Poisons Board | Home. <http://www.pharmacyboardkenya.org/index.php?id=109> (accessed December 14, 2011).

<sup>43</sup> Ibid

<sup>44</sup> All Africa 19 October 2011

Counterfeiting Taskforce (IMPACT) was launched in 2006<sup>45</sup>. With an estimated 10% of the world's drug supplies suspected to be counterfeit IMPACT will not always be able to assist very much at the local level. Therefore, it is up to Kenyan and Tanzanian drug regulators alike to take charge of what happens within their borders.

### The Implications of Counterfeiting:

#### *Economic:*

Drug counterfeiting has negative implications for both pharmaceutical companies and local economies. Counterfeiters cheat large corporations out of billions of dollars when their fake drugs are purchased instead of genuine drugs. The counterfeit drugs cause the real drugs to undersell<sup>46</sup>. Alternatively, for the local economy, because counterfeit drugs are smuggled into the country illegally the counterfeiters avoid paying important duties and sales taxes. Therefore, the local economy suffers, whilst the patients gain no real benefits. Meanwhile, the only actors making a profit out of this trade is the counterfeiters themselves.

According to Consultancy Africa:

A 2009 UN report showed that revenues from 45 million fake anti-malarial drugs were worth around US\$ 438 million, which is greater than the gross-domestic product (GDP) of Guinea-Bissau.<sup>47</sup>

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<sup>45</sup> International Medical Products Anti-Counterfeiting Taskforce (IMPACT). "About Us." World Health Organization. [www.who.int/impact/about/en/](http://www.who.int/impact/about/en/) (accessed December 14, 2011).

<sup>46</sup> Fenoff, Roy S., and Jeremy M. Wilson. "Africa's Counterfeit Pharmaceutical Epidemic: The Road Ahead." *Anti Counterfeiting And Product Protection Programme*. University of Michigan, 1 Oct. 2009. Web. 7 Nov. 2011. <<http://a-capp.msu.edu/sites/default/files/publications/Africa%20Pharma%20Paper.pdf>>.

<sup>47</sup> Meissner, Richard. "The trade in counterfeit goods: What is it, why is it a problem and what is its impact on Africa?" Consultancy Africa Intelligence - Assist | Inform | Empower. [http://www.consultancyafrica.com/index.php?option=com\\_content&view=article&id=475:the-trade-in-counterfeit-goods-what-is-it-why-is-it-a-problem-and-what-is-its-](http://www.consultancyafrica.com/index.php?option=com_content&view=article&id=475:the-trade-in-counterfeit-goods-what-is-it-why-is-it-a-problem-and-what-is-its-)

The lucrative nature of the trade makes it harder to deter, especially if the selling of one type of drug, anti malarial drugs, is enough to generate wealth worth the GDP of a small African nation. Moreover, because few African countries have tough enough penalties on counterfeiting, the economic gains far outweigh the risks involved. In Nigeria, Akunyili attempted to change the law to make it harder on the perpetrators, thus deterring them from engaging in counterfeiting. However, so far the legislation in Nigeria only imposes fines as a penalty, as opposed to a harsher punishment like jail time.

*Social:*

Patients who take counterfeits and fail to get better understandably lose faith in the healing powers of modern medicine, and especially in poor countries they may turn instead to traditional healers.<sup>48</sup>

Apart from putting a strain on the public healthcare system, drug counterfeiting also instills a great deal of mistrust in patients: Patients may boycott the biomedical system, because they feel that it has failed them. Officials, like Edith Ngirwamungu, the president of the Medical Association of Tanzania, fear that by “having these counterfeit drugs, [it] makes people fearful of conventional drugs and revert back to traditional drugs”.<sup>49</sup> This in itself may be dangerous, because at times traditional healers prescribe “western” medication. If these medicines happen to be counterfeit as well, then the patient will continue to suffer ill health or worse, be poisoned by the counterfeit drugs. Regardless of which system of

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<sup>48</sup> Heller, Matthew. "Report Urges Global Crackdown on Counterfeit Medicines | FairWarning." FairWarning: News of safety, health and corporate conduct | FairWarning. <http://www.fairwarning.org/2011/02/report-urges-global-crackdown-on-counterfeit-medicines/> (accessed December 14, 2011).

<sup>49</sup> IRIN. "IRIN Africa | TANZANIA: Counterfeit drugs put lives at risk | Tanzania | Economy | Health & Nutrition ." IRIN • humanitarian news and analysis from Africa, Asia and the Middle East - updated daily . <http://www.irinnews.org/report.aspx?reportid=82374> (accessed December 14, 2011).

healing (biomedical or traditional) they choose to consult, in the end if counterfeit drugs are involved the patient is the one who suffers – they may suffer prolonged illness or death.<sup>50</sup>

*Biomedical:*

Perhaps the most devastating consequence of drug counterfeiting is that it causes drug resistance for fatal diseases like Malaria, Tuberculosis and HIV/AIDS. Diseases, like malaria and tuberculosis, which were once curable, are getting increasingly harder to cure. Counterfeit drugs that have trace amounts of active ingredients cause drug resistance to occur. In response to this recent surge of drug resistance, many researchers have come to believe that counterfeit drugs without any active materials are ultimately much safer, than counterfeit drugs with some active materials. They claim, “low levels of active ingredient assist the microorganisms in adapting to the drugs making the drugs less effective”.<sup>51</sup>

Drug resistance has had fatal results on children, who have much weaker immune systems than adults. In the case of malaria, “counterfeit medicines have been indicated as a major reason why malaria has become, over the past 30 years, the biggest cause of child deaths in Africa, when previously it was an illness that was easily treated with medicine.”<sup>52</sup> Similarly, there have been

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<sup>50</sup> Sengiyumva, Gasirigwa . "allAfrica.com: Tanzania: War On Counterfeit Drugs Still On." allAfrica.com: Home. <http://allafrica.com/stories/201007050338.html> (accessed December 14, 2011).

<sup>51</sup> Fenoff, Roy S., and Jeremy M. Wilson. "Africa's Counterfeit Pharmaceutical Epidemic: The Road Ahead." *Anti Counterfeiting And Product Protection Programme*. University of Michigan, 1 Oct. 2009. Web. 7 Nov. 2011. <<http://a-capp.msu.edu/sites/default/files/publications/Africa%20Pharma%20Paper.pdf>>.

<sup>52</sup> Gibson , Hannah . "A dangerous case of mistaken identity: Counterfeit medicines in West Africa." Consultancy Africa Intelligence - Assist | Inform | Empower.

reports of resistance towards medications for tuberculosis and even anti-retroviral drugs.<sup>53</sup> Beyond rendering some of these diseases virtually incurable, drug resistance has shown that it can create new strains of disease. These new strains might be even harder to cure than the ones presently in circulation.

According to the World Health Organization, drug resistance will put the healthcare systems of developing countries in worse shape than they already are. First, cheap drugs will become ineffective in the treatment of these diseases. Then, new drugs will have to be developed to replace the old ones, which cost a great deal of money. It will cost more money than many of these nations can afford, thus placing an economic burden on these countries.<sup>54</sup> While drug resistance is a direct consequence of counterfeit drugs that have small amounts of active ingredients, allergic reactions and possibly even death are the side-effects of taking drugs with too much active ingredient or ingredients that are poisonous. These versions of counterfeit drugs evidently cause more direct and tangible harm.<sup>55</sup>

### Does Technology Offer the Solution For This Problem?

Large corporations have resorted to using technologies such as

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[http://www.consultancyafrica.com/index.php?option=com\\_content&view=article&id=460:a-dangerous-case-of-mistaken-identity-counterfeit-medicines-in-west-africa&catid=60:conflict-terrorism-discussion-papers&Itemid=265](http://www.consultancyafrica.com/index.php?option=com_content&view=article&id=460:a-dangerous-case-of-mistaken-identity-counterfeit-medicines-in-west-africa&catid=60:conflict-terrorism-discussion-papers&Itemid=265) (accessed December 14, 2011).

<sup>53</sup> Harris, Julian, Philip Stevens, and Julian Morris. "Keeping It Real." *African Liberty*. Health Issues, May 2009. Web. 7 Nov. 2011. <<http://africanliberty.org/pdf/Keepingitreal.pdf>>.

<sup>54</sup> Kelesidis, Theodore, Iosif Kelesidis, Petros I. Rafailidis, and Matthew E. Falagas. "Counterfeit or substandard antimicrobial drugs: a review of the scientific evidence." *JAC Online: Oxford Journals*. [jac.oxfordjournals.org/content/60/2/214.full#xref-fn-1-1](http://jac.oxfordjournals.org/content/60/2/214.full#xref-fn-1-1) (accessed December 14, 2011).

<sup>55</sup> *Ibid*

holograms and barcodes to make their products harder to counterfeit.<sup>56</sup> These are wasted efforts, because the best counterfeiters have managed to mimic the holograms and create barcodes that look like carbon copies of those from the big corporations. In the case of the hologram, officials explain that the ones that are produced by counterfeiters are dull in comparison to the holograms produced by the pharmaceutical companies. These indicators are complicated and difficult for the ordinary person to use when trying to differentiate between the genuine product and the fake.<sup>57</sup> In addition, these technologies are expensive. Realizing the many faults of the use of holograms and barcodes, the United States Pharmacopeial Convention decided to find a much cheaper solution.

They suggested the use of mobile phones by offering the explanation that it was making use of “a technology that millions of people have access to”.<sup>58</sup> The system they set up makes use of a unique identification code that each box is inscribed with. Upon purchase, the customer scratches the box to reveal the number. The customer will then send a text message to the central register, which will send a message that indicates whether the product is genuine or counterfeited. The system has been in use in Nigeria for quite some time, and was adopted by Kenya in October of 2011. Orange, a telecommunications network, is the body that is regulating the use of this system in Kenya.<sup>59</sup> There are presently no statistics or research to indicate how successful this new system

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<sup>56</sup> Harris, Julian, Philip Stevens, and Julian Morris. "Keeping It Real." *African Liberty*. Health Issues, May 2009. Web. 7 Nov. 2011. <<http://africanliberty.org/pdf/Keepingitreal.pdf>>.

<sup>57</sup> *Bad Medicine*. DVD. Directed by Karen O'Connor. London: British Broadcasting Corporation, 2005.

<sup>58</sup> Harris, Julian, Philip Stevens, and Julian Morris. "Keeping It Real." *African Liberty*. Health Issues, May 2009. Web. 7 Nov. 2011. <<http://africanliberty.org/pdf/Keepingitreal.pdf>>.

<sup>59</sup> "Orange Kenya launches programme to fight counterfeit drugs | Medicalkenya." Medical Kenya: your best health now. <http://medicalkenya.co.ke/2011/10/orange-kenya-launches-programme-to-fight-counterfeit-drugs/> (accessed December 15, 2011).

has been, but frequent reports, published by journalists and Non-Governmental Organizations, like the WHO, would suggest that so far the system seems to be running very well.

### What Does the Future Hold for Counterfeit Drugs in Africa?

Presently, there is no agreement on how to define a counterfeit drug, let alone a scheme in international law to make counterfeiting a crime and pursue its perpetrators around the globe.<sup>60</sup>

Drug counterfeiting is not an issue that is unique to these countries. It is an issue that affects most of Sub-Saharan Africa. These countries may have made strides to combat the issue within their own borders, and they may even have made vast improvements, but there is only so much that one country can do to tackle a regional problem. The porous borders between many African nations means that even if one country, for example, Nigeria, manages to resolve the issue of counterfeit drugs within its own borders, counterfeit drugs will still be prevalent, albeit to a lesser extent, unless its neighboring countries do the same.

Eradicating counterfeit drugs from the continent will require the effort of all affected countries. To start, perhaps, the African Union can formulate a definition of what a counterfeit drug is, within the context of the African continent. Once all the countries have a clear idea of what they are looking to eradicate, they can then form a legal collective, such as the Africa and the East African Society, and create laws that impose more deterrent punishments on the drug counterfeiters. Many African officials see tougher penalties as the next

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<sup>60</sup> Bate, Roger, and Amir Attaran . "A counterfeit drug treaty: great idea, wrong implementation : The Lancet." TheLancet.com - Home Page.  
<http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2810%2961416-X/fulltext> (accessed December 14, 2011).

logical step towards the eradication of this lethal trade.<sup>61</sup> There are no estimates on when Africa will be free of counterfeit drugs, however, even without an end in sight many African countries are taking the necessary steps to safeguard the welfare of their people.

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<sup>61</sup> Mcdiarmid, Jessica , and Poindexter Sama. "allAfrica.com: Sierra Leone: Substandard And Counterfeit Drugs Flood the Market." allAfrica.com: Home. <http://allafrica.com/stories/201106190011.html> (accessed December 14, 2011).

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