SUBCOMMITTEE HEARING
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515-0128

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, AND HUMAN RIGHTS
Christopher H. Smith (R-NJ), Chairman

Fighting Malaria: Progress and Challenges

December 5, 2011

Congressional Testimony by Dr Roger Bate, Legatum Fellow in Global Prosperity at the American Enterprise Institute in Washington DC, and a Director of Africa Fighting Malaria, a research organization based in Washington and South Africa.

Mr Chairman, members of the committee, thank you for inviting me to testify on this important topic.

Seven years ago I testified before this committee on what was then a relatively weak domestic and international effort against malaria. United States Government (USG) and other donors were then not funding all viable preventive measures, most notably refusing to support the use of the insecticide DDT. International donors were also supporting out of date medicines which exacerbated significant resistance problems and failed to treat malaria cases effectively. Leading malaria scientists, ably lead by Dr Amir Attaran, exposed this folly and pressured for change. But with limited funding available at both the domestic and international level, change was slow to materialize.

Reforms then came about rapidly. Within fourteen months of that hearing, the WHO publicly defended the use of DDT at a press conference in Washington chaired by my colleague, Richard Tren.[1] President Bush announced the billion dollar President's Malaria Initiative (PMI) and PMI began buying DDT and promoting its use.[2] The Global Fund to Fight AIDS, TB and Malaria (Global Fund) ramped up spending on both preventative efforts as well as treatment efforts that included the best drugs to fight malaria, artemisinin-based combination therapies (ACTs).[3]

---

[1] *Africa Fighting Malaria Annual Report January 2007*, Annual Report, page 2, http://www.fightingmalaria.org/pdfs/2006%20AFM%20Annual%20Report.pdf.
[2] "WHO gives indoor use of DDT a clean bill of health for controlling malaria," World Health Organization, last modified September 15, 2006, http://www.who.int/mediacentre/news/releases/2006/pr50/en/.
[3] *REVIEW OF THE GLOBAL FUND GRANT PORTFOLIO – FUNDING THE RIGHT THINGS?*, A TERG Technical
Report August 2006, page 4,
http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CC4QFjAB&url=http%3A%2F%2Fwww.theglobalfund.org%2Fdocuments%2Fterg%2FTERG_FiveYearEvaluationPortfolioReview_Paper_en%2F&ei=yD-5Tr3fOaW22gXqzr2pBw&usg=AFQjCN G49slEC3d0fIvDr9u8RTTeCEV-Hw.

Progress was swift and impressive, particularly in locations targeted by PMI such as the Tanzanian island of Zanzibar. Where all available preventive and treatment measures were used, cases and fatalities plummeted. By 2007, the disease had almost been eliminated from the island.[4] In all PMI-targeted countries, child mortality fell impressively by between 23% and 36%.[5] Since malaria is often the leading cause of child mortality, improved malaria control significantly lowers all cause child mortality, and in PMI countries the only major public health program in recent years was for malaria control.[6] For this reason, the PMI can take credit for a large portion of these saved lives. Across the board malaria rates have fallen, although it is difficult to know the magnitude of the decrease because reporting is sparse and health systems across the region are poor. According to the Lives Saved Model (LiST), supported by the Roll Back Malaria Partnership, over 1 million malaria related deaths have been prevented since 2000.[7] Most of these deaths would have been prevented since the reforms began in the latter part of the last decade.

Nigeria and the DR Congo, home to half of the continent's malaria cases, were recently added as PMI focal countries. At the same time, the Global Fund and other donors began scaling up their programs in these two nations in the hope that success is possible there too. Reductions in disease can be achieved in both nations, but it is not yet possible to contemplate eliminating malaria because health systems are so weak in these countries.

Parts of southern Africa are attempting disease elimination. The Southern African Development Community (SADC) has agreed to a Malaria Elimination 8 (E8) program that targets malaria elimination in Botswana, Namibia, South Africa and Swaziland and scales up interventions in support of (with the long term goal of) elimination in Angola, Mozambique, Zambia and Zimbabwe. If governments demonstrate strong political will at the highest levels, donors sustain funding, and the two partner to effectively utilize all available techniques, there is a chance that these efforts will succeed in eliminating malaria, as Mauritius and the United Arab Emirates have.[8]

So overall there is good news, but significant challenges remain.

Challenges:

Artemisinin-based Combination Therapies (ACTs) are the best treatment available for falciparum malaria, but resistance to current artemisinin has already been noted in the Thai,

---

[4] Peter McElroy, "Zanzibar: Beyond Malaria Control ," President's Malaria Initiative, http://www.pmi.gov/countries/profiles/zanzibar.html.
[5] Katie Todd, "The President's Malaria Initiative: Success Stories from Senegal," Malaria Policy Center, last modified June 19, 2011, http://www.malariapolicycenter.org/blog/?tag=pmi.
[6] "Countries," President's Malaria Initiative, http://www.pmi.gov/countries/index.html.

[7] *A Summary of Regional Progress from A Decade of Partnership and Results*, Roll Back Malaria Partnership Progress & Impact Series, page 2, http://www.rollbackmalaria.org/ProgressImpactSeries/docs/report8factSheet2-en.pdf.
[8] *Progress Against Malaria: Winning the Fight Against a Deadly Disease*, Gates Foundation Progress Sheet, page 3, http://www.gatesfoundation.org/livingproofproject/Documents/progress-against-malaria.pdf.

Cambodia,[9] and Burmese borders.[10] While new versions of ACTs, such as the Wellcome Trust supported DHA-PPQ drug,[11] are being developed, there are no effective substitutes for ACTs yet. Early trial results for the new malaria vaccine have generated significant hype, but even if the vaccine becomes available in the next few years, it will only afford a 50% protection level for approximately one year.[12,13] Limiting resistance to the most effective current treatments for malaria is therefore vital.

There are several reasons that resistance is likely to increase:

Substandard and fake medicines. Fake and substandard antimalarial medications are a major problem in Africa. In the first study my research team did in 2007, we found that nearly a third of the drugs failed basic quality control tests. Many of these were fakes and contained no active ingredient. [14] While these medicines are potentially lethal, fakes with no active ingredient do not increase drug resistance. But fakes with some active ingredient and substandard medicines are likely to increase drug resistance. Substandards are badly produced medicines made by legal manufacturers. They do not work properly because they contain some of the wrong ingredients, the right active ingredients in the wrong amounts, or the right ingredients in the right proportions but improperly formulated. Substandard drugs threaten the patient's life and may contribute to drug resistance. It is impossible to know the extent of the effect but it may be significant, particularly given the increasing proliferation of brands.[15] A report from 2004 found more than 200 different antimalarial brands in Kenya alone.[16] Across all of our studies we found that perhaps 15% of the dozens of brands of artemisinin therapies were substandard. Cutthroat competition is driving prices downwards, increasing pressure on small manufacturers to cut corners to keep costs low enough to stay in the market.

N.B. I should add one point of good news and that is USG's funding of efforts to limit fake and substandard drugs directly. USG through USAID funds the US Pharmacopea program on quality medicines (PQM). This program, totaling $35m over five years aims to improve the medical regulatory authorities in emerging countries so as to improve oversight and lessen likelihood of

---

[9] *Progress Against Malaria: Winning the Fight Against a Deadly Disease*, Gates Foundation Progress Sheet, page 3, http://www.gatesfoundation.org/livingproofproject/Documents/progress-against-malaria.pdf.

[10] Chansuda Wongsrichanalai and Steven R Meshnick, "Declining Artesunate-Mefloquine Efficacy against Falciparum Malaria on the Cambodia-Thailand Border," *EID Journal*, 14th ser., no. 5 (May 2008.

[11] "Malaria treatment approved for use by the European Medicines Agency," Wellcome Trust, last modified October-November 3, 2011, http://www.wellcome.ac.uk/News/2011/News/WTVM053342.

[12] Martin Enserink, "New Hope for 'Crazy' Malaria Vaccine," Science, last modified September 8, 2011, http://news.sciencemag.org/sciencenow/2011/09/new-hope-for-crazy-malaria-vacci.html.

[13] "Part II: The Global Strategy," in *Global Malaria Action Plan*, Roll Back Malaria Action Plan, http://www.rbm.who.int/gmap/2-4a.html.

[14] Roger Bate, Philip Coticelli, Richard Tren, and Amir Attaran, "Antimalarial Drug Quality in the Most Severely Malarious Parts of Africa: A Six Country Study," *PLoS One* (May 7, 2008).

[15] *Fact Sheet N°275: Counterfeit Medicines February 2006*, World Health Organization Fact Sheet, http://www.gphf.org/images/downloads/library/who_factsheet275.pdf.

[16] Kaur, Harparkash, Michael D Green, Dana M Hostetler, Facundo M Fernandez, and Paul N Newton. Antimalarial drug quality: methods to detect suspect drugs.http://www.actconsortium.org/data/files/kaur_et_al_in_therapy012010.pdf.

fake and substandard medicines in these markets.[17] While this applies to all medicines, poor quality antimalarials are often rife in some of these markets. My team's research found that unregistered medicines were five times more likely to fail quality standards than registered medicines.[18]

Monotherapies. Six years ago the WHO demanded that manufacturers stop making and selling artemisinin monotherapies[19] since the likelihood of artemisinin resistance developing is much higher if malaria strains are exposed to it alone. When combined with another less effective but still useful drug, the odds on the parasite developing resistance to both simultaneously is far lower. But it appears this warning was not heeded. My research team found over a dozen brands of artemisinin monotherapies for sale in 2007.[20] In another study earlier this year in Accra and Lagos, my colleagues found several monotherapy brands still on sale.[21] According to WHO data from November of last year, 53 of the 78 nations in need of ACTs have outlawed these products, but the other 25 nations have been less proactive.[22] Additionally, producers from China, India and Vietnam in particular ignore WHO policies and demands, and continue manufacturing these drugs.[23]

Over supply – AMFm . In many highly malarial countries, most people purchase malaria treatment from private shops and pharmacies. The Affordable Medicines Facility malaria (AMFm) was established in an attempt to increase access to the most effective medicines and drive out the ineffective and proscribed treatments (such as oral artemisinin monotherapies) by providing highly subsidized ACTs via the private sector. AMFm is currently being piloted in 8 countries. It holds some promise because it recognizes the important role played by the private sector in malaria treatment; however, its implementation leaves a great deal to be desired. Although the first year of the pilot phase is not yet completed, significant problems are already evident. For instance, AMFm does not address diagnosis problems, which could exacerbate the inappropriate use of these valuable treatments (notably non-malarial fevers being treated with antimalarials). Furthermore, the Global Fund has authorized and subsidized ACT deliveries that can only be described as inappropriate. For instance, the Global Fund authorized the delivery of 240,000 ACT treatments to Zanzibar, which as I have already described, has almost no malaria. AMFm orders that have been approved for just four countries account for 80 percent of the total annual global ACT production capacity. Over 70 percent of these approved orders are for adult treatments – which is odd as malaria is mostly a childhood disease (adult dose packs often

---

[17] Phil Taylor, "USAID, USP launch counterfeit meds programme," Securing Pharma, last modified October 27, 2009, http://www.securingpharma.com/usaid-usp-launch-counterfeit-meds-programme/s40/a265/.
[18] Roger Bate, Loraine Mooney Kimberley Hess, Medicine Registration and Medicine Quality, Research and Reports in Tropical Medicine, December 2010 Volume 2010:1 Pages 89 - 93
[19] *WHO informal consultation with manufacturers of artemisinin-based pharmaceutical products in use for the treatment of malaria: August 24, 2007*.
http://www.who.int/malaria/publications/mtgmanufacturersartemisininderivatives.pdf. (page 8)
[20] Roger Bate, "One in Three Malaria Drugs Failing in Africa," International Policy Network, http://www.policynetwork.net/health/media/one-three-malaria-drugs-fai
[21] Richard Tren et al., *Africa Fighting Malaria Policy Paper-September 2011*, http://www.malariaworld.org/sites/default/files/AMFmPolicyPaper.pdf.
[22] *Marketing of oral artemisinin-based monotherapy medicines at country level: November 19, 2010*, page 1, http://www.who.int/malaria/monotherapy_NDRAs.pdf.
[23] "WHO Launches Effort to End Misuse of Malaria Drug," Daily News Central, last modified January 20, 2006,http://health.dailynewscentral.com/content/view/0002070/58/.

contain four-fold the number of pills at only a bit more in price, and so I speculate that each pack is being split up and sold to treat more than one child - increasing profit but increasing risk of inappropriate dosing and even product degradation). My colleagues repeatedly asked the Global Fund for the rationale behind subsidizing so many adult treatments for a childhood disease, but have not been given any answers. There is no medical or public health justification for it. Based on leaked documents exposed by Africa Fighting Malaria in its recent report, this one treatment program will soon contribute to a global shortage of ACTs. The report[24] describes several instances of mismanagement of public funds and an apparent disregard of how the malaria treatments will be used. While the US Government has refused to fund AMFm, tightening global ACT supply is affecting US Government programs and hindering their ability to purchase the best quality malaria treatments.

The AMFm also aims to lower resistance. In highly malarial countries, most people presumptively treat fevers with malaria drugs, in part because the cheapest malaria drugs are less expensive than the cheapest diagnostic test. But a study from 2007 found that up to half the cases presumed to be malaria were in fact something else.[25] Such self-diagnosis and over-prescription is an extreme waste of scarce resources and may also further create resistance. This is inevitable to some degree given levels of poverty, lack of education and lack of access to free diagnostics (at government clinics).

While in principle the AMFm could work, and in some locations it may be doing so, it is flooding the market with ACTs, some of which are being stolen and diverted (often degrading as they are transported in poor conditions) to other markets. Ignoring its disruption to systems, it is also increasing stock-outs in other areas. And while all the producers are prequalified by WHO, there is doubt as to whether quality is being maintained as production dramatically increases. My colleagues and I have a paper passing through peer review at this moment, which will support this statement. Previous research touched on the theft of drugs of which the latest research also comments.[26] Finally, in my team's recent research, we found that domestically produced drugs (notably antimalarials made by African companies) had the worst quality problems.[27] AMFm drives increased production by such companies, who hope that at some stage they will be able to compete for AMFm funding. African country representatives are lobbying hard for their companies to take part and African companies are aware of, if not financing, this lobbying.

All in all, AMFm is disrupting distribution systems and causing medicine procurement to operate on a first-come, first-served basis, creating huge problems for donors (including PMI).

Insecticide resistance. The World Health Organization is rightly concerned about the rise in insecticide resistance and is currently formulating a comprehensive strategy to deal with the problem. To address this challenge, resistance management programs will require the use of

---

[24] Available at: http://www.fightingmalaria.org/pdfs/amfmpolicypaper.pdf

[25] Africa in an era of combination therapy," World Health Organization, http://www.who.int/bulletin/volumes/86/2/07-042259/en/index.html.

[26] Roger Bate Lorraine Mooney and Kimberly Hess , Antimalarial Medicine Diversion, Research and Reports in Tropical Medicine, September 2, 2010

[27] Roger Bate, Lorraine Mooney, and Julissa Milligan, "The Danger of Substandard Drugs in Emerging Markets: An Assessment of Basic Product Quality," *Pharmacologia* 3, no. 2 (2012): page 46-51, http://www.aei.org/docLib/Pharmacologia-Published.pdf.

several different insecticides with different active ingredients and modes of action to break the spread of resistant genes. However, decades of anti-insecticide activism have deterred research into this vital area of public health; even with the rise in malaria research and development funding in recent years, only 4 percent has been spent on disease vector control[28] (mosquito control) and only a fraction of that would be devoted to insecticides. This is a challenge that must be addressed sooner rather than later, and it will be difficult to root out since anti-insecticide activism reaches the highest echelons of the United Nations bureaucracy.[29]

Malarial country support. Malaria control requires ongoing and sustained funding. The United States has led the way and is the most generous nation when it comes to malaria control.[30] It is time, however, for malarial countries to start contributing to their own programs. While some malarial countries have genuinely limited budgets, others, particularly those in West Africa, have massive oil reserves and for several years have enjoyed windfall revenues thanks to high oil prices. US taxpayers have, for the most part, been happy to support life saving programs abroad, but it is time for these relatively wealthy malarial countries to start acting as true partners and begin funding some or all of their own programs.

USG funding of other agencies. The Global Fund is to be commended for its transparency, but it has failed to act on the information it has gleaned, and continues to allow its funds to be used by governmental distribution systems known to be corrupt. The recent High-Level Independent Review Panel recommended the Global Fund "Mandate the outsourcing of drug storage and delivery as the norm, except where the Fund certifies a local institution according to international standards."[31] The Global Fund Board decided at its 24th Board Meeting to merely give consideration to this recommendation rather than to begin its implementation.[32] It has also used, and continues to use, UNDP as an intermediary even though it has no idea how UNDP has used its funds (since UNDP will not allow audit internal reports to be seen by the Global Fund[33]). UNDP's role as a principle recipient has been a significant barrier to Global Fund OIG audits.

---

[28] Program for Appropriate Technology in Health, "Staying the Course – Malaria Research and Development in a Time of Economic Uncertainty," June 2011, PATH, available: http://www.malariavaccine.org/files/RD-report-June2011.pdf

[29] Roberts, D, and Tren, R, "International advocacy against DDT and other public health insecticides for malaria control," *Research and Reports in Tropical Medicine*, Vol 2011:2, pp 23-30, January 2011, available: http://www.dovepress.com/articles.php?article_id=6101

[30] "Who Gives Money to the Global Fund?" Avert: Global Fund, http://www.avert.org/global-fund.htm#contentTable2.

[31] The Global Fund to Fight AIDS, TB and Malaria. Turning the Page from Emergency to Sustainability. The Final Report of the High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, TB and Malaria. Page 66. September 19, 2011. http://www.theglobalfund.org/en/highlevelpanel/

[32] The Global Fund to Fight AIDS, TB and Malaria. 24th Board Meeting Decision Points. September 26, 2011. http://www.theglobalfund.org/en/board/meetings/twentyfourth/

[33] The Global Fund to Fight AIDS, TB and Malaria. Turning the Page from Emergency to Sustainability. The Final Report of the High-Level Independent Review Panel on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, TB and Malaria. Page 17. September 19, 2011. http://www.theglobalfund.org/en/highlevelpanel/

Overcoming these problems:

1. The US Government should continue to control its own financing for malaria, targeting focus countries that agree to play by the rules and maintaining quality standards on drug quality and procurement. It must continue to use its own distribution systems where recipient governments are incompetent or corrupt. USG should encourage others (notably Global Fund) to do likewise or risk losing funding.
2. Future USG funding to the Global Fund must only continue if the Fund genuinely addresses the problems it has: the Fund should stop using UNDP in any role until UNDP provides audit reports on its spending; it must use different distribution systems when current systems have led to theft or corruption; USG should also pressure the Global Fund to prohibit medicine procurement from companies that manufacture and market oral artemisinin monotherapies[34].
3. USG should formulate policies to encourage investment in much needed new public health insecticides and to combat anti-insecticide activism.
4. USG should continue to fund the US Pharmacopea program on quality medicines through USAID. USP's PQM program is a good value for US taxpayers. This program could be expanded or at least extended in time.
5. USG should continue to boycott AMFm; indeed, it should provide regular updates on how AMFm distribution problems are negatively affecting its own programs and publicize such failings.

It is important that these actions are taken, and all entities including PMI are even more transparent (especially with information provided by contractors, which is often limited and highly redacted for external reviewers). Great progress is being made and thousands, maybe millions, of lives have already been saved. In the past, aid fatigue brought on by slack performance and measurement and sheer laziness reversed great gains made against malaria. It would be tragic if the excellent advances made against malaria in the past seven years were undermined by what are at the moment minor, but expanding, self-serving policies of African governments and producers, western producers and some western donors.

[34] See WHO for latest list of official positions of companies – some of these may not be complying with their own policies - http://www.who.int/malaria/monotherapy_manufacturers.pdf

United States House of Representatives
Committee on Foreign Affairs

"TRUTH IN TESTIMONY" DISCLOSURE FORM

Clause 2(g) of rule XI of the Rules of the House of Representatives and the Rules of the Committee require the disclosure of the following information. A copy of this form should be attached to your written testimony and will be made publicly available in electronic format, per House Rules.

1. Name:	2. Organization or organizations you are representing:
Roger Bate	American Enterprise Institute

3. Date of Committee hearing:
12/5/2011

4. Have you received any Federal grants or contracts (including any subgrants and subcontracts) since October 1, 2008 related to the subject on which you have been invited to testify?	5. Have any of the organizations you are representing received any Federal grants or contracts (including any subgrants and subcontracts) since October 1, 2008 related to the subject on which you have been invited to testify?
☐ Yes ☑ No	☐ Yes ☑ No

6. If you answered yes to either item 4 or 5, please list the source and amount of each grant or contract, and indicate whether the recipient of such grant was you or the organization(s) you are representing. You may list additional grants or contracts on additional sheets.

7. Signature:


Please attach a copy of this form to your written testimony.