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To: Representative Chris Smith, Chairman of Subcommittee on Africa, Global Health, Global Human Rights and International Organizations, House Committee on Foreign Affairs

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RE: Meeting the Challenge of Drug-Resistant Diseases in Developing Countries

The Problem

In an increasingly interconnected world, drug resistance has increased the costs of effectively fighting major diseases in developing countries, including HIV/AIDS, tuberculosis and malaria, as well as pneumonia, the leading killer of children in the world.[1] Drug resistance is so challenging because the efficacy of drugs is a collective global resource, one that will run out if overused by countless people around the world. Under business as usual, the pool of drugs that works will continue to shrink, and the costs of drug resistance to human life and society will inevitably increase, often with devastating impacts.[2]

The Opportunity

The U.S. government has an untapped opportunity to offer global leadership in the race against drug resistance through the key donor agencies of development assistance for health that it already supports. Addressing drug resistance may be cost-effective globally, but may not be cost-effective for developing countries, thus suggesting the importance of donor funding and attention to this neglected issue.

The United States is a major bilateral funder of global health against the 'big three' through the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (henceforth 'the Global Fund'), and has a major stake in ensuring that these investments are not wasted because of drug resistance. For PEPFAR, the largest transnational source of AIDS funding, purchases of antiretroviral (ARVs) represented 38% of the annual cost of treatment to PEPFAR.[3] Similarly, the Global Fund, the second largest international financier for AIDS and the largest international financier for tuberculosis and malaria, has historically spent about 40% of total funds on drugs for all three diseases. Finally, the President's Malaria Initiative (PMI), which is the second largest financier for international malaria efforts, spent almost 50% on drugs. Together, these three global-health agencies represent major purchasing power against these three diseases – and leverage against drug resistance of these three diseases.

Key Considerations for the U.S. Government

The Center for Global Development (CGD) published a 2010 report on *The Race Against Drug Resistance*, and made four key recommendations:

(1) Improve surveillance by collecting and sharing resistance information across networks of laboratories;

(2) Secure the drug supply chain to ensure quality products and practices;
(3) Strengthen national drug regulatory authorities in developing countries; and
(4) Catalyze research and innovation to speed the development of resistance-fighting technologies.

Below we highlight key considerations for Congress with respect to these recommendations and the key channels of U.S. development assistance for health that greatly affect drug resistance.

1. **A need for a systematic policy against drug resistance.** The first three recommendations above have major implications for all global-health funding agencies, including PEPFAR and the Global Fund. It is unclear, however, if these agencies view drug resistance as a serious threat. To our knowledge, neither PEPFAR nor the Global Fund has a publicly available and systematic policy to fight drug resistance, despite being actively involved in area (1) on surveillance and laboratory capacity along with area (2) on drug supply chains and health-care practices.

2. **Shift focus from numbers to retention and/or quality and appropriateness of treatment.** Both PEPFAR and the Global Fund have placed less attention on retention rates for HIV/AIDS (and treatment failure rates), which in turn creates drug resistance. Current performance indicators generally focus on the total number of people treated, irrespective of the quality or appropriateness of treatment. A retention indicator would help to align the incentives for health-care providers to deliver more appropriate care. Comparable indicators for appropriate tuberculosis and malaria treatment are also needed.

3. **Further strengthen surveillance and laboratory capacity.** Surveillance and laboratory strengthening through PEPFAR and the Global Fund are done on a country-by-country basis, which may well be done without explicit consideration of drug resistance or any connection to regional or global information sharing mechanisms, e.g. through the World Health Organization (WHO)'s Global Laboratory Directory or WHONET software which in theory collects drug resistance data from worldwide laboratories. In the case of PEPFAR, it is unclear whether surveillance and laboratory capacity strengthening is leveraging the Centers for Disease Control & Prevention's long historical expertise and forte in disease surveillance. Support by PEPFAR and the Global Fund for laboratory and surveillance may be ad hoc and inadequate and is given insufficient attention amidst other competing institutional priorities, e.g. the Global Fund's recent reform or upcoming replenishment, or PEPFAR's reauthorization.

4. **Leveraging resources in the race against drug resistance.** Although PEPFAR and the Global Fund represent a major financing source by which surveillance and laboratory capacity against drug resistance could be addressed, attention on them are likely to be crowded out by other issues each agency faces, particularly without designated funding or an institutional policy. One proposed alternative is to use the World Bank's International Development Association (IDA) as a key funding mechanism for global public goods including surveillance and laboratory capacity against drug resistance and emerging pandemic threats. Here, countries could request support to strengthen surveillance and laboratory capacity for diseases not covered by the Global Fund, e.g. pneumonia.

5. **Securing integrity of drug supply chains**. Both PEPFAR and the Global Fund to a lesser extent rely on the Partnership for Supply Chain Management (PSCM) to provide a cost-effective, reliable, secure and sustainable supply chain that can save millions of lives. But in the case of the Global Fund, it is unclear how countries that do not rely on PSCM (under voluntary pooled

procurement) are able to ensure the integrity of their drug supply chains. Careful study into the Global Fund's supply chain management for drugs not using PSCM is needed.

[1] www.unicef.org/media/files/UNICEF_P_D_complete_0604.pdf
[2] CGD Drug Resistance report
[3] www.pepfar.gov/documents/organization/188493.pdf