Congress of the United States
Washington, DC 20510

January 26, 2005

The President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President:

Two years ago, in your State of the Union address, you announced your initiative to fight the AIDS epidemic in the developing world, emphasizing the extraordinary value of generic medications. You rightly noted that, due to the availability of generic drugs, "seldom has history offered a greater opportunity to do so much for so many."[1]

We commend you for the bold vision of that initiative, but are concerned that this historic opportunity is being squandered. Nearly two years after those stirring words were uttered, not a single dollar of direct American AIDS funding has been used to purchase the generic drugs described in your Address. Not a single patient has been treated with them, using funds from your initiative.

Yesterday, the U.S. Food and Drug Administration announced the first approval of a generic HIV drug regimen for use as part of your AIDS initiative. This is a welcome initial step, but it is a limited one. The price and potential distribution of the approved regimen is not yet known, and many other generic drugs, including the most highly recommended triple combination therapies, are still ineligible for U.S. funding.

Today, we are transmitting to you a copy of a report by the Government Accountability Office (GAO) that identifies another important gap in the Administration's record on generic drugs. GAO found that the Administration still has not committed to purchasing safe and effective generic drugs when the U.S. patent holder objects. Without a commitment to purchase these drugs, GAO found that the Administration is dissuading manufacturers from seeking approval. GAO determined that one consequence may be that your AIDS initiative "may not expand rapidly enough to address the AIDS emergency."[2]

Yesterday's announcement does not address GAO's concern. The manufacturer of the regimen that received tentative approval reportedly had negotiated a license from

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[1]President Bush, *State of the Union Address* (Jan. 28, 2003).

[2]U.S. Government Accountability Office, *Global HIV/AIDS Epidemic: Selection of Antiretroviral Medications Provided under U.S. Emergency Plan Is Limited* (January 2005).

the two patent holders. Patent holders may be unwilling to grant similar licenses for other combination therapies that can make all the difference in the developing world. Such unwillingness should not stand in the way of saving lives.

The report also makes clear that alone among major international funders of AIDS programs, the United States has insisted on a separate review of the generic medications used extensively by respected international agencies such as the World Health Organization (WHO), Doctors Without Borders and the Global Fund for AIDS, TB, and Malaria. Almost a year ago, the Administration announced that these supplementary reviews would be "rapid" with a goal of approval in two to six weeks.[3] Many public health advocates have questioned the necessity of this additional level of review, and have urged the United States to allow the purchase of any drug pre-qualified by the WHO.

Almost a year later, the first of these reviews has finally been completed. We urge you to redouble your efforts to fulfill the original promise of speedy reviews for the many other generic medications that have enormous potential to save lives and alleviate suffering. We also urge you to join with the international community and participate in the WHO process.

Yesterday's announcement is an opportunity to clarify the Administration's policy on generic drugs. We urge you to fulfill the promise outlined in your State of the Union Address by making a meaningful commitment to using safe and effective generic medications.

GAO's Findings

In its study, GAO evaluated the use and cost of generic HIV drugs in developing countries. GAO found that generics have several important advantages over brand name drugs, including:

- **Generics are less expensive**. First-line generic AIDS drugs cost hundreds of dollars less per year than brand-name drugs, and could save the United States hundreds of millions of dollars — which translates into many more lives saved.

- **Generics are easier to use**. Some generic drugs — but no brand name drugs — combine an entire regimen into one pill, simplifying treatment and decreasing the likelihood of drug resistance.

- **Generics are supported by other donors.** International donors are purchasing a wide range of generic drugs for AIDS efforts in the developing world, recognizing that patent restrictions for wealthy nations should not apply to poor countries facing public health emergencies.

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[3]U.S. Department of Health and Human Services, *HHS Proposes Rapid Process for Review of Fixed Dose Combination and Co-Packaged Products* (May 16, 2004).

- **Generics are preferred by some developing countries**. Many developing countries, as they map out national plans to combat AIDS, are relying on generic drugs.

Despite these advantages, however, GAO found that the Administration still has not committed to purchasing generic drugs in the future – even those found to be safe and effective by FDA — without the agreement of the U.S. patent holder.

According to GAO, Administration officials perceive the Foreign Assistance Act of 1961 as a barrier to generic drug procurement. This Act states that when a drug is still under U.S. patent (as are all current antiretroviral drugs for AIDS), funds can only be used to purchase a foreign generic equivalent if the patent holder agrees to waive the patent.[4]

As GAO reports, the Global AIDS Coordinator has the authority to waive this Act and permit the purchase of drugs covered by U.S. patents for use abroad. Under each Foreign Operations Appropriations Bill since fiscal year 2002, the Coordinator has been given the right to pursue the fight against global AIDS notwithstanding any other provisions of law. This broad power allows the Global AIDS Coordinator to waive the Foreign Assistance Act requirements.

Despite this statutory authority, GAO found that the Administration is refusing to commit to a position on purchasing generics. Officials in the Office of the Global AIDS Coordinator told GAO that a waiver would only be issued "if the ARV [drug] in question is critical to the plan's treatment responsibilities and no readily available substitute exists."[5] The State Department commented that the Coordinator has decided to exercise this authority "as necessary."[6]

These standards are vague and meaningless. Because brand name versions of generic drugs exist, it is possible that no generic product will ever be deemed "necessary" or "critical," despite being safe and far more affordable.

The Administration's refusal to clarify the patent situation appears to have created reluctance among generic manufacturers who otherwise would apply for expedited review. One told GAO that it is "hesitating to apply to FDA because it has sought, but not yet obtained, assurances from the Coordinator's Office that once its products have met the plan's quality assurance requirement these products will be eligible for purchase under the Emergency Plan."[7]

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[4]Foreign Assistance Act of 1961, P.L. 87-195, §606, 75 Stat. 424, 440 (1961) (codified, as amended, at 22 U.S.C. §2356 [2000]).

[5]U.S. GAO, *supra* note 2 at 16.

[6]*Id.* at 35.

[7]*Id.* at 17.

GAO found that unless the Global AIDS Coordinator commits to waiving patient requirements for generic drugs, your AIDS initiative "may not expand rapidly enough to address the AIDS emergency."[8]

Indeed, if the Administration only permits purchase of generic drugs with the permission of U.S. patent holders, then those holders may demand licensing fees that could lead to significant price increases — canceling out the potential public health benefits.

Conclusion

Two years ago, you recognized the potential of generic drugs to turn the tide on this massive humanitarian catastrophe. This potential still exists, and yesterday's announcement could prove to be an important step forward. To ensure further progress, we strongly urge your Administration to waive domestic patent requirements for the purchase of safe and effective generic AIDS drugs for use in the developing world.

Our allies have already taken this step, and FDA's action yesterday provides a clear opportunity for you to do so as well. We urge you to join them and commit to developing a coordinated strategy to halt the AIDS epidemic.

Sincerely,

Edward M. Kennedy
Ranking Member
Committee on Health, Education,
Labor and Pensions
U.S. Senate

Henry A. Waxman
Ranking Member
Committee on Government Reform

U.S. House of Representatives

[8] *Id.* at 17.