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April 18, 2007

The Honorable Mark R. Dybul
U.S. Global AIDS Coordinator
U.S. Department of State
2201 C Street NW
Washington, DC 20522

Dear Mr. Ambassador:

I am writing to request detailed information about drug purchasing within the President's Emergency Plan for AIDS Relief (PEPFAR).

The United States has made an enormous contribution to global health through its support of HIV treatment. According to your recently-released annual report, PEPFAR has supported antiretroviral treatment for nearly one million people worldwide, with 822,000 in the 15 PEPFAR "focus countries." The U.S. has provided both "upstream" support, such as training and laboratory systems, and "downstream" support of clinics. I thank and commend you, your staff, your colleagues in other U.S. agencies, and your international partners for this accomplishment.

Downstream support includes the purchase of drugs, and in your most recent annual report, your office notes its commitment to purchasing "the lowest-cost ARVs [anti-retrovirals] from any source, regardless of origin – whether they are innovator, generic, or copy drugs, as long as those medications have been proven safe, effective, and of high quality, and their purchase is consistent with international law."¹ Further, you note that the purchase of generics "has made Emergency Plan resources go farther, giving thousands of additional people access to prevention, treatment, and care."² I agree that PEPFAR should take advantage of high-quality, affordable generics as a way to maximize patient access.

¹ Office of the U.S. Global AIDS Coordinator, *The Power of Partnerships: The President's Emergency Plan for AIDS Relief Third Annual Report to Congress*, 69 (March 2007) (online at <http://www.pepfar.gov/press/c21604.htm>).

² *Id.* at 70.

However, your report also notes that in fiscal year 2006, only 27% of PEPFAR funds for antiretroviral drugs went to the purchase of generics.³ I am concerned that this figure may mean the program is not taking full advantage of the savings that generic drugs provide. In addition, the report does not provide detailed information on the prices that PEPFAR is paying for innovator drugs, nor on purchases of drugs to treat opportunistic infections.

These questions are particularly pressing in light of the higher cost of second-line HIV treatment. An estimated 5-10% of patients on first-line ARV regimens develop resistance in a given year and need to switch to second-line treatment.⁴ Second-line drugs are less likely to be available as generics and are much more expensive: in 2005 the average weighted price paid by low income countries for second-line regimens was \$1,700 per patient per year, compared to \$144 for first-line regimens.⁵ As your annual report notes, currently fewer than 10% of PEPFAR patients require second-line drugs.⁶ However, this percent is likely to grow over time, and at any level, the higher costs of second-line medications should be of concern to the program.

In addition, it is important to know the extent to which FDA-approved drugs are actually available in different countries. Specifically, it is unclear whether patent or registration issues are affecting purchasing decisions within PEPFAR.

Understanding recent drug purchasing patterns is essential to maximizing the use of affordable generics in the future. I am therefore writing to request the following detailed information about drug purchasing under PEPFAR.

1. ARV Purchases

Please provide a list, sorted by medication, of all ARV purchases made with PEPFAR funding for FY2006 and for the first two quarters of FY2007, with the following information about each medication:

- Medication name
- Supplier
- Date of purchase
- Recipient country
- Procuring agent, if applicable
- If purchased from innovator, whether FDA-approved generic/copy exists and, if yes, name and supplier, and whether it was available for purchase by the country in question at the time of purchase

³ *Id.*

⁴ Médecins Sans Frontières, *Untangling the Web of Price Reductions 9th Edition (revised)*, 6 (July 2006) (online at <http://www.accessmed-msf.org/documents/untanglingtheweb%209.pdf>).

⁵ *Id.* at 6.

⁶ *The Power of Partnerships*, supra note 1, at 56.

- Dosage
- Unit
- Quantity
- Unit price paid (please indicate if price does not include freight, insurance, or other fees)
- Total amount paid
- Equivalent price per patient per year

2. Drugs for Opportunistic Infections

For each purchase of medication for the prophylaxis or treatment of opportunistic infections made with PEPFAR funding, please provide the same information as requested in Question 1.

3. Patents and Registration:

For each medication listed under questions 1 and 2, please provide:

- Patent status in all countries receiving PEPFAR funding
- If applicable, whether the drug was manufactured under a voluntary or compulsory license
- Registration status in all countries receiving PEPFAR funding

4. Second-Line Medicines

Please provide:

- A list of regimens supported by PEPFAR as first-line treatment
- A list of regimens supported by PEPFAR as second-line treatment
- For patients receiving drugs purchased with PEPFAR funding, the most recent number and percentage on second-line treatment, by country
- The percentage of ARV purchase funding allocated to second-line ARVs in fiscal year 2006 and fiscal year 2007 to date, by country

The Honorable Mark R. Dybul

April 18, 2007

Page 4

I request a response by **Monday, April 30, 2007**. If you have any questions, please contact Naomi Seiler at 202-225-5056. I appreciate your time and look forward to working together to maximize PEPFAR's already profound impact on HIV worldwide.

Sincerely,

A handwritten signature in black ink that reads "Henry A. Waxman". The signature is written in a cursive style with a long horizontal stroke at the end.

Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member

Congress of the United States
House of Representatives

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Responding to Oversight Committee Document Requests

In responding to the document request from the Committee on Oversight and Government Reform, please apply the instructions and definitions set forth below.

Instructions

1. In complying with the request, you should produce all responsive documents in your possession, custody, or control.
2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Committee.
3. In the event that any entity, organization, or individual denoted in the request has been, or is currently, known by any other name than that herein denoted, the request should be read also to include them under that alternative identification.
4. Each document produced should be produced in a form that renders the document capable of being copied.
5. When you produce documents, you should identify the paragraph or clause in the Committee's request to which the documents respond.
6. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. To the extent that documents were not stored with file labels, dividers, or identifying markers, they should be organized into separate folders by subject matter prior to production.
7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph or clause of the request to which the documents are responsive, should be provided in an accompanying index.
8. It is not a proper basis to refuse to produce a document that any other person or entity also possesses a nonidentical or identical copy of the same document.

9. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, memory stick, or computer backup tape), you should consult with Committee staff to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above. Documents produced in an electronic format should also be produced in a searchable format.
10. In the event that a responsive document is withheld on any basis, you should provide the following information concerning the document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author, and addressee; and (e) the relationship of the author and addressee to each other. Please note that the Committee generally recognizes only constitutional privileges.
11. If any document responsive to this request was, but no longer is, in your possession, custody, or control, you should identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, custody, or control.
12. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.
13. This request is continuing in nature and applies to any newly discovered document. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.
14. All documents should be bates-stamped sequentially and produced sequentially.
15. Two sets of documents should be delivered, one set to the majority staff and one set to the minority staff. The majority set should be delivered to the majority staff in Room 2157 of the Rayburn House Office Building, and the minority set should be delivered to the minority staff in Room B350A in the Rayburn House Office Building.
16. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee or identified in a privilege log provided to the Committee.

Definitions

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone calls, meetings or other communications, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto). The term also means any graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotape, recordings and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, memory sticks, and recordings), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “documents in your possession, custody, or control” means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that you have placed in the temporary possession, custody, or control of any third party.
3. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise.
4. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of the request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.
5. The terms “person” or “persons” means natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures,

proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.

6. The terms “referring” or “relating,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.