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HEALTH GAP COALITION

HEALTHGAP (global access project) COALITION
P.O. Box 19367
Washington, D.C. 20036

Joseph Papovich
United States Trade Representative
600 17th Street NW
Washington, DC, 20508

Wednesday, June 14, 2000

Dear Mr. Papovich,

Thank you for your participation in the follow-up meeting between the USG and representatives from the Health GAP Coalition and Medecins Sans Frontieres (MSF), discussing trade policy and access to medicines vis-á-vis intellectual property on April 12, 2000. This letter endeavors to express our recommendations in writing, and also confirm our understandings of the meeting.

Our understanding of the new US trade policy relating to access to essential medicines as promulgated by President Clinton and USTR on December 1, 1999 is that it "will permit the application of U.S. trade-related intellectual property law to remain sufficiently flexible to react to public health crises brought to the attention of USTR. It will also ensure that the minimum standards of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are respected." This is reinforced by the USTR 2000 Special 301's declaration that "[i]n the view of the U.S. Government, should a government determine to avail itself of the flexibility the TRIPS Agreement provides to address a health care crisis, the United States will raise no objection, provided the policy employed is consistent with the provisions of the WTO TRIPS Agreement."

The use of the phrase "essential medicines" below includes but is not limited to the World Health Organization's list of essential drugs and medicines. In addition, the use of the phrase "essential medicines" below includes but is not limited to HIV/AIDS drugs.

1. We understand that the collaboration between USTR and HHS in determining future US trade policy decisions as they relate to public health crises is an inchoate process with no hard-and-fast criteria formulated for implementing this new policy.

2. We understand that USTR will drop its "TRIPS-plus" policy and apply the new policy of "TRIPS-compliance only" for all sub-Saharan Africa with respect to intellectual property and access to

essential medicines as promulgated by President Clinton's Executive Order 13155-Access to HIV/AIDS Pharmaceuticals and Medical Technologies.

3. We understand that USTR will not initiate Special 301 actions against Brazil for its compulsory licensing provisions so long as they are "TRIPS-consistent."

4. We understand that USTR will initiate WTO dispute settlement proceedings against Argentina for the failure to provide exclusive marketing rights for pharmaceuticals and the failure to protect confidential test data.

5. We understand that USTR will initiate WTO dispute settlement proceedings against Brazil for the qualification in its patent law which requires "local working" as a condition for the exploitation of exclusive patent rights.

6. We understand that USTR is considering possible future WTO dispute settlement cases against the Dominican Republic, Egypt, India, Israel, Poland, and Uruguay for failure to meet WTO TRIPS obligations. These obligations include issues related to intellectual property and access to medicines such as exclusive marketing rights for pharmaceutical products, compulsory licensing of pharmaceutical products, local working requirements, patentable subject matter, "unfair" commercial use of test data, exclusive patent rights, term of protection, and protection for test data.

Recommendations of the Health GAP Coalition:

1. In light of the contradictory messages sent to Brazil from Commerce Secretary Daley pressuring the Brazilian government to derogate its compulsory licensing decree, we request that the White House and USTR author a letter making explicit the USG policy on TRIPS compliance as it relates to access to medicines and circulate it to the Department of Commerce, State Department, US PTO, DHHS, and any other relevant agencies in addition to foreign trading partners.

2. USTR must send a letter to the Government of the Dominican Republic making explicit that TRIPS-consistent industrial property law with respect to pharmaceuticals is adequate and will not be linked to the benefits accrued by the GSP program and the Caribbean Basin Initiative.

3. We seek a written confirmation of the three following understandings:

a. USTR will not initiate unilateral actions or WTO dispute settlement proceedings against countries for the following issues related to generic drugs: generic labeling, pharmacy substitution of generics, and physician prescribing of generics.

b. USTR will not initiate unilateral actions or WTO dispute settlement proceedings against developing countries for employing compulsory licensing and parallel importing as mechanisms to

mitigate national health emergencies provided that these mechanisms are TRIPS-consistent.

c. USTR will drop its "TRIPS-plus" policy and apply the new policy of "TRIPS-compliance only" for all developing countries with respect to intellectual property and access to essential medicines.

4. USTR and HHS must endorse the establishment of a Working Group on Access to Medications at the WTO (see HAI/MSF/CPT Amsterdam Statement: (http://www.cptech.org/ip/health/amsterdamstatement.html).

We hope you share our outrage about the dramatic inequalities regarding international access to medications for HIV and other life threatening illnesses. We appreciate the distinct change in tone of the USTR 2000 Special 301 Report which we understand is indicative of the new U.S. trade policy with respect to intellectual property and access to essential medicines. We look forward to hearing from you in writing and respectfully request a quick response. Should we not hear from you within two weeks, we will contact you for follow up.

Sincerely,

Thiru Balasubramaniam, for the Health GAP Coalition

CC:

President William J. Clinton
Vice President Albert A. Gore, Jr.
Donna Brazille, Gore 2000
Dr. Ken Bernard, National Security Advisor
Leon Fuerth, National Security Advisor
Jim Babbitt, Office of the Vice President
Tom Rosshirt, Foreign Affairs Spokesperson,
Sandra Thurman, Office of National AIDS Policy
Dr. Stuart Nightingale, Food and Drug Administration
Dr. Thomas Novotny, Department of Health and Human Services
Claude Burcky, United States Trade Representative
Robert Stoll, US Patent and Trademark Office
Jason Wright, Department of Health and Human Services