

**Congress of the United States**  
**House of Representatives**

Washington, DC 20515  
May 25, 2016

The Honorable Michael Froman  
United States Trade Representative  
600 17<sup>th</sup> Street, NW  
Washington, DC 20508

Dear Ambassador Froman:

We are writing to express our serious concern that, according to recent press reports, U.S. officials may have discouraged Colombian government officials from issuing a compulsory license on a cancer medicine, Gleevec (imatinib), produced by the Swiss pharmaceutical company Novartis. A Senate Finance Committee spokeswoman also recently suggested that the issuance of a compulsory license “may be inconsistent with international trade obligations.” The press reports suggest that Colombian officials were left with the deeply troubling impression that \$450 million in U.S. funding to aid peace efforts could be in jeopardy if Colombia failed to change course.

As you know, the issuance of compulsory licenses is permissible under U.S. trade agreements and the WTO Agreement. Indeed, the 2001 WTO Doha Declaration on public health recognizes this “flexibility” that WTO Members have to protect public health: “Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” U.S. officials should respect the flexibilities that are recognized in that Declaration. In fact, that is precisely what Congress instructed our trade officials to do, most recently through the passage of Trade Promotion Authority last year. (See section 102(b)(5)(C) (“to respect the Declaration on the TRIPS Agreement and Public Health”).) We therefore find it deeply troubling that U.S. officials may not be respecting the Doha Declaration.

To be sure, the issuance of compulsory licenses can raise legitimate concerns in some circumstances. For example, under Article 31 of the WTO TRIPS Agreement, compulsory licenses should be issued only on a case-by-case basis, not as part of a blanket policy. And, even where a government issues a compulsory license, that government is required to pay the patent holder “adequate remuneration”. But we are not aware of any actions that Colombia has taken or is considering taking that are inconsistent with those rules. For example, Colombia appears to be considering a compulsory license on this medicine – which the World Health Organization has listed as an “essential medicine” – based on its individual merits and not as part of a blanket policy. In fact, to our knowledge, Colombia has not issued a compulsory license on any other product.

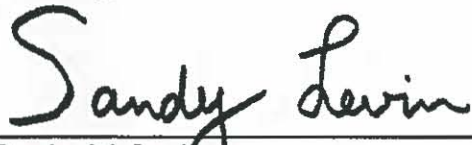
Discouraging the issuance of compulsory licenses would be inconsistent not only with the Doha Declaration and with TPA, but also with the historic May 10 Agreement of 2007. The May 10 Agreement included several critical changes to U.S. trade policy to better ensure access to affordable medicines. Our bilateral trade agreement with Colombia incorporates those changes –

including adding to the Colombia trade agreement language from the Doha Declaration, to clarify that the intellectual property obligations in the agreement "do not and should not prevent [Colombia] from taking measures to protect public health by promoting access to medicines for all".

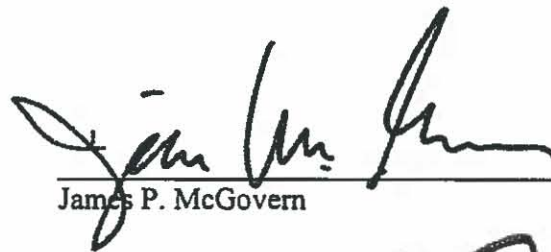
There are growing concerns about the very high and increasing costs of pharmaceuticals in the United States and in other nations. And the annual price of this medicine in Colombia is almost twice as much as the average annual income per person in Colombia. As policymakers struggle to address this issue, we should not seek to limit the existing, agreed upon flexibilities public health authorities have to address these concerns.

We ask that you clarify the position the Administration has taken in meetings with Colombian officials on this important issue as soon as possible, particularly given that USTR's recent Special 301 report did not mention compulsory licensing in Colombia but instead, in another section of the report, included the general statement that "the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement and the Doha Declaration[.]" Just as we expect our trading partners to act transparently and in accordance with the rule of law, our policies and practices should follow that same course.

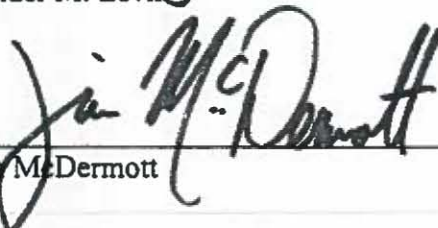
Sincerely,



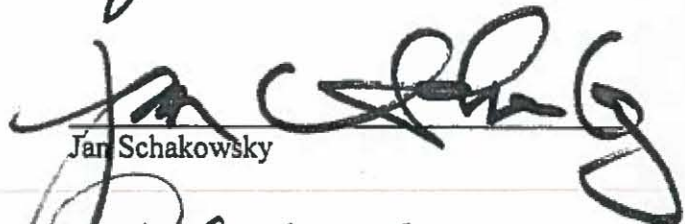
Sander M. Levitt



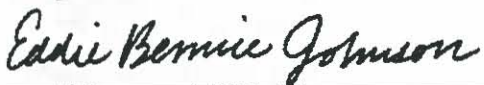
James P. McGovern



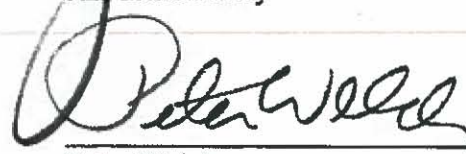
Jim McDermott



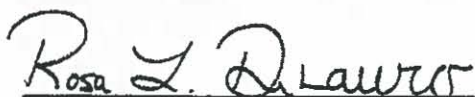
Jan Schakowsky



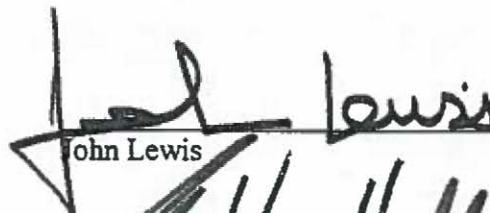
Eddie Bernice Johnson



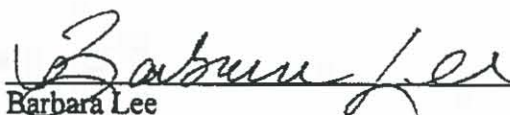
Peter Welch



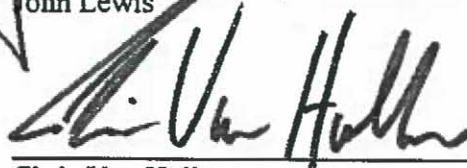
Rosa L. DeLauro



John Lewis



Barbara Lee



Chris Van Hollen

*Peter DeFazio*  
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*Lloyd Doggett*  
Lloyd Doggett

*David Price*  
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*Carolyn B. Maloney*  
Carolyn B. Maloney

*Sam Farr*  
Sam Farr