Congress of the United States
Washington, DC 20515

July 25, 2014

Juan Manuel Santos
President of the Republic of Colombia
Casa de Nariño
Bogotá, D.C., Colombia

Dear President Santos:

As members of the Colombia Caucus and strong supporters of the U.S.-Colombia bilateral trade relationship, we are writing to express concern about your government's release on July 10, 2014, of a new draft of a presidential decree on biological medicines. While we are pleased with the progress being made by the Colombian Ministry of Health to develop a comprehensive framework for registration of biological medicines, we urge you to direct your government to continue working on improvements, rather than issuing this draft as a final decree. In particular, we are concerned that the draft gives inadequate attention to international standards and guidelines and could compromise the quality, safety, and effectiveness of biological medicine, thereby undermining public confidence in the health system and lifesaving medicines.

Specifically, we are concerned that the proposed terms of the "abbreviated route" for biological medicines in the draft decree do not provide for the careful scientific analysis that is expected under World Health Organization (WHO), U.S. Food and Drug Administration (FDA), and European Medicines Agency (EMA) guidelines. Nor does the draft meet the standards set by other medicines agencies in developed countries around the world. Because of the complexity of biological medicines, it is vital that a robust regulatory system based on sound scientific principles is in place to ensure the safety and efficacy of biopharmaceuticals. It is not clear that the "abbreviated route" as defined in the draft decree provides for such a pathway.

Colombia currently has in place two regulatory pathways through which biologics may be approved: the "complete file" route, which requires a review of a new product on a standalone basis with a full review of supporting quality, preclinical, and clinical evidence; and the "comparability" route, which is based on a robust analytical, preclinical, or clinical comparison with a previously approved innovative biologic. These dual approaches promote both access to biologic medicines and patient safety – and we believe that these high standards have proven to be effective and appropriate.

By contrast, the terms of the "abbreviated route" as defined in the draft decree do not require applicants to demonstrate high similarity in quality, safety, and efficacy to an already approved biologic. Additionally, the draft lacks requirements that applicants submit preclinical and clinical data and allows applicants to rely on information from health authorities outside Colombia

concerning products marketed by other manufacturers. In combination, these criteria could potentially undermine the safety and effectiveness of biological pharmaceuticals, given the complexity of such compounds.

As you know, we are strong supporters of Colombia's interest in joining the Trans-Pacific Partnership (TPP) once negotiations have been concluded. TPP must include strong protections for biological pharmaceuticals, however, so we would be concerned if Colombia were to take the lead in setting uniquely low standards for these lifesaving products.

Finally, we are concerned that it appears that this draft of the decree is being considered within an unduly rapid timeframe that does not provide parties with an adequate opportunity to comment on such a significant and consequential issue. Instead, we urge you to proceed through a process that provides all parties a full and reasonable opportunity to comment on this draft so that your government is better able to complete a full evaluation and make a thoughtful and careful decision.

Thank you for your attention to this important issue. We respectfully request that you continue to engage with industry on this issue and consider improvements to the July 10 draft decree, to ensure that the final decree reaches international standards and protects the integrity of the biopharmaceutical approval process.

Respectfully,

Aaron Schock
Member of Congress

Henry Cuellar
Member of Congress

Mario Diaz-Balart
Member of Congress

Gregory W. Meeks
Member of Congress