

Congress of the United States
Washington, DC 20515

April 5, 2017

The Honorable Robert Aderholt
Chairman
House Appropriations Subcommittee on
Agriculture, Rural Development, Food and
Drug Administration, and Related Agencies
2362-A Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

The Honorable Sanford Bishop
Ranking Member
House Appropriations Subcommittee on
Agriculture, Rural Development, Food and
Drug Administration, and Related Agencies
1016 Longworth House Office Building
United States House of Representatives
Washington, DC 20515

Dear Chairman Aderholt and Ranking Member Bishop:

As you consider fiscal year 2018 appropriations legislation, we write to request that you include report language to support assistance to start-up life sciences companies regarding regulatory pathways for their products. These firms are at the forefront of research and development of treatments that will be the next medical breakthroughs, help save lives, and reduce health care costs.

Despite their significance of their work, these emerging companies do not have the resources that larger companies have to understand regulatory pathways and how to efficiently advance their products toward approval. Because the development of medical technologies often require substantial financial investment and many life sciences start-ups do not earn revenue until their products are available to consumers, a lengthy and complicated approval process could cause these companies to fold and prevent access to their pioneering technologies. Since the peak of investments in the early-stage medical device companies in 2007, investment dollars have dwindled, new company formations are down, and the total number of start-ups has decreased. These factors put the future of medical innovation in jeopardy.

Start-up medical companies tend to cluster around "innovation hubs," where there are known skills in engineering, entrepreneurship, venture capital, academic research centers, and more. While most of the nation's life sciences companies are based far from the Washington, DC region, we understand that the Food and Drug Administration (FDA) does not retain staff with the expertise to provide guidance to companies regarding regulatory pathways outside of the DC metropolitan area. Even where the FDA has local offices, many in the life sciences community are not aware of its presence in their area. We believe there must be greater direct outreach in life sciences hubs to demystify both the FDA's regulatory process and organizational structure, and ensure their groundbreaking treatments can reach patients in need. Therefore, we request the inclusion of the following report language:

The Committee recognizes the value of emerging life sciences companies and their innovative treatments that improve quality of life for patients. The Committee understands that many of these companies, which lack the resources of their larger competitors, struggle to understand how to efficiently advance their products through the FDA's approval processes. The Committee further understands that the development of life sciences products often requires significant financial investment and start-up companies can fold while waiting for FDA approval, thus preventing patient access to their products. Therefore, the Committee directs the Commissioner to submit a plan to the Committee within 180 days of enactment of this Act to retain relevant FDA staff in life sciences hubs to brief start-up companies on regulatory pathways and provide follow-

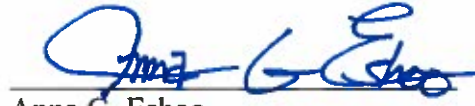
up outreach, and information regarding additional resources, if any, needed to accomplish this mission.

We look forward to working with you to promote medical innovation and improve the health and wellbeing of all Americans. Thank you for your time and consideration.

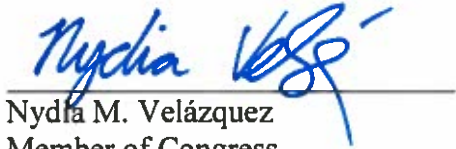
Sincerely,



Eric Swalwell
Member of Congress



Anna G. Eshoo
Member of Congress



Nydia M. Velázquez
Member of Congress



Juan Vargas
Member of Congress



Debbie Wasserman Schultz
Member of Congress



Mark DeSaulnier
Member of Congress



Donald M. Payne, Jr.
Member of Congress



Bonnie Watson Coleman
Member of Congress



Elijah E. Cummings
Member of Congress



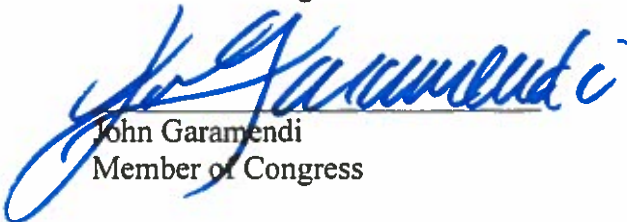
Darren Soto
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