ERIC SWALWELL
15TH DISTRICT, CALIFORNIA
PERMANENT SELECT COMMITTEE ON INTELLIGENCE
• RANKING MEMBER SUBCOMMITTEE ON CIA
• SUBCOMMITTEE ON DEPARTMENT OF DEFENSE INTELLIGENCE AND OVERHEAD ARCHITECTURE
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
• SUBCOMMITTEE ON ENERGY
• SUBCOMMITTEE ON RESEARCH & TECHNOLOGY

Congress of the United States
House of Representatives
Washington, DC 20515–0515

DEMOCRATIC STEERING & POLICY COMMITTEE
REGIONAL DEMOCRATIC WHIP
DEMOCRATIC POLICY & COMMUNICATIONS COMMITTEE

1260 B STREET, SUITE 150
HAYWARD, CA 94541
(510) 370-3322

5075 HOPYARD ROAD, SUITE 220
PLEASANTON, CA 94588
(925) 460-5100

129 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-5065

December 9, 2016

The Honorable Robert M. Califf, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

I am writing to urge you to provide assistance to start-up biotechnology companies based in the San Francisco Bay Area 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.

As chair of Future Forum, a group of the 19 youngest members of the House Democratic Caucus that focuses on issues important to and engaging with millennials, I hosted a roundtable with biotechnology start-up executives at the University of California's biosciences incubator, QB3. At this event, some attendees expressed their concerns regarding the complexity and length of the regulatory process. Despite the 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. Since the development of medical technologies often require substantial investment and many biotechnology start-ups do not earn revenue before their products are available, a lengthy approval process could cause these companies to fold and prevent access to their innovative treatments.

Several attendees asked that the FDA establish an office in the San Francisco Bay Area to provide guidance on the regulatory process. Such a local office would provide the opportunity to entrepreneurs for beneficial face-to-face discussions of complex regulatory and medical issues.

While I understand that there are FDA offices in the region, I am concerned that biotechnology executives with years of experience were not aware of them. I recognize these FDA locations are primarily focused on regulating imports; but, the lack of awareness of their existence shows more FDA outreach to the community is necessary. And, they provide a prime opportunity that the FDA should not squander at the local level to demystify both the regulatory process and otherwise help the biotechnology community.

Since the San Francisco Bay Area is the home to nearly one-third of the biotechnology industry, it is critical that FDA offers industry education and outreach in the region. I request that the FDA participate at an event or a series of events in the area to brief companies on regulatory pathways. After such educational programming, follow-up outreach will be needed to ensure that new companies are afforded

the same information and opportunities going forward. Therefore, I also ask that the FDA retain staff in the San Francisco Bay Area at its local offices with the expertise to continue these efforts to engage with the industry in person. I believe that these steps would greatly advance opportunities for biotechnology start-ups and the realization of their pioneering technologies.

I look forward to working with you to promote medical innovation and improve the health and wellbeing of all Americans. Thank you for your attention to this matter.

Sincerely,

Eric Swalwell
Member of Congress