

June 10, 2019

Ms. Vanessa A. Countryman  
Acting Secretary  
Securities and Exchange Commission  
100 F Street, NE  
Washington, DC 20549

Re: Amendments to the Accelerated Filer and Large Accelerated Filer Definitions; Proposed Rules; Request for Comments [File Number S7-06-19]

Dear Ms. Countryman:

The California Life Sciences Association (CLSA) appreciates the opportunity to submit written comments in response to the Securities and Exchange Commission's (SEC or "the Commission") proposed rules on Amendments to the Accelerated Filer and Large Accelerated Filer Definitions. [File Number S7-06-19]

CLSA is the statewide public policy organization representing California's life sciences innovators, including medical device, diagnostic, biotechnology and pharmaceutical companies, research universities and private, non-profit institutes, and venture capital firms. CLSA's diverse membership represents the spectrum of organizations throughout California working to develop life-saving and life-sustaining therapies and treatments in the life sciences innovation ecosystem.

At the outset, CLSA would like to commend the Commission for recognizing the need for amendments to the accelerated filer and large accelerated filer definitions to promote capital formation for smaller issuers. In particular, CLSA strongly supports the proposal to exclude from the accelerated and large accelerated filer definitions smaller reporting companies with annual revenues of less than \$100 million. We are also supportive of the proposals to increase the transition thresholds for accelerated and large accelerated filers becoming non-accelerated filers (from \$50 million to \$60 million) and for exiting large accelerated filer status (from \$500 million to \$560 million); and the proposal to add a revenue test to the transition thresholds for exiting both accelerated and large accelerated filer status.

We applaud the Commission for acknowledging how critical these improvements will be for low-revenue issuers, who will particularly benefit from the cost savings associated with non-accelerated filer status and could re-direct those savings into growing their businesses without significantly affecting the ability of investors to make informed investment decisions based on the financial reporting of those issuers.

California's 3,418 biomedical and life sciences companies employ over 133,000 people throughout the state (representing approximately 18 percent of the total U.S. biopharmaceutical workforce, and 19 percent of the total U.S. medical device workforce), truly leading the world in

life sciences research and development.<sup>1</sup> The work of innovators in California has led to groundbreaking therapies and technologies to diagnose, treat, and prevent conditions such as diabetes, arthritis, cancer, cardiovascular disease, chronic pain, hepatitis, HIV/AIDS, and Parkinson’s disease. Just as important, the life sciences sector is an increasingly important component of our state’s economic engine, employing nearly 958,000 people, paying \$37.1 billion in wages, and accounting for \$25.2 billion in exports annually.<sup>2</sup>

The overwhelming majority of biopharmaceutical and medical device innovators in California (and nationwide) are small, start-up, pre-revenue companies without a single product on the market. Still, these firms spend hundreds of millions of dollars on research, development, clinical trials, and FDA reviews to bring effective treatments and cures to patients. In novel fields like gene therapy and regenerative medicine, and in conducting the science and developing therapies and technologies for some of the most challenging conditions with unmet needs like ALS, Alzheimer’s disease, and ultra-rare diseases, the stakes are even higher. A recent report analyzing trends in biopharmaceutical R&D investment concluded that emerging biopharmaceutical (EBP) companies now account for over 70 percent of the total late-stage R&D pipeline.<sup>3</sup> Additionally, EBP companies were responsible for almost two-thirds of the patents for new drugs launched in 2018, bringing critical new innovations to patients in need.<sup>4</sup> Pre-revenue innovators simply cannot afford costly compliance burdens like Sarbanes-Oxley 404(b), which often serve as roadblocks and detract investment along the way of the decades-long, billion-dollar path to a new therapy or technology.

We strongly encourage the Commission to include these important reforms in the final rule, in order to support innovative small, start-up, pre-revenue companies in California – and across the country – as they continue their search for the next generation scientific advancements. On behalf of CLSA, and our state’s innovative life sciences sector, thank you for the opportunity to share our views. Should you have any questions or comments about our views, please contact me at [REDACTED] or [REDACTED].

Thank you for your consideration.

Sincerely,



Jennifer Nieto  
Vice President – Federal Government Relations and Alliance Development  
California Life Sciences Association – CLSA

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<sup>1</sup> *California Life Sciences 2019 Industry Report*. California Life Sciences Association/PwC, 15 Nov. 2018, <https://info.califesciences.org/2019report>.

<sup>2</sup> Ibid.

<sup>3</sup> *The Changing Landscape of Research and Development*. IQVIA Institute for Human Data Sciences, 23 Apr. 2019, [www.iqvia.com/institute/reports/the-changing-landscape-of-research-and-development](http://www.iqvia.com/institute/reports/the-changing-landscape-of-research-and-development). The report defines “emerging biopharmaceutical companies (EBP)” as companies that are estimated to spend less than \$200 million annually on R&D and have less than \$500 million in revenue.

<sup>4</sup> Ibid.