June 6, 2019

The Honorable Richard E. Neal
Chairman, House Ways & Means Committee
1102 Longworth House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.
Chairman, House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Kevin Brady
Ranking Member, House Ways & Means Committee
1139 Longworth House Office Building
Washington, D.C. 20515

The Honorable Greg Walden
Ranking Member, House Energy & Commerce Committee
2322 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Neal, Chairman Pallone, Ranking Member Brady, and Ranking Member Walden:

On behalf of the California Life Sciences Association (CLSA), thank you for the opportunity to submit comments in response to the solicitation for feedback on draft legislation to reform and improve the Medicare Part D program.

CLSA is the premier statewide public policy and business leadership 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. California's 3,418 biomedical and life sciences companies directly 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.[1] The work of California's innovative companies and research institutions 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.[2]

We applaud Committee Leadership for soliciting feedback on legislation to lower costs for Medicare Part D patients. The discussion draft proposes to do this, in part, by setting an out-of-pocket spending cap for beneficiaries based on the current catastrophic threshold. In concept, CLSA is supportive of legislation that aims to cap or limit the amount that seniors pay out-of-

[1] *California Life Sciences 2019 Industry Report.* California Life Sciences Association/PwC, 15 Nov. 2018, https://info.califesciences.org/2019report .
[2] Ibid.

pocket for prescription drugs in Part D. Notably, according to a recent poll, a majority of voters (76 percent) are supportive of this concept as well.[3] While Medicare Part D has been critical to ensuring tens of millions of seniors and individuals with disabilities receive access to life-saving therapies, out-of-pocket costs for prescriptions drugs remain unaffordable for too many Americans. In 2016, the more than 5 million Medicare beneficiaries who did not qualify for low-income subsidies, and therefore paid extra for Part D plans, incurred out-of-pocket costs anywhere from hundreds of dollars to an average of nearly $1,600 per beneficiary.[4] For 2020, the annual out-of-pocket spending threshold is projected to increase by an additional $1,250.[5] CLSA and our membership are committed to protecting patients from unaffordable out-of-pocket costs and supporting increased access to prescribed medicines. We believe that no one – and especially not seniors living on fixed incomes – should have to choose between paying the rent, putting food on the table, and paying for the therapies they need.

While CLSA is supportive of the concept of an out-of-pocket cap for Medicare Part D beneficiaries, we also urge Committee Leadership to ensure that in practice the cap does not result in other barriers to accessing medications – such as restricted formularies or requiring patients to pay all their costs at the beginning of the plan year. With regards to the first concern, CLSA believes that strong anti-discrimination protections, and enforcement of such protections, are critical to prevent health plans from restricting access to certain drugs – or categories of drugs such as the six protected classes – in the name of cost savings. Additionally, special care must be taken to ensure that patients are not hit with the full amount of their out-of-pocket costs all at once at the beginning of the plan year. Instead a beneficiary's financial responsibility should be spread out so that patients on fixed incomes are still able to afford their medications.

CLSA also urges Committee Leadership to avoid any reforms that would disproportionately affect the most innovative medicines or risk creating access challenges for low-income patients. Changes put forth should continue to support the development of new treatments, including the search for cures for life-threatening diseases such as cancer, multiple sclerosis, ALS, and HIV/AIDS.

Finally, CLSA urges the Committees to carefully consider the impact of cost-containment policies on innovation and take care that such policies do not prevent the life-saving therapies of the future from being discovered. The life sciences industry in California consists both of relatively small, entrepreneurial, and venture capital-backed firms that have yet to bring products to market, and established pharmaceutical, biotech, and device companies with products on the market that enhance, improve, and save patient lives on a daily basis. Patent rights, and the ability to legitimately enforce them against bona fide infringers, is what incentivizes companies to engage in the high-risk, high-cost R&D that makes the discovery, development, and commercialization of life-saving medicines possible. That is why CLSA opposes policies to

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[3] *Understanding Voters' Views on Prescription Drug Costs*. Morning Consult, 3 Apr. 2019, www.bio.org/sites/default/files/BIO_Polling_Memo_4.3.19.pdf.

[4] Cubanski, Juliette, et al. *Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What's Ahead*. Henry J Kaiser Family Foundation, 21 Aug. 2018, www.kff.org/medicare/issue-brief/closing-the-medicare-part-d-coverage-gap-trends-recent-changes-and-whats-ahead/.

[5] Ibid.

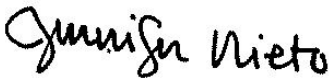
allow the exercise of so-called "march-in rights" that go against the very aim of the *Bayh-Dole Act*, which is to stimulate the transfer of medical technology between academic institutions and commercial companies to bring new medicines and therapies to patients' bedsides.

Similarly, policies to institute compulsory licensing would undermine the intellectual property that gives innovators the ability to attract investment for the development of the discoveries of tomorrow. An unreliable patent system would create significant uncertainty for the life sciences sector – especially for small and emerging companies, not to mention other IP-reliant sectors – and undermine incentives for future research. CLSA therefore encourages Committee Leadership to make sure that the policies it considers to decrease out-of-pocket costs for patients in the short term do not have unintended consequences for the ability of future patients to benefit from the next breakthrough therapy.

On behalf of CLSA, and our state's biomedical innovators, thank you for considering our views. Should you have any questions or comments, of if you would like to discuss our views further, please do not hesitate to contact Molly Fishman, CLSA's Director of Federal Government Relations, at mfishman@califesciences.org or (202) 743-7560.

We thank you for your attention to this important issue.

Sincerely,



Jennifer Nieto
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California Life Sciences Association – CLSA