Dear Commissioner Califf and Director Vidal:

Generation Patient was created—and is led *entirely*—by young adult patients. Through our nonpartisan work and focused initiatives—the Health Policy Lab and the Crohn's and Colitis Young Adults Network —we work to increase the health literacy, confidence, self-management skills, public policy knowledge, and advocacy strategies of young adult patients. We have developed programming related to navigating the higher education landscape as well as educating people about health policy with independent research and analysis. Additionally, we have facilitated more than four hundred virtual meetings and events during the past two years focused on connecting young adult patients around the world and providing them with critical peer support. Our organization does not accept funding from the pharmaceutical, insurance, hospital, or related healthcare industries.

Through our only disease-specific program, the Crohn's and Colitis Young Adults Network (CCYAN), we work to empower adolescents and young adults with inflammatory bowel diseases. Humira, a medication needed by many in our CCYAN community, has been granted 166 patents and has delayed biosimilar entry until 2023 in the U.S. This is just one of many examples which illuminates the need for the USPTO-FDA Collaboration.

We appreciate this opportunity to address the USPTO and FDA Public Listening Session. The following points are divided into sections based on what we feel is most critical to address.

Engage patient stakeholders

Patient stakeholders are critical but are often underrepresented as equal stakeholders in policy and regulatory discussions. The USPTO and FDA must have accountability to those most impacted, patients, in all aspects of the collaboration. We recommend the development of an independent public advisory committee, inclusive of patients who represent areas from chronic to rare diseases, different age groups, and more. This independent public advisory committee could play a critical role in advising on public dissemination of information, best practices for engaging the public and patient stakeholders, and ways in which this collaboration could be even more patient-centered. We commend that the FDA already has a variety of existing patient engagement opportunities. Rather than just having patients serve on separate patient councils, we encourage the integration of patients in all core activities of this collaboration. We also wish to encourage the foremost engagement of individuals and organizations that are independent of pharmaceutical industry funding. Further, as part of an advisory council, we uphold that patients must be compensated for their time and experience to ensure that there is an equitable representation of who can provide this insight.

Value-based patents
Before a patent extension is granted, it is important to understand what benefit the drug actually has on patients. Does a secondary patent meaningfully increase the clinical benefit and pose a transformative impact on patient quality of life? We have to acknowledge the misuse of patents to extend market exclusivity through evergreening. Modifying a drug without a meaningful impact on the utility proves unnecessary in improving patient lives. Should it warrant a new patent that allows drug manufacturers to continue escalating the cost of lifesaving drugs for patients? As patients, we need novel medications, not the ones we have already tried and which have not worked for us. When we reward pharmaceutical companies with new patents on old drugs, we remove the financial incentive to do the hard work to find truly novel treatments and cures.

FDA and USPTO should establish channels for sharing information about an applicant
Patent examiners should have access to a wider array of information when conducting prior art searches, including updated information from the Orange and Purple Books, FDA decisions, and scientific information. We also recommend that when considering secondary patents, sponsors can be better held accountable to share robust evidence, diversity in clinical trials, and adequate documentation of safety data earlier on.

This a unique opportunity to advocate for children, adolescents, and young adult patient populations
Through this collaboration, we believe there is an opportunity to place an emphasis on pediatric, adolescent, and young adult populations, patient populations that have historically been left behind within clinical research. We encourage novel ways of thinking to incentivize pharmaceutical companies to truly innovate to develop drugs for pediatric populations.

Further, there must be better incentives for evidence generation earlier rather than nearing the end of an initially granted patent. A study showed that approximately 1 in 10 pediatric trials ended early and that the results of the majority of these had not been published even three years later. We feel that the incentive is low for actually completing pediatric studies, rather it feels like there is a simple “encouragement” of earlier pediatric research, without actual timely completion. We suggest a sense of urgency for creating a collaborative system in which there is a true incentive to bring pediatric-approved therapeutics to market, rather than creating opportunities to delay generic/biosimilar competition.

We also wish to note that when the patent system is misused and when me-too drugs are created, our demographic of young people with chronic conditions is disproportionately affected. We run out of treatment options quickly and we have a lifetime ahead of us. We need novel innovation, fairly priced.

Over 85% of young people with chronic conditions are now surviving into adulthood, many of whom live with complex, lifelong conditions. For us as young adult patients, access to prescription medications is a basic human need. According to the Georgetown University McCourt School of Public Policy, 53% of people ages 18-34 use prescription drugs. Moreover, 21% of people ages 18-49 years old say they have difficulty affording their medication. The share is likely to be even higher for younger adults given that the highest poverty rate in the United States is between the ages of 18-24, but given that research does not sufficiently focus on young adult populations, there is no specific data to cite. This collaboration is a unique opportunity to ensure the adequate representation of young adult patients within actions to make medications more affordable.

We welcome elaborating on any of the above and continuing to partner with USPTO and FDA to include patients at the forefront of all actions taken through this important collaboration.

Sincerely,

Sneha Dave
Executive Director
Generation Patient