ConnectedHealthInitiative

July 17, 2025

The Honorable Marty Makary, M.D., M.P.H.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

**RE: Connected Health Initiative Request for the Creation of a Food and Drug Administration Medical Device Commissioner's Priority Review Voucher Program**

Dear Dr. Makary:

The Connected Health Initiative (CHI) welcomes your leadership at the U.S. Food and Drug Administration (FDA) and shares your priority for bringing new innovative treatments to market more quickly. To accomplish this goal, **the CHI community calls on the FDA to establish a Commissioner's National Priority Voucher (CNPV) program for medical devices, modeled after the FDA's drug CNPV programs.** Such a program would catalyze innovation to address the chronic disease public health crisis, delivering more innovative prevention and treatment to address the unmet public health needs of countless Americans.

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs using digital health innovations. CHI aims to realize an environment in which Americans can see improvements in their health through policies that allow for connected health technologies to advance health outcomes and reduce costs. CHI members develop and use connected health technologies across a wide range of use cases. We advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies, where we seek to promote responsible pro-digital health policies and laws in areas including coverage and payment, privacy and security, health data interoperability, FDA regulation of digital health, and the rising role of artificial intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

Chronic disease has become a defining national health crisis in America, with nearly 60 percent of adults (more than 129 million people) living with at least one chronic condition such as heart disease, diabetes, obesity, or cancer, and 40 percent managing multiple chronic diseases.[1] This burden is rapidly escalating due to an aging population, rising rates of obesity and depression among young adults, and persistent increases in conditions like high blood pressure and high cholesterol.[2] Chronic diseases now account for 90 percent of the nation's $4.5 trillion annual

[1] Benavidez GA, Zahnd WE, Hung P, Eberth JM. Chronic Disease Prevalence in the US: Sociodemographic and Geographic Variations by Zip Code Tabulation Area. Prev Chronic Dis 2024;21:230267. DOI: http://dx.doi.org/10.5888/pcd21.230267.
[2] Watson KB, Wiltz JL, Nhim K, Kaufmann RB, Thomas CW, Greenlund KJ. Trends in Multiple Chronic Conditions Among US Adults, By Life Stage, Behavioral Risk Factor Surveillance System, 2013–2023. Prev Chronic Dis 2025;22:240539. DOI: http://dx.doi.org/10.5888/pcd22.240539.

healthcare spending, overwhelming the health system and driving up costs for individuals and society.[3] The prevalence of these conditions is projected to nearly double by 2050, particularly among adults over 50, underscoring the urgent need for comprehensive public health strategies and policy interventions to address this growing epidemic.[4]

Further, new technology solutions are needed to support the expanding clinician shortage, with a 42 percent shortage of primary care physicians alone by 2037.[5] To address workforce shortages that will most acutely impact underserved Americans in rural areas of the country, FDA must act to responsibly introduce new improvements and efficiencies into its processes in order to get efficacious connected medical devices into the care continuum that will enable clinicians to more effectively and timely treat more patients.

Wearable health devices have become widely available as tools to empower patients to proactively engage in their own efforts to combat disease. In an increasingly digital age, our society is experiencing a profound shift in its collective health consciousness. The population at large is demonstrating a growing technological literacy, fostering an environment where individuals are not only more willing but also increasingly capable of actively managing their own well-being. This newfound empowerment is driven by the widespread availability of health-related information and innovative digital tools, which provide unprecedented opportunities for self-monitoring, personalized health insights, and proactive care. Wearables that provide timely and actionable patient-generated health data (PGHD) enhance situational awareness for both the patient and their care team, better informing decisions related to preventative measures and treatment plans.

Recent advancements in edge computing (processing and storing data closer to the device), cloud computing, and AI/machine learning have enabled the development of numerous personal and population health innovations. Notably, wearables provide health insights through measuring various physiological and therapeutic metrics, including activity levels, sleep patterns, heart rate variability, and oxygen saturation. While such readings are indispensable in disease treatment, they also enable the detection of early warning signs that often signal the onset or further development of disease, providing a critical window to prevent disease. These functionalities that support disease prevention and improve engagement in care provide an immense opportunity to reduce costs. We encourage FDA to improve its review processes for regulated functions to streamline the pathway for new and beneficial features to reaching the market.

While the FDA's device approval pathways (510(k), PMA, HDE) provide a robust framework for ensuring medical device safety and effectiveness, the extensive time and resource burdens associated with device development remain significant barriers to bringing new innovations that fully leverage timely patient-generated health data (PGHD), such as health wearables and software as a medical device (SaMD) AI, to providers and patients in the market. Furthermore, the intricate and often ambiguous nature of existing regulatory frameworks presents substantial hurdles for developers of innovative medical devices. The lack of clear, consistent guidelines for novel technologies creates a climate of uncertainty, making it exceptionally challenging for these

[3] https://nihcm.org/publications/the-growing-burden-of-chronic-diseases.
[4] Ansah JP, Chiu CT. Projecting the chronic disease burden among the adult population in the United States using a multi-state population model. Front Public Health. 2023 Jan 13;10:1082183. doi: 10.3389/fpubh.2022.1082183. PMID: 36711415; PMCID: PMC9881650.
[5] https://www.ruralhealth.us/blogs/2025/06/rural-physician-burnout-and-staffing-shortage-impact-in-2025.

companies to accurately forecast the time, resources, and investment required to bring a product to market. These challenges are especially evident in the case of SaMD technologies, which are distinct from both the classic medical device regulatory framework and the wellness guidance. This regulatory opaqueness can deter potential investors, as the path to commercialization appears fraught with unpredictable delays and escalating costs. Consequently, promising medical advancements may languish in development or fail to materialize altogether, denying patients access to potentially life-saving or life-improving technologies. Far too many Americans experience limited prevention and treatment options as a result.

Building on the existing Priority Review and Priority Review Voucher (PRV) programs, the FDA's new drug CNPV program reduces standard drug reviews from 10–12 months to just one to two months using a multidisciplinary, team-based review model that brings together experts for a focused, collaborative evaluation, modeled after the "tumor board" approach used in oncology. Designed to address urgent national priorities such as health crises and unmet public health needs, the drug CNPV enables companies to submit most of their application materials before clinical trial completion, speeding market access while ensuring patient safety.

We call on FDA to build on the drug CNPV program and create a similar CNPV program for medical devices. Extending a similar incentive to the device sector would encourage investment in devices for underserved populations and critical public health priorities and accelerate the introduction of innovative technologies by reducing regulatory uncertainty and time-to-market. CHI recommends that the device CNPV program includes the following features:

- Awards a priority review voucher upon approval of a device addressing the chronic disease public health crisis or other declared public health emergency or other designated national priority;
- Allows a voucher can be applied to a product at any stage in development;
- Allows a voucher to be redeemed for expedited review of a subsequent device application, with clear timelines and performance metrics; and
- Provides transparency and guidance on eligibility, use, and transferability, modeled after the existing drug CNPV framework.

CHI believes that the technologies and systems that enable the timely use of PGHD, which include wearables and SaMD AI, are ideal solutions for the device CNPV program. Wearables provide real-time health data that empower patients and enable early intervention, while AI analyzes this data to predict risks, personalize care, and optimize resource allocation at scale. These technologies are poised to revolutionize healthcare by enabling continuous monitoring and advanced data analyses that demonstrably improve patient outcomes, enhance population health management, and reduce costs.

The FDA is fully enabled to implement a device CNPV program under its existing authority and such a decision would align with FDA's mission to protect and promote public health, foster innovation, and respond to evolving healthcare challenges. Section 515 of the Food, Drug, and Cosmetic Act grants FDA broad discretion over the premarket approval process, including the establishment of review priorities and special procedures for breakthrough or high-priority devices. Further, the Medical Device User Fee Amendments authorize FDA to set performance goals and review timelines, demonstrating congressional support for expedited review mechanisms.

CHI stands ready to support the FDA in developing and implementing a device CNPV program. Thank you for your leadership and commitment to advancing patient-centered innovation.

Sincerely,

Brian Scarpelli
Executive Director

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