California Public Employees' Retirement System
Executive Office
400 Q Street, Sacramento, CA 95811 |Phone: (916) 795-3829 | Fax: (916) 795-3410
888 CalPERS (or **888**-225-7377) | TTY: (877) 249-7442 | **www.calpers.ca.gov**

Secretary Robert F. Kennedy, Jr.
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Administrator Mehmet Oz
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Commissioner Marty Makary
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

November 21, 2025

Subject: Commending Agencies' Efforts on Biosimilars Initiatives and Affordable Prescription Drugs

Dear Secretary Kennedy, Commissioner Makary, and Administrator Oz,

On behalf of the California Public Employees' Retirement System (CalPERS), I would like to commend the Department of Health and Human Services (HHS), the Centers for Medicare and Medicaid Services (CMS), and the Food and Drug Administration (FDA) for their efforts to accelerate biosimilar development and utilization. Eliminating certain clinical trials, advancing interchangeability standards, and streamlining the approval process for biosimilar drugs, provided these changes are implemented with appropriate safeguards to protect patient safety, aligns with CalPERS' strategic goal of ensuring our members have access to equitable, high-quality, and affordable health care.

With more than 1.5 million members, CalPERS is the largest purchaser of public employee health benefits in California and the second largest public purchaser in the nation after the federal government. In 2024, we spent over $12.4 billion to purchase health benefits for active and retired members and their families on behalf of the State of California (including the California State University) and nearly 1,200 public agencies and schools. Approximately 20% of our $12.4 billion spend was for outpatient prescription drugs alone. CalPERS strongly supports regulatory actions to increase timely access to lower cost biosimilars, including the FDA's draft guidance that eliminates the need for certain costly and timely clinical trials for these drugs.

Prescription drugs play an important role in the health and well-being of our members and their families. Rising drug costs are driven largely by the growing utilization and increasing launch

prices of specialty drugs and gene therapies. While specialty drugs represent a small fraction of drugs prescribed and dispensed to our members, they account for a disproportionately large portion of the overall CalPERS spend. Specialty medications accounted for 46% of CalPERS outpatient pharmacy spend in 2024, but only 1.7% of utilization. Our experience demonstrates that the use of generics, biosimilars, and evidence-based pharmacy benefit management strategies are critical to controlling increasing prescription drug cost trends.

In 2021, CalPERS partnered with the third-party administrator for our preferred provider organization plans to launch a Biosimilars First program for one reference drug that requires the use of biosimilars under the Medical Benefit for new adult patients when a biosimilar is available and clinically appropriate. The program achieved widespread acceptance among patients and providers. Following this success, we expanded the program in 2022 to include all reference drugs with available biosimilars.[1] According to a study from the American Journal of Managed Care, substituting biosimilar drugs for biologics could drive down the price of expensive medicines, with savings estimated to be $38.4 billion, or 5.9 percent of projected total U.S. spending on biologics from 2021 to 2025. [2]

In continuing efforts to further promote the utilization of lower cost and equally safe and effective biosimilars, our new pharmacy benefits contract, which starts January 1, 2026, requires that the Pharmacy Benefit Manager formulary prefer low-WAC (wholesale acquisition cost) biosimilars over high-WAC biosimilars and biologics whenever a low-WAC biosimilar is available. Both Humira and Stelara are currently excluded from the CalPERS formulary in favor of low-WAC biosimilars. That requirement will continue in the new contract.

We believe our work in advancing access to biosimilar drugs aligns with the FDA's goal of increasing affordability and competition in this space. CalPERS strongly supports policies that accelerate generic and biosimilar drug market entry and limit anti-competitive arrangements used by drug manufacturers that block or delay the entry of lower-cost generic drugs and biosimilars. Accordingly, CalPERS would like to reiterate its support for CMS's continued monitoring to ensure Part D plans provide beneficiaries with broad access to generic and biosimilars through cost-effective drug utilization management programs. Additionally, we urge you to accelerate access to biosimilar drugs by working with Congress to reform antitrust laws such as the Sherman Act and address patent abuses called "patent thickets." Addressing such anticompetitive behavior is critical to ensuring the timely market entry of biosimilar drugs.

Again, we thank you for bringing attention to this important issue. CalPERS prioritizes strengthening key agencies under HHS, including the FDA and CMS, to advance their missions of curbing chronic disease, increasing utilization of preventive health care services (such as screening and vaccinations), ensuring medication safety and efficacy, and driving scientific innovation in health care. As such, CalPERS welcomes the opportunity to work with you on our shared goal to improve health care affordability.

[1] See CalPERS Health Team Pushes for Broader Acceptance of Biosimilars, available at https://news.calpers.ca.gov/calpers-health-team-pushes-for-broader-acceptance-of-biosimilars/.
[2] See Projected US Savings From Biosimilars, 2021-2025, available at https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025.

Please do not hesitate to contact Donald Moulds, Chief Health Director, at (916) 795-0404, or Danny Brown, Chief of our Legislative Affairs Division, at (916) 795-2565, if we can be of any assistance.

Sincerely,

Marcie Frost
Chief Executive Officer