

**“21st Century Cures: Examining the Role of Incentives in Advancing
Treatments and Cures for Patients”**

**United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health**

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Chairman Pitts, Ranking Member Pallone, and Members of the Committee, on behalf of the California Public Employees Retirement System (CalPERS), we thank you for convening this hearing to address the critical issue of improving the discovery, development, and delivery of promising new cures to patients and we commend you on your bipartisan effort to address these issues via the “21st Century Cures” initiative. We strongly believe in the need to close any existing gaps between scientific discovery and federal regulation of therapies so that innovation can survive and thrive into the future. CalPERS is pleased to submit testimony for the record to discuss the importance of innovative therapeutic development and our commitment to finding federal policy solutions to support this innovation, while maintaining accessibility and affordability for consumers.

This statement includes a brief overview of CalPERS health programs and benefits, a discussion of our support for federal incentives aimed at driving new drug development and acceleration of approval -- particularly as it relates to biopharmaceuticals -- and our perspective on the need to protect patient access and affordability in the overall pharmaceutical market.

Background on CalPERS

CalPERS was established by state law in 1932 to provide retirement benefits for California public sector employees. In 1962, state law authorized CalPERS to provide health benefits to their members. Our mission is to advance the financial and health security for all who participate in the system.

In 2012, CalPERS spent over \$7 billion for health care benefits for over 1.3 million active members, retirees, and their families, including almost \$1.5 billion for prescription drugs, or 21 percent of total health care spending. CalPERS prides itself on ensuring access to safe, effective, and affordable prescription drugs, including generic medications. In 2012, CalPERS spent nearly \$400 million on generic drugs for its active members, retirees, and their families; and, every year, CalPERS and its members save tens of millions of dollars through the use of safe, effective generic medications.

Biomedical Innovation: Finding Cures for All Patients

Over the past three decades, biomedical research has made historic achievements that have led to new, powerful tools in identifying effective therapies to treat well-known diseases such as cancer, heart disease, and diabetes. Breakthroughs in academic research – much of it federally funded -- as well as a strong biopharmaceutical industry and balanced government regulation has positioned the U.S. as the leader in biomedical innovation. CalPERS is proud to be a partner in accelerating these important scientific breakthroughs while ensuring an appropriate balance between innovation, access, and affordability of critical therapies.

That said, much remains to be done. Despite historic breakthroughs in scientific research, clinical trials, and new, life-saving therapies, many common diseases remain incurable. Heart disease and stroke continue to be leading causes of mortality, psychiatric diseases are serious burden on patients, their families, and society as a whole, and infectious disease presents new, critical challenges in terms of drug-resistance. On top of this, a full 96 percent of orphan diseases remain incurable. These incurable diseases present a “cost” to patients which includes a lack of therapeutic effectiveness as well as a significant economic burden. For example, in 2012, CalPERS spent more than \$83 million on just three biologics used to treat rheumatoid arthritis.

In 2012, the President’s Council of Advisors on Science and Technology (PCAST), the advisory group made up of the nation’s leading scientists and engineers who directly advise the President, set an important goal to “Double the current annual output of innovative new medicines for patients with important unmet medical needs, while increasing drug efficacy and safety, through industry, academia, and government working together to double the efficiency of drug development, by decreasing clinical failure, clinical trial costs, time to market, and regulatory uncertainty.” CalPERS supports this important goal and is proud to continue to be a partner in supporting efforts to increase federal funding to both further scientific research and bring critical medicines to market.

Balancing Innovation with Access and Affordability

As we continue to support scientific research and an accelerated process to bring breakthrough drugs to market, we must also be mindful of the ability for consumers to access and afford essential medications. Overall, breakthroughs in biomedical research and the pace of scientific research have not always led to a significant increase in access to medicines for our employees and retirees. The critical tool to ensure affordability of brand name prescription drugs is timely competition from cost-effective generic alternatives.

The passage of the Drug Price Competition and Patent Term Restoration Act of 1984 provided an important tool for brand name drug companies to recoup costs incurred from research and development for new medications. Patent protection occurs for 50 percent of the development time of a certain drug and 100 percent of the time a drug is under review at FDA. The market exclusivity period for brand drugs is five years. CalPERS believes that the exclusivity period established under current law is appropriate to properly incent innovation while still ensuring generic competition in the marketplace.

Furthermore, many of the most innovative, life-saving therapies available and in development today are in the biopharmaceutical marketplace, known as biologics. However, the significant cost burden of these medications has a measurable, negative impact on consumers and purchasers, including CalPERS. Between 2004 and 2011, the percent of CalPERS participants utilizing specialty medications increased by 33 percent; and, specialty drugs comprised 1.2 percent of drugs dispensed yet represented 17 percent of CalPERS total drug spend. A full 94 percent of CalPERS' specialty drug spending is associated with biologics. CalPERS' total spending for specialty drugs exceeded \$250 million in 2011, a 43 percent increase since 2007, and a 120 percent increase since 2004.

The Affordable Care Act (ACA), signed into law by President Obama in March 2010, contained an important provision establishing an abbreviated pathway for biological products that are demonstrated to be "biosimilar" to, or "interchangeable" with, an FDA-licensed biological product. As a result of the passage of the ACA, innovator products were granted a period of at least 12 years of exclusivity on the market before patents may be challenged. We believe that 12 years is more than a sufficient amount of time to allow innovator companies to recoup their investments in research, development and marketing and would not support an extension to the exclusivity period in the law. The FDA is currently establishing standards for the licensing of these products and CalPERS is pleased to be a collaborator and partner as FDA develops policy on this important issue.

Conclusion

Mr. Chairman, CalPERS applauds the efforts of this committee and of Chairman Upton and Congressman DeGette to highlight the issue of innovation. CalPERS supports a balanced approach to creating strong incentives for pharmaceutical innovation and ensuring appropriate access and affordability of medications for consumers. In so doing, we strongly believe the current market incentives under federal law that allow for appropriate multi-year exclusivity and patent protection should be maintained. We look forward to continuing to partner with the public and private sector to ensure that consumers have timely access to safe, innovative and affordable medications.