NO MISLEADING Rx MEASURE

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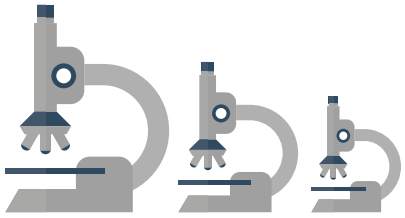
Why the Misleading Rx Measure Will Stifle Scientific Research and Development and Reduce Prescription Drug Access for Patients

In November, California voters will vote on an initiative that attempts to prohibit certain state agencies from entering into contracts for prescription drugs unless the contracted prices are the same or lower than the prices paid by the U.S. Department of Veterans Affairs (VA). This poorly written initiative, which covers only a small fraction of state programs, would interfere with existing state drug contracting practices and could actually reduce access to medicines for patients, while increasing costs. The measure would also serve to discourage additional research into treatment and cures.

The measure could have a negative effect on cutting edge medical research and cures.



According to the Tufts Center for the Study of Drug Development,[1] on average, it costs pharmaceutical companies $2.6 billion to do the years of research and tests necessary to develop a single new drug.

If California and other states pass laws that set price limits on innovative drugs, it would limit investments in the research and development of new drugs and cures.

- A 2005 National Bureau of Economic Research working paper found that cutting drug prices by half could result in 30-60% fewer R&D projects being undertaken in the early stages of drug development.[2]

Limiting investment could cause medical research facilities in California to lose funds for cutting edge research, resulting in lost California jobs and fewer cures.

Importance of California Life Sciences Research and Development

In 2015, there were **1,235 new drugs** in California's drug development pipeline.

- **366 to treat cancer**
- **151 for infectious disease**
- **109 to address central nervous system conditions**

California's life sciences industry generates **nearly one million jobs, with 281,000 people being directly employed in the industry.**[3]

There were a total of 3,111 clinical trials in California in 2013, with 125,613 clinical trial participants.

The measure could result in more physician paperwork and more hassle for patients, reducing or delaying access to prescription drugs.

California's Medi-Cal Fee for Service program has currently negotiated many agreements with pharmaceutical manufacturers, where manufacturers provide "state rebates" in order to be included on the state's preferred drug list.

The Medi-Cal Fee for Service supplemental rebate contracts guarantee that a manufacturer's drug will be placed on the Medi-Cal List of Contract Drugs (List). Drugs not on the List require a prior authorization to

be prescribed by doctors and dispensed for patients.

One potential consequence of this measure could be that the state is forced to invalidate many existing supplemental rebate agreements it has with pharmaceutical manufacturers if the net price of those agreements is higher than the VA price.

If the state was not able to maintain these current contracts with manufacturers, it would result in fewer drugs on the List, which would create a new prior authorization hurdle for doctors and their patients.

As a result, this measure could delay or even eliminate patient access to needed medicines and cost the state tens of millions of dollars in supplemental rebates.

"Drug price controls would stifle the introduction of valuable new drugs, because innovators will spend less pursuing new drugs." [4]

– Darius Lakdawalla
Professor of Pharmaceutical Development and Regulatory Innovation
USC School of Pharmacy

There is tremendous uncertainty around how the measure would be implemented.

The measure's language is legally flawed and at odds with how the sale and purchase of prescription drugs work.

The measure, as written, does not compel pharmaceutical manufacturers to sell their products to state agencies at certain prices. Rather, it seeks to prohibit the state from entering into "agreements" (contracts) with pharmaceutical manufacturers above the VA price.

The measure contains absolutely no language for how it is to be implemented, and as recently noted by the state's independent Legislative Analyst's Office,[5] many VA prescription drug prices are not publicly available. So the state may not even be able to obtain the basic information it would need to begin to implement this measure.

The measure only applies to a limited number of state programs.

The ballot initiative **does not apply to more than 34 million Californians,** including 20 million Californians covered by private sector plans, 10.2 million patients covered by Medi-Cal Managed Care, representing nearly 80% of all Medi-Cal patients; and 1.5 million patients in Covered California, the state's new health insurance exchange under Obamacare.

34 million Californians would be excluded from the measure

1 PhRMA adaptation based on Dimasi JA. Cost of developing a new drug. Tufts Center for the Study of Drug Development (CSDD). R&D Cost Study Briefing; November 18, 2014. Boston Mass.: CSDD. Accessed November 2015.

2 California Biotechnology Foundation, "Biopharma Facts for a Balanced Discussion", Volume 1, Number 1.

3 California Life Sciences Association (CLSA), "California Life Sciences Industry: 2016 Report", http://califesciences.org/2016report/ .

4 (http://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-end-up-costing-patients-their-health)

5 http://www.scpr.org/news/2015/12/23/56415/will-calif-ballot-measure-lower-drug-prices/

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