

Drug Price Relief Act

SDCTA POSITION:

OPPOSE

RATIONALE FOR POSITION:

SDCTA opposes the Drug Price Relief Act, as policies aimed at lowering prescription drug prices come with a trade-off. Price fixing prescription drugs to the VA would reduce healthcare costs for the State of California, but shift the burden of drug costs to private buyers or even the VA itself, which has been receiving discounts in recognition of veterans' service and general health care needs. Moreover, pharmaceutical companies may offset profit losses by allocating less investment toward drug research and development, negatively affecting future innovation in medicine as well as San Diego's large biotechnology and pharmaceutical industry and economy. The measure neither promotes efficiency nor equity in the drug market, and therefore will not relieve the cost burdens of prescription medicine for patients as intended. The fiscal effects also remain unclear.

Title: Drug Price Relief Act of 2016

Jurisdiction: State of California

Type: Statewide Initiative

Vote: Majority

Status: On November 8, 2016 General Election Ballot

Issue: Prescription drug prices and health care costs in California

Description: The proposed measure seeks to reduce the amount any government or state agency would pay for prescription drugs, on par with or below prices paid by the U.S. Department of Veterans Affairs (VA). This applies to direct purchases such as prison health care as well as indirect payments such as for drug plans under Medi-Cal and CalPERS. The VA fixes drug prices and is offered lower rates than the federal price ceiling (FPC), with drug coverage restricted to a list of drugs on the Federal Supply Schedule (FSS). Because prescription drug prices are one of the primary drivers of increasing health care costs, California taxpayers are burdened with excessively priced drugs that benefit executives and large pharmaceutical companies.

Fiscal Impact: In 2013-14, California's Department of Health Care Services reported the gross cost of prescription drugs at \$2.8 billion. If matched to the VA, the amount California will spend on a drug will be around 20% below the current market value though exact values are unknown due to the confidentiality of VA prescription drug prices.

BACKGROUND:

Prescription Drug Pricing Standards

Pure profiting schemes by pharmaceutical companies have been largely criticized across the nation. In September 2015, Turing Pharmaceuticals increased the price of Daraprim, a drug used to treat parasitic infections especially vulnerable to patients with AIDS and cancer. The price hike went from \$13.50 to \$750 per tablet, driving censure on the lack of affordability of drugs needed to treat chronic diseases.¹ The challenge is creating legislation that reduces costs of specialty drugs without sacrificing incentives for innovation by drug manufacturers. California has the highest concentration of biotechnology firms in the United States, comprised mostly of biopharmaceutical companies.²

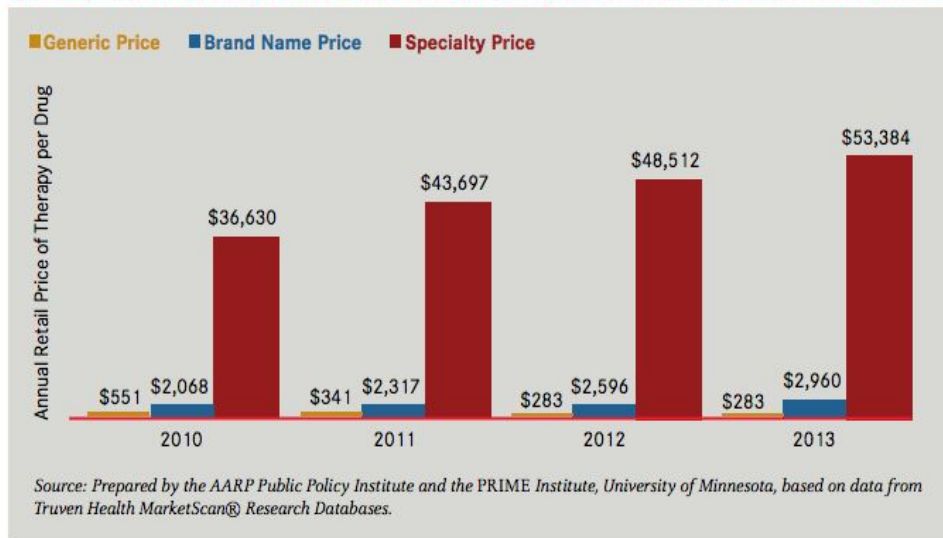
Unlike traditional prescription drugs, specialty drugs are less moderated with spending expected to increase 16% per year from 2015 to 2018.³ Because of their high development costs, specialty drugs make up a disproportionate share of overall drug spending. Currently, brand-name specialty drugs are comprised largely of a subset known as biologics (made from complex molecules versus traditional chemical compounds) are given 12-year exclusivity periods after FDA approval, also known as a patent. In order to incentivize pharmaceutical companies to take on risks of drug development, exclusivity periods allow drug manufacturers to charge higher prices as a monopoly during that time. Without the economic benefits of price competition, sellers with market power can price discriminate (charging different prices for different buyers) and make it difficult for patients with the most need to manage cost constraints.

¹ Pollack, Andrew. "Drug Goes from \$13.50 a Tablet to \$750, Overnight." *The New York Times*. 20 Sep 2015.

² Decillis, Daniel. "California Considers Drug Pricing Measures." *California Council on Science & Technology*. 19 Nov 2015.

³ Specialty Drugs: Issues and Challenges. Issue Brief. *America's Health Insurance Plans*. Jul 2015.

Specialty Prescription Drug Prices Are Considerably Higher than Other Prescription Drug Prices



Under California Assembly Bill 339, privately insured patients in California with life-threatening conditions cannot be asked to pay out-of-pocket costs that exceed \$250 per outpatient prescription drug per month. For people on bronze-level plans with low monthly premiums, the cap is at \$500 for a single 30-day prescription. This is consistent with drug pricing limits adopted by Covered California, the state’s health insurance exchange. California is the first state to set caps on co-payments in the nation, arguing that formularies for prescription drugs should not discourage the enrollment of individuals with chronic health conditions that require high-cost medications.

U.S. Department of Veterans’ Affairs

In order to induce drug manufacturers to keep drug prices low, buyers and health plans adopt lists of preferred drugs they will agree to pay for (the formulary). Based on military service, the VA medical benefits package includes coverage for monthly supplies of prescription drugs. Prescription drug costs negotiated for the VA are the lowest pricing available to any government agency. Under the Veterans Health Care Act of 1992, drug prices are negotiated based on vendors’ most favored commercial customer pricing. In other words, compared to private sector drug sales, prices paid by federal buyers are subject to regulations that allow for deeper discounts.

As one of the “Big 4” federal purchasers of pharmaceuticals, the VA is able to obtain further price reductions that go below the federal price ceiling. The price cap at which manufacturers can charge the VA is based on a measure of average manufacturer prices and inflation. Moreover, the VA average drug price may be even lower than the “Big 4” because it negotiates further price reductions using its preferred formulary. As a result, the VA average price has been around 42% of the Average Wholesale Price (AWP) for the private sector, where discounts offered are offset by increases in

purchase volume and prompt payments to vendors.⁴ The VA now pays 20% below the lowest pricing for other state agencies because of statute and its massive purchasing power. Note however, final prices remain confidential. The VA is not required to make their pricing data publicly available; therefore poor access to information could make this measure difficult to implement if the VA decides not to cooperate with the State.

Drug Price Relief Act

The passing of this initiative would require state agencies to pay for drugs at prices that are on par or below the prices paid by the U.S. Department of Veterans Affairs. The main driver for this measure is the exorbitant increase of prescription drug prices in the last 15 years, particularly on specialty medications required to treat chronic diseases like HIV/AIDS and other conditions. Between 1990 and 2013, prescription drug spending increased by more than 800%, making it one of the largest components of increasing health care costs in the nation. The rising burden of drugs on taxpayers reduces the accessibility to health care services and providers for those in need. Beneficiaries would be limited to those under state-sponsored healthcare, including:

- 7 million Medi-Cal beneficiaries (non-HMO)
- 2 million CalPERS and California State Teachers' Retirement System members
- 112,000 inmates
- 31,000 residents who receive AIDS or other chronic-need drugs with government assistance⁵

In application, the passing of the initiative does not mean that pharmaceutical companies are required to sell to state agencies with the new price mandates. Instead, state agencies in California are not allowed to enter purchasing contracts with pharmaceutical companies for any drugs above VA prices. Thus, if the state is unsuccessful in negotiating drug prices at the same or lower rate than the VA, a specific set of drugs will be excluded from state programs. Note that this initiative only applies to drugs on the VA formulary, so external drugs will continue to be priced based on traditional methods of calculation.

Economic Analysis of Price Fixing

Fixing California's drug prices to the VA may not generate the intended benefits and can lead to increased costs for patients, taxpayers, and veterans. If the state government acts a large buyer receiving significant discounts in prescription drug purchases, then the costs to pharmaceutical companies also become greater. Because the pharmaceuticals industry is so large in California, imposing the VA pricing model will lead to price changes for all drug consumers.

Forcing prices to be lower for a significant share of the market is unsustainable without shifting costs to other groups. The larger the group receiving reduced pharmaceutical prices, the greater the

⁴ "Prices for Brand-Name Drugs Under Selected Federal Programs." *U.S. Congressional Budget Office*. Jun 2005.

⁵ "Measure To Control Rx Drug Prices Qualifies for 2016 California Ballot." *California Healthline*. 21 Dec 2015.

incentive for drug manufacturers to charge higher prices. In order to retain profits from large investments in drug development, pharmaceutical firms would have to charge higher prices to non-governmental purchasers including private health care plans and other federal buyers that do not receive special federal drug pricing like the “Big 4.” Furthermore, if drug manufacturers have to make discount prices available to a larger market, there are incentives to offset losses by raising costs for purchasers that have traditionally received lower prices like the VA. Granting special pricing to substantial buyers like the State of California could thus undermine the costs of drugs aimed at supporting civil servants, veterans, and members of the military.

A 2006 study by researchers from Stanford University suggests that restrictions in the VA drug formulary result in costly, new and innovative drugs being excluded from list of covered drugs. Further research from The Manhattan Institute disclosed that since 2000, only 19% of drugs approved by the FDA are on the VA formulary.⁷ These observations imply that the formulary discourages access to new pharmaceuticals in order to control overall drug costs. Economically, fixing drug prices against the VA means pegging to a relatively small market that fails to cover a majority of expensive and innovative drugs. Closing the market to drug manufacturers unwilling to match VA prices also limits access to a wide selection of prescription and newly innovated drugs. As a result, aligning with the VA’s restrictive formulary to price pharmaceuticals would make it difficult for patients to obtain drugs appropriate for their needs and conditions, with the additional negative externality of closing a significant source of research and development funding to pharmaceutical manufacturers.

Drug Rebate Programs

A comparative example includes previous Medicaid rebate policies aimed at reducing the costs of prescription drugs. Prior to the rebate program, Medicaid was paying market prices for outpatient drugs despite being the single largest purchaser of prescription drugs. After the program was enacted, pharmaceutical companies were required to pay rebates to Medicaid programs to help reduce government costs in drug coverage. In response to the enactment of rebates, drug manufacturers increased prices for large private purchasers such as hospitals.⁸ Consequently, there was a trade-off between large-scale discounts for Medicaid programs and reduced benefits for other significant buyers. Hence similar price interventions could increase drug costs for a large portion of the population over time.

340B Drug Pricing Program

⁶ Enthoven, Alain and Kyna Fong. “Medicare: Negotiated Drug Prices May Not Lower Costs.” *National Center for Policy Analysis*. 18 Dec 2006.

⁷ Lichtenberg, Frank. “Older Drugs, Shorter Lives? An Examination of the Health Effects of the Veterans Health Administration Formulary.” *Manhattan Institute*. 1 Oct 2005.

⁸ “Expanding Access to Federal Prices Could Cause Other Price Changes.” *United States General Accounting Office*. Aug 2000.

After the Medicaid Drug Rebate Program was shown to cause dramatic price increases for drugs outside the program (often medication needed to treat chronic conditions) and hospitals to share a much higher burden of low-income patients and uncompensated care, federal law began to allow discount pricing of outpatient prescription drugs for participants of the 340B program. Eligibility included hospitals and health care facilities with disproportionate shares of Medicaid and specialty treatment patients (e.g. cancer hospitals, AIDS clinics, rural referral centers, etc.). Manufacturers that participate in Medicaid must also participate in the 340B program and cannot charge beyond the ceiling price for each covered outpatient drug, including biologics. 340B prices on average are estimated to be 22.5% less than the average sales price of covered medications with nearly 45% of all Medicare acute care hospitals participating in the program.⁹

In recent years, drug manufacturers have sought to narrow the scope of the program and minimize the amount of patients receiving discounts, while 340B hospitals have argued for the program to continue without additional restrictions. Potential threats to the 340B program include the Bipartisan Budget Act of 2015, which will enact stipulations on whether “child site” outpatient facilities (not in the same physical address as the “parent” entity) are eligible for the 340B program.

Research and Development

Price fixing to the VA would also adversely impact funding toward research and development and harm innovation. Drugs that cure chronic conditions like cancer and AIDS may cost billions of dollars to develop because serious diseases require more clinical trials, tests, and overall expenditure and opportunity costs. Compared to drugs for minor treatments, the cost of failure is much higher for specialty drugs and may discourage pharmaceutical companies from allocating resources toward developing better and more complex medicine.

Assessing the economic value of drug development is complex and varies based on cost estimates. In 2014, the Tufts Center for the Study of Drug Development estimated that costs for pharmaceutical firms to develop a new drug were about \$2.6 billion, highlighting how expensive and risky it is to develop new medicine. Drug failures contribute largely to development costs where estimates of clinical-approved success rates are around 11.8%.¹⁰ When expected profits decrease, risky investments become even riskier. Thus, pharmaceutical companies may be encouraged to avert spending on drug research and development.

However, prior studies have revealed research and development costs incurred by drug manufacturers may not be as high as they claim. A 2008 study in *PLoS Medicine* concluded that pharmaceutical companies spend almost twice as much on drug promotion and marketing as they do

⁹ “Report to The Congress: Overview of the 340B Drug Pricing Program.” *Medicare Payment Advisory Commission*. May 2015.

¹⁰ Avorn, Jerry. “\$2.6 Billion Pill – Methodologic & Policy Considerations.” *N Engl J Med*: 372 (2015): 1877-1879.

on research and development.¹¹ Real investment costs in R&D have also been overstated, as drug manufacturers have failed to disclose grants and other investments by the federal government. The lack of full pricing transparency makes it difficult to assess what portion of funds goes toward research, development, marketing, or administration costs.

Innovation Economy in San Diego

In 2015, the innovation sector accounted for 11.3% of San Diego's traded economies with wages related to biotechnology and pharmaceuticals valued at around \$3.2 billion.¹² The concentration of life sciences companies and major research institutions like the University of California, San Diego make the region one of the most innovative and renowned biotechnology markets in the world. Large pharmaceutical firms such as Pfizer and Johnson & Johnson also maintain a strong presence in San Diego to foster technological progress and product development in the sector. As a result, health care and innovation remain significant drivers of San Diego's leadership in medicine and pharmaceutical advancements.

Biotechnology and pharmaceuticals currently employ around 23,600 people while venture capital investments in the sector were valued above \$550 million in 2014, higher than any other industry in San Diego.¹¹ If lowering the state's costs for pharmaceuticals adversely affects drug manufacturers' profits and incentives to innovate, the region may experience a decrease in valuable employment. The loss of jobs could include life scientists, biotechnology and medical scholars, and other important affiliates of top research institutions that fuel product growth and scientific development. More than 7,000 Science, Technology, Engineering, and Math students graduate from higher education in the region each year, many of which may not be able to attain local jobs with less demand and inducement for innovation. As a result, weakening biotechnology and pharmaceuticals as one of San Diego's leading industries will slow the innovation economy and lead to negative economic impact.

It also important to note that in California, institutions and companies receive significant tax credits to drive large incentives for innovation and R&D. Calculated based on research activities and expenditure, tax incentives aim to compensate entrepreneurs such as pharmaceutical firms for some of the risk they bear in the drug development process. A 1994 study by the U.S. Government Accountability Office revealed that tax credits for drug manufacturers have increased over time and the greatest beneficiaries of these incentives have been large pharmaceutical companies valued at \$250 million or more. However, that real value of these incentives for relevant regions like San Diego remain unclear due to challenges in identifying eligible research activities and disputes on whether credits are substantial enough for taxpayers to invest in complex disease research.

Market Failure

¹¹ Gagnon, Marc-Andre and Joel Lexchin. "The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States." *PLoS Med* 5.1 (2008): 29-33.

¹² By The Numbers: Healthcare. *San Diego Regional Economic Development Corporation*. 30 Sep 2015.

The initiative essentially argues for a policy intervention to regulate and mandate drug prices because pharmaceutical markets are riddled by market failure. In an optimal economic setting, pharmaceutical buyers and sellers could transact efficiently without government interference and the relationship between supply, demand, pricing, and competition would not be distorted. The ability of pharmaceutical companies to act as a monopoly and impose exorbitant price hikes indicates that market failure does indeed exist. When an expensive and in-demand drug has no competition, patients do not have the option of choosing another product. For many, the lack of affordability means that they cannot access the drug at all. Thus, current issues within the pharmaceuticals industry represent a failure in market forces to provide a competitive outcome in price or availability of resources for those in need.

In developing innovative and increasingly complex medicine, pharmaceutical companies bear all the risk while benefits extend to greater society. In the drug industry where significant amounts of profit must be maintained to continue attracting potential innovators in the future, the social benefits of newly developed drugs may be larger than the welfare losses in the price discrimination that evidently occurs. Externalities arise when private and social costs do not align.

For example, if fixing drug prices to the VA reduces consumer access to necessary and appropriate medicine, then negative externalities exist because that population might be worse off than welfare losses caused by overall price discrimination by drug manufacturers. A system that charges most people high drug prices and offers discounts to a few may be more unfair than a system that allows some people to enjoy low discounted prices and then imposes an additional charge on some other portion of the population. Hence, it may be more beneficial to the patient for drugs to be available, though expensive, than for them to be unavailable and for new research opportunities to be unexplored due to price constraints.

Clearly, price fixing is not the appropriate policy intervention. In California, how can the most vulnerable patients such as low-income and chronically ill citizens better afford and access the medications they need? Some initial policy suggestions are provided below.

- *Recommendation #1: Increase transparency in drug pricing and costs*
 - Imperfect information is a significant driver of market failure because buyers are usually uninformed about the true price paid for drug development. Consumers are thus unable to make informed choices (e.g. when to use certain prescription medicine versus alternatives). Because of this, pharmaceutical companies maximize profits by charging the highest price consumers are willing to pay, which can be extremely high in cases of specialty medicine for chronic illnesses. Greater transparency in clinical research and drug development data will allow patients to make informed treatment decisions and reduce pricing abuse by drug monopolies.

- *Recommendation #2: Decrease the patent period of newly innovative drugs*

- For very complex drugs like biologics, the 12-year patent period granted by the FDA may not be necessary. A 2009 Federal Trade Commission report showed that drug companies are unlikely to introduce new products at notable discounts and industry's rapid growth means that new drugs retain up to 90% of their market share years after entry. Thus, allowing lower-cost competitors to enter the market sooner does not significantly affect revenue and further prevents product-hopping issues where pharmaceuticals companies make minor,¹³ invaluable changes to existing drugs in order to extend their exclusivity periods.
- *Recommendation #3: Amend the tier and drug classification in formularies*
 - Drug formularies currently fix prices of drugs categorized into 4 or 5 tiers with the exception of the highest tier of specialty drugs. When all drugs targeted at one type of illness are placed at the top tier with the highest levels of patient cost-sharing, chronically ill patients who need specialty medicine are unable to access or afford these drugs the most. Research has shown that increasing patients' out-of-pocket costs are ineffective in controlling costs of drug coverage because patients with the most need do not have the option of choosing cheaper drugs. As a result, formularies should include low-cost alternatives on different tiers and encourage physicians to prescribe substitutes when appropriate and possible.
- *Recommendation #4: Allow state negotiations to lower high-cost prescription drug prices*
 - The State of California should be authorized to negotiate prices for relatively expensive drugs, including specialty drugs and biologics that lack alternatives. While discounts may not match VA levels, savings could increase if the state were to set drug prices administratively and put regulations in place for pharmaceutical companies to offer discounts to a certain extent. As a large purchaser, California should be able to leverage deeper discounts and influence manufacturers toward higher cost-sharing of drugs. The state's ability to negotiate meaningful price reductions for expensive and life-saving drugs is significant because of its membership size and ability to shift market share. Consequently, reliable benchmarks for sufficient discounts should be utilized to assure low-income and chronically ill Californians are getting the medicine they need.

FISCAL IMPACT:

In 2013-14, California's Department of Health Care Services reported the gross cost of prescription drugs at \$2.8 billion, reflecting a minor increase to the \$2.7 billion in 2006-07.¹⁴ If matched to the VA, the amount California will spend on a drug will be around 20% below the current market value.

¹³ Daniel, Hilary. "Stemming the Escalating Cost of Prescription Drugs." *Annals of Internal Medicine*. 29 Mar 2016.

¹⁴ Graham, John. "To Control Drug Prices, Pursue Fraud, Not Manufacturers." *Pacific Research Institute*. 21 Dec 2015.

Because exact VA pricing of prescription drugs is not publicly available information, detailed estimations of fiscal impact from the state's Legislative Analyst have yet to be released.

PROPONENTS:

- AIDS Healthcare Foundation

PROPONENTS' ARGUMENTS:

- This comprehensive drug price reduction will increase transparency on the cost of drugs, reduce excess profits of large pharmaceutical companies, and make medicine and health care more affordable for at least 5 million California residents under programs like Medi-Cal.
- Overpriced drugs burden taxpayers and lead to cuts in health care services and providers and under-usage of medication of those in need.
- If California pays the same prices for prescription drugs as the VA, the imbalance of government payers toward drug purchases will be improved. Greater discounts would help state agencies better serve chronically ill patients, retirees, inmates, and low-income people.

OPPONENTS:

- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Johnson & Johnson, Inc.
- Bristol-Myers Squibb Company
- Purdue Pharma, L.P.
- AstraZeneca Pharmaceuticals L.P.
- Novartis
- Otsuka America, Inc.

OPPONENTS' ARGUMENTS:

- These price distortions would drive up drug prices overall by reducing the availability of some drugs and shifting the costs to a different segment of the population.
- Drug companies will be incentivized to increase VA prices to offset losses in the long run, penalizing those not covered by the measure's provisions.
- Reducing drug prices would limit the incentives and resources available for innovation by pharmaceutical companies and harm patients over time.
 - Prices for drugs like antibiotics have become so low that most companies can no longer justify high research and development costs.
- Egregious prices for top-tier drugs are only temporary because competitors will enter the pharmaceuticals market with similar medicine.
- Analysts have noted that differences in out-of-pocket expenses would not be that significant, as most people served in relevant programs already pay relatively low costs for health care.



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- The measure would lead to millions of dollars in lawsuits that burden taxpayers, in order to enforce lowered drug costs. The current language on how to implement these proposed changes remains vague.