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September 2016

ISSUE BRIEF

Health Care

HIGHER PRICES, FEWER CHOICES

Why California's Prop. 61 Will Not Bring Drug-Price Relief

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Executive Summary

On November 8, 2016, Californians will vote on the California Drug Price Relief Act ("Proposition 61"). Prop. 61 would prohibit California government agencies—with the notable exception of managed-care plans operating within Medi-Cal, the state's Medicaid program—from paying more for a prescription drug than the price paid for the same drug by the U.S. Department of Veterans Affairs (VA).

According to its supporters, Prop. 61 would enable California "to negotiate the same or even better deals [than the VA] for taxpayers, which could save [California] billions in healthcare costs."[1] Instead, Prop. 61 would likely unleash numerous unintended consequences, including *increased* state spending on prescription drugs, *higher* drug prices for veterans, *reduced* (or delayed) access to medicines, and *slower* growth and investment in one of California's vital industries.

Higher Medi-Cal Drug Spending. Prop. 61 would require California to abandon previously negotiated fee-for-service (FFS) Medi-Cal discounts unless they resulted in drug prices that were equal to, or lower than, the price on the VA "formulary" (a list of prescription drugs covered by public or private insurance plans). Because federal law requires Medi-Cal to cover medically necessary drugs for enrollees, Medi-Cal would still have to purchase medicines for patients who need them—potentially at a higher price than what FFS Medi-Cal currently pays.

Fewer Drug Choices for Public-Sector Workers / Higher CalPERS Spending on Some Medicines. Prop. 61 cannot force drug manufacturers to offer California the same prices that the VA pays for drugs. If the California Public Employees' Retirement System (CalPERS), the state's public-pension fund, could not secure VA-level prices for the drugs that the VA covers, CalPERS would have to drop such drugs from its coverage—sharply curtailing access to medicines for CalPERS's 1.4 million beneficiaries. CalPERS could also find itself paying for more expensive medicines among the remaining 54% of branded drugs and 39% of generics that it covers that the VA does not cover.

Higher Drug Costs for the VA. In 1990, Congress passed legislation tying Medicaid drug prices to the lowest price paid by private or public purchasers, including the VA. Rather than simply lowering their drug prices for Medicaid, drug manufacturers raised the prices that they charged the VA—by 21% in 1991. Congress repealed the law the following year. Faced with the combination of Prop. 61 and Medicaid "best price" regulations—which would require drug manufacturers to extend VA prices not only to CalPERS (1.4 million enrollees) but to *all* 50 state Medicaid programs (60 million enrollees and 20% of U.S. prescription-drug spending)— manufacturers would inevitably hike drug prices for the VA.

Higher Drug Costs for CalPERS. If CalPERS were forced to limit its coverage to more expensive medicines, California taxpayers would foot the bill, while CalPERS members would be protected by their gold and platinum health plans.

Less Investment in California's Biotech Start-Ups. If adopted and emulated by other states or the federal government, Prop. 61's drug-price controls could significantly reduce financial returns for biotech investors, leading to a downturn in drug research and development. In 1993, just the threat of nationwide price controls reduced U.S. firms' R&D investment by about $1.5 billion. Slashing U.S. drug prices by 40%–50% (on the scale of VA price reductions) would lead to a 30%–60% reduction in R&D dedicated to U.S. early-stage drug development, according to another estimate. Such an outcome would devastate California's world-class ecosystem of biotech start-ups, which depend on venture-capital funding.

I. Introduction

The California Drug Price Relief Act is being promoted as a tool to reduce state spending on prescription drugs. Prop. 61 would require California agencies (excluding Medi-Cal managed-care plans) that purchase medicines directly (as does the California Department of Corrections and Rehabilitation) or indirectly (as does Medi-Cal fee-for-service) to pay no more for drugs than the lowest price negotiated for the same drugs by the U.S. Department of Veterans Affairs.

Supporters of Prop. 61 project that the law would save California billions of dollars in lower drug spending. Alas, prescription-drug pricing is much more complicated than Prop. 61 advocates suggest: artificially suppressing drug prices for California government agencies, by linking them to VA prices, would unleash numerous unintended consequences—nearly all of them undesirable.

II. Dynamics of Drug-Price Negotiations

> "Although California has engaged in efforts to reduce prescription drug costs through rebates, drug manufacturers are still able to charge the State more than other government payers for the same medications, resulting in a dramatic imbalance that must be rectified."[2] — Proposition 61

Advocates of Prop. 61 suggest that California taxpayers are victimized by drug-industry price-gouging and lack sufficient negotiating leverage. Yet if Prop. 61 were to become law, California taxpayers would likely pay more for at least some medicines, as well as forfeit discounts that they benefit from today.

Medi-Cal, America's largest Medicaid program and California's largest prescription-drug purchaser, almost certainly[3] enjoys deeper discounts than nearly all other private and public U.S. payers: by federal law, Medicaid programs must receive the lowest price available, defined as either the best price that manufacturers offer to private purchasers or a flat 23.1% rebate.[4] Drug manufacturers must also refund state Medicaid programs any increases in drug prices that exceed consumer inflation.[5] These refunds can be substantial.

A 2014 Government Accountability Office (GAO) paper found that 62% of branded prescription-drug revenues were rebated to Medicaid programs;[6] Medicaid's pricing structure even ensures lower drug costs than other federal programs,[7] including those for the U.S. Department of Defense (DOD) and Medicare Part D. Only the VA pays less for drugs.

The VA secures lower drug prices than everyone else for several reasons.[8] Drug manufacturers must list all their drugs for purchase by federal programs (the "Federal Supply Schedule") when negotiating with the VA. If drug manufacturers decline to give the VA a deep discount—by federal law, at least 24% off the retail price—manufacturers are prohibited[9] from selling to Medicaid and nearly all other federal programs.[10] The VA gains even more leverage with manufacturers by offering a very narrow national drug formulary (i.e., the VA does not buy many drugs that are available to patients on other private and public health plans).

In other words, drug manufacturers have little choice but to offer, quid pro quo, substantial discounts to the VA if they wish to sell to far more lucrative state and federal clients. To secure a place on the VA's formulary, drug manufacturers must then offer additional concessions.

For manufacturers, offering the VA uniquely deep discounts is sustainable because the discounts do not influence pricing for much larger segments of the U.S. market. Why?

First, the VA does not publicly disclose the final price that it pays manufacturers for drugs—which prevents other drug purchasers from using the VA's lowest price as leverage in their own negotiations with drug manufacturers. Second, because the VA runs a "closed" pharmacy system (i.e., VA hospitals and pharmacies dispense drugs directly to veterans), drug manufacturers need not worry that their drugs will later be resold by the VA (which would undercut manufacturers' prices for other segments of the market).

However, Medi-Cal, given its clout as America's largest Medicaid program,[11] may be able to secure discounts that are comparable with (if not better than) those achieved by the VA for at least some drugs.[12] Current Medi-Cal officials have suggested that this is, in fact, the case (because such discounts are confidential, we cannot know for sure). Other California government programs might be able to secure similar discounts, too, but only by embracing a narrow VA-style formulary.

For example, CalPERS and other large state programs rely on private companies, "pharmacy benefit managers" (PBMs), to negotiate discounts with drug manufacturers. PBMs already enjoy significant flexibility in deciding

which drugs to cover; under Prop. 61, the state would have to rewrite contracts with PBMs, prohibiting them from purchasing drugs at higher than VA prices.

It is true that, by instructing PBMs to cover only medicines on the VA formulary, California could secure much deeper discounts—but at the cost of access to far fewer medicines. (CalPERS currently covers 120 more branded medicines and 113 more generic medicines than the VA national formulary, according to Avalere Health, a consultancy.)[13] Yet this unsavory trade-off—lower drug prices in return for dramatically fewer drug choices—is ignored by Prop. 61 supporters because it would be extremely unpopular with CalPERS beneficiaries and physicians.

III. Unintended Consequences of Prop. 61

Higher Drug Prices for Taxpayers, Fewer Drugs Choices for Patients

Under Prop. 61, if California negotiators failed to win VA prices, California could not buy the same drugs that the VA covers. Prop. 61 proponents argue that this requirement would strengthen California's negotiating hand; in reality, it would weaken it in critical ways.

Whereas the VA's narrow formulary strengthens its negotiating leverage, Medi-Cal, for instance, must cover *all* medically necessary drugs for enrollees.[14] Under Prop. 61, if manufacturers chose not to offer VA prices, Medi-Cal would still have to purchase medicines for patients who needed them at a *higher* price than what California currently pays.[15]

Why a higher price? Medi-Cal often negotiates additional discounts, "supplemental rebates," on top of the federally mandated 23.1% minimum price reduction; were FFS Medi-Cal barred from buying such low-priced drugs (albeit more expensive than what the VA pays for the same drugs), the alternative would inevitably be pricier because existing contracts would be voided. [16]

Now consider California's non-Medi-Cal programs. According to Avalere Health, the VA formulary covers 46% of the brand-name drugs and 61% of the generic drugs available to CalPERS beneficiaries on the Basic Plan Drug List.[17] If, under Prop. 61, CalPERS and other non-Medi-Cal programs could not secure VA discounts for VA-covered drugs, they could be required to drop VA-covered drugs—thereby restricting patients' access to useful medicines.

For CalPERS, the prohibited medicines would include Seroquel (for depression), Eliquis and Xarelto (blood-clot and stroke prevention), Flovent and Spiriva (asthma), Lantus (diabetes), and Tamiflu (flu). Ironically, California taxpayers could also find themselves spending more on CalPERS drugs that were not covered by the VA—if such drugs were more expensive than alternatives that became inaccessible in the wake of Prop. 61.[18]

Higher Drug Prices for the VA

Manufacturers could also respond to Prop. 61 by raising the VA's own drug prices. They have done so before. Congress aimed to tackle rising Medicaid drug prices in the Omnibus Reconciliation Act of 1990 (OBRA),[19] which mandated the same low drug prices for, among others, Medicaid, the VA, and the DOD (i.e., OBRA mandated the "lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States").[20]

As a result, the VA's prices became Medicaid's prices. How did drug manufacturers react? By raising prices for the VA itself.

In 1991, the VA and the DOD experienced significant drug-price increases—drugs purchased from the Federal Supply Schedule saw their average price increases nearly double.[21] Prices for a dozen drugs rose by more than 300%.[22] According to the GAO, "based on the preliminary results of its analysis of utilization data from a sample

of medical centers for 30 widely used drugs … the higher prices will increase VA's costs by $28 million (about 21 percent) over 1990 costs."[23] In response, Congress passed the Veterans Health Care Act of 1992, which henceforth excluded the VA, the DOD, and several other federal programs from Medicaid's best-price drug requirement.

Protracted, Expensive Litigation for California

Heretofore, we have assumed that, under Prop. 61, California could find out the (final) lowest price that the VA pays for various drugs; but this is far from assured. As is standard in the drug industry, VA discounts are protected by confidential contracts. Though California could sue to access this information, it would likely be blocked because federal law trumps state law.[24] In any event, California would face a protracted period of expensive, uncertain litigation after adopting Prop. 61.[25]

Even More Perks for CalPERS Beneficiaries

California's public employees already receive far greater pension benefits than the vast majority of California's private-sector workers, whose taxes fund the former's salaries, pensions, and health benefits. CalPERS also offers far more generous health coverage than the state's private-sector workers enjoy. In 2015, the actuarial value (the percentage of total average costs for covered benefits that a plan will pay) of most private-employer U.S. health plans was 83%.[26]

Consider that, on the Affordable Care Act exchanges, federal subsidies are pegged to the cost of a silver plan, which covers about 70% of expected health-care costs; gold plans cover 78% of expected costs; and platinum plans, 88%. Of the six CalPERS plans offered in 2014, three were "platinum plus," with actuarial values of 94%–95%, and three were "gold plus," with actuarial values of 79%–87%.[27] In the event that CalPERS could secure VA-level prices for the relevant subset of drugs, California public employees' coverage would become still more lavish compared with that of the state's private-sector workers.

If manufacturers declined to offer VA prices—because such prices would then become the Medicaid "best price" for 49 other state Medicaid programs—some of the remaining medicines on offer might become more expensive than the withdrawn alternatives. California taxpayers would then be on the hook for these higher prices, while CalPERS beneficiaries would be protected by their generous health plans.

Less Investment in California's World-Class Biotech Start-Ups

California's ecosystem of leading universities, experienced venture-capital firms, and large life-sciences companies makes it a magnet for venture-capital investment. In 2015, California attracted $4.8 billion in biotech and medical-device venture funding, more than double that of the next highest state, Massachusetts.[28]

If America's medicines industry became significantly less profitable—the explicit aim of Prop. 61—it would weaken financial incentives for supporting entrepreneurship and innovation among the Golden State's many start-up biotech companies, which depend on venture funding to develop their technologies.

Even the threat of drug-price controls on a large scale (which could occur if Prop. 61 passed and was emulated by other states or the federal government) can reduce incentives to invest in drug research and development by depressing expected returns to investors. For instance, firms responded to the specter of drug-price controls in the 1993 Health Security Act by reducing pharmaceutical research and development funding by $1.5 billion.[29]

Other researchers suggest that a 40%–50% reduction in U.S. drug prices (comparable to the effect of mandating VA prices) would slash investment in early-stage drug-development efforts by 30%–60%.[30] California's start-up community—responsible for developing cutting-edge technologies, such as gene splicing,[31] that have redefined American medicine—would bear the brunt of this decline in U.S. investment capital.

IV. Conclusion

Californians should disregard the fanciful rhetoric advanced by Prop. 61 supporters: Prop. 61 will not bring drug-price relief. Prop. 61 is fatally flawed because it ignores federal laws that constrain drug-price negotiations and would unleash many undesirable consequences, not least weakening an innovative industry that delivers vast economic and health benefits to the Golden State.

Rather than target straw men, California's legislators should lower health-care inflation by reducing the incidence and impact of chronic illness: 40% of California residents report having at least one of five major chronic illnesses (asthma, diabetes, high blood pressure, heart disease, or severe psychiatric distress), and the Centers for Disease Control estimates that chronic illness is responsible for 86% of U.S. health-care spending.[32] In this pursuit, the growing number of private-sector companies and insurers that have embraced value-based contract designs[33]—which link the price of medicines to the benefits, in better health and lower overall costs, delivered to patients with chronic illness—offers California a useful model.

Endnotes

1 California General Election Official Voter Information Guide.

2 California Drug Price Relief Act.

3 Supplemental rebates negotiated by Medi-Cal are confidential. We can therefore say only that Medi-Cal "almost certainly" enjoys deeper discounts than nearly all other private and public U.S. payers.

4 "Medicaid Drug Rebate Program," Medicaid.gov.

5 Quarterly growth in the consumer price index.

6 "Prescription Drugs: Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices," U.S. Government Accountability Office, June 2014. According to GAO, Medicaid paid a lower average net unit price—the price after subtracting any beneficiary-paid amounts and post-purchase price adjustments—than DOD and Medicare Part D across the entire sample of 78 prescription drugs and the subsets of brand-name and generic drugs.

7 Based on per-unit drug costs.

8 Drugs listed on the VA's formulary also face fewer competitors and enjoy higher utilization rates than would be the case for plans that offer patients and physicians more choices. The flip side: having more therapeutic options—common for employer and Medicaid plans—helps doctors and patients adapt treatment strategies to fit patients' specific needs and preferences.

9 There are "carrots" that come with the VA "sticks." The VA serves a highly valued population: 5.5 million veterans and their dependents. The VA also connects manufacturers that agree to provide discounted drugs with a large cohort of physicians-in-training. This is a coveted perk: doctors who become familiar with medicines early in their careers tend to prescribe them for years afterward. See Gretchen A. Jacobson, Sidath Viranga Panangala, and Jean Hearne, "Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid, and Medicare Policies," Congressional Research Office (January 2007).

10 The two exceptions are the Federal Employees Health Benefit Program and Medicare Part D.

11 "Total Monthly Medicaid and CHIP Enrollment," Kaiser Family Foundation.

12 CALmatters.com, "Would a California Ballot Measure Cut Drug Costs? Nobody Knows," April 10, 2016.

13 Kelly Brantley, "Veterans Administration and California Medicaid Drug Lists Cover Less than 60 Percent of Drugs Available to California Public Employees," Avalere.com, Feb. 17, 2016.

14 It can require that doctors seek additional approval, "prior authorization," for medicines that are not listed on Medi-Cal's preferred formulary.

15 Voiding these contracts would not free California from its obligation to reimburse for medicines that patients are currently taking. For new patients, physicians would have to apply for prior authorization from the state, which can be a time-consuming, difficult process. See "Medical Authorizations & Claims," CA.gov.

16 As of July 2015, 23% of Medi-Cal beneficiaries were enrolled in FFS Medi-Cal and 77% were enrolled in managed-care Medi-Cal. See Julia Paradise and Rachel Garfield, "Medi-Cal Managed Care: An Overview and Key Issues," Kaiser Family Foundation, Mar. 2, 2016.

17 Brantley, "Veterans Administration and California Medicaid Drug Lists."

18 Prices depend on the elasticity of demand for various drugs—and for their close competitors or substitutes; but the tactic is clearly available to companies.

19 OBRA's key provision required that, in order to participate in the Medicaid program, drug manufacturers had to offer states at least a minimum rebate; states, in turn, had to cover all the drugs offered by the manufacturer under that rebate agreement. H.R.5835—Omnibus Budget Reconciliation Act of 1990.

20 "Pension and Health Benefits Committee: Agenda Item 10," CalPERS, June 14, 2016.

21 Based on the 1990 producer price index for prescription drugs.

22 "Medicaid: Changes in Drug Prices Paid by VA and DOD Since Enactment of Rebate Provisions," U.S. General Accounting Office, September 1991.

23 Ibid.

24 Federal law trumps state law, a doctrine known as "federal preemption."

25 The basic VA prices are publicly available; in some cases, they may be lower than the prices currently paid by Medi-Cal or CalPERS. But if the prices are publicly available, why have California state agencies not been able to obtain at least the "basic" VA discount? And why is Prop. 61 even needed? The answer lies in the types of formularies offered by the respective programs; in Medi-Cal's case, its formulary design is constrained by federal law.

26 "2015 Milliman Medical Index: Will the Typical American Family of Four Be Driving a 'Cadillac Plan' by 2018?" Milliman Research Report, May 2015. A plan with an actuarial value of 83% means that for a standard population, the plan will pay 83% of their health-care expenses while the enrollees will pay 17% out-of-pocket, through some combination of deductibles, copays, and coinsurance.

27 "Opportunities and Challenges under the ACA for Covered California, CalPERS, and Purchasing Pools," California Association of Joint Powers Authorities, Sept. 11, 2014.

28 "California Life Sciences Industry 2016 Report," California Life Sciences Association.

29 Joseph Golec et al., "Pharmaceutical Stock Price Reactions to Price Constraint Threats and Firm-Level R&D Spending," NBER Working Paper 11229 (2005).

30 Thomas A. Abbott and John A. Vernon, "The Cost of U.S. Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions," NBER Working Paper 11114 (2005).

31 See "Herbert W. Boyer and Stanley N. Cohen," Chemical Heritage Foundation.

32 "Chronic Disease Prevention and Health Promotion," Centers for Disease Control and Prevention.

33 See, e.g., Mari Edlin, "Value-Based Formularies Take Hold: Efficacy Can Off-Set High Drug Costs," *Managed Healthcare Executive*, Jan. 21, 2015.

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