

Price Strategy Bulletin

Pharma Claims Victory after California Drug Discount Ballot Stalemate, Gears up to Fight DC's 'Excessive Price' Law

CA's Propositions 78 & 79 Both Rejected

Californians were asked through a special ballot held on November 8 to choose between two competing prescription drug discount measures - Proposition 78 (Cal Rx) and Proposition 79 (Cal Rx Plus) – both aimed at improving access by low income patients of all ages. Pre-election polls revealed considerable public confusion on the merits/demerits of either measure and it was not surprising that both were rejected. Industry, which had firmly backed 78 and criticized 79 - spending a reported \$80 million on lobbying, mailshots and media advertising in the process, a record for a state initiative campaign - expressed satisfaction. For it, defeating Proposition 79 was seen as a bigger priority than getting Proposition 78 passed.

Under both offerings, eligible residents would have been able to buy, for a modest annual fee, a discount card to obtain prescription drugs at prices negotiated by the state with manufacturers and pharmacies. Current California law only requires pharmacies to offer discounts to residents enrolled in the federal Medicare program. Whereas Cal Rx targeted only the most needy uninsured, Cal Rx Plus had less restrictive entry requirements. The main difference between the two proposals was, however, whether the discounts would be offered voluntarily or under legislative threat.

According to Proposition 79 (backed by consumer groups and labor unions), a company refusing to provide significant discounts might see its products removed from the Medi-Cal formulary and require prior authorization for use under the program. Medi-Cal provides about \$4 billion in drugs annually to 6.8 million poor and elderly people in the state. Proposition 79 would also allow individuals to sue pharma companies if they believed these engaged in illegal profiteering.

Cal Rx Plus is similar to a program with the same name in Maine. This was fought all the way to the US Supreme Court in 2003 and, though it has now started, consumers have reportedly yet to see the benefit of manufacturer discounts. PhRMA's

counter-proposal is similar to a program used in Ohio, Best Rx. Both plans were held up as examples in the California debate. Each claimed to provide cheaper drugs than the other to the uninsured, which likely contributed to voter confusion. Throughout, industry has argued Proposition 78 would offer Californians more immediate benefits being based on a firmer legal footing than Proposition 79.

Aside from price discounts, a report submitted to the California HealthCare Foundation by RAND Health found considerable uncertainty over the fiscal impact of each proposition and how it might affect Medi-Cal patients, other Californians and employers in the state. In particular:

- The state could lose millions of dollars in Medi-Cal rebates if a significant number of manufacturers chose not to participate in Cal Rx Plus. A lack of participation also could adversely affect Medi-Cal patients' access to essential medication.
- Both proposals provided incentives for employers to offer less generous drug benefits, or drop coverage altogether.
- Under Cal Rx Plus, the Department of Health Services had the option to expand the drug discount program to small businesses. If exercised, the number eligible for discounts might increase dramatically.
- Cal Rx could be terminated if discounts were insufficient or too few enrolled in the program.
- The 'excess profiteering' provision of Cal Rx Plus had the potential to stimulate numerous lawsuits against drug manufacturers and distributors by individuals who may or may not be directly involved in prescription drug transactions.

Both sides now say they will continue to push for improvements to prescription drug access by California's uninsured. 'We are committed to enacting a workable drug discount program', a PhRMA spokesman stressed, while the group that fronted

Proposition 79, Health Access California, said: 'The pharmaceutical industry may have succeeded in blocking prescription drug reform at the ballot, but we'll be back next year'.

DC's New Price Law

With attention focused on the west coast special election ballot, new legislation for the District of Columbia was passed not a mile from Washington's Capitol Hill that represents the most overt action yet by any US state or local government to rein in pharmaceutical prices. Selling patented prescription drugs at 'excessive prices' could be illegal in the District from mid-January next year.

Under the Prescription Drug Excessive Pricing Act of 2005 (A16-171), a *prima facie* case of excessive pricing is established where a drug's wholesale price is over 30% higher than the comparable price in any of four 'high income' reference countries - Australia, Canada, Germany or the UK - in which the product is protected by patent or other exclusive marketing rights. 'This is a simple consumer protection issue', argues the Act's author, Health Committee Chairman David Catania (Independent, At Large). It was passed 13-0 by the DC Council and signed into law by Mayor Anthony Williams on October 4.

Where a *prima facie* case of excessive pricing is shown, the burden of proving otherwise transfers to the manufacturer or its licensee (retailers are exempt). The DC government, or any person directly or indirectly affected (including organizations representing their interest), can require the defendant show in court that a drug is not excessively priced given 'demonstrated costs of invention, development and production, global sales and profits to date, consideration of any government funded research that supported the development of the drug, and the impact of price on access'. If it fails to do so, sales at the elevated price may be halted and other civil penalties applied, including fines and triple economic damages, with costs added.

The District spends more than \$250 million a year to provide medicines to its employees and its neediest residents, Catania has estimated. A survey by his office of local prices of 15 of the top-20 US brands found that in all but two cases these were more than 30% higher than the average in the four reference countries cited in the Act. With support from labor unions and churches during its drafting phase, he now seems prepared for the legal battle ahead. "The

law is very careful; we do not set prices', Catania told the *Washington Post*, only a threshold for what excessive prices are. His campaign was boosted when a spokesperson for DC Attorney General Robert Spagnoletti said: 'We stand firmly behind the legislation as passed'.

PhRMA/BIO Fights Back

PhRMA reacted immediately. It sued its host city in a federal court to try to block publication of A16-171 in the DC Register, When this failed it sought a preliminary injunction to bar the Act's enforcement.

PhRMA argued the measure would bring about 'government-mandated price controls', and also conflict with federal patent laws and commerce provisions by allowing local judges to rule on cases based on drug prices in foreign countries. 'The DC government's claimed interest in lowering prices for only its citizens at best simply shifts the burden of funding pharmaceutical research to other states and at worst diminishes the amount of funding available', it added. PhRMA's lawsuit was followed by one from the Biotechnology Industry Organization. 'This [the DC measure] is not the balance that Congress established, and this not the DC Council's decision to make', it said.

A hearing is scheduled for November 18.

Councilman Catania is no stranger to controversial measures against the pharmaceutical industry. PhRMA managed to rally sufficient opposition from the DC congressional oversight panel to stifle a bill earlier this year that would have allowed the District to compulsorily license a patented product if its price was considered excessive, authorize an alternate manufacture to produce it more cheaply, and give the original patent holder a default 4% royalty rate. These are the type of measures usually only proposed by poor, undeveloped countries.

Last year Catania pushed through Access Rx, which contained District provisions on importation, bulk purchasing and regulating PBMs.

Implications for Strategy Development

Companies across the industry in the US will have supported PhRMA's actions against Proposition 79 in California and against the Excessive Pricing Act in DC fearful that if established these mechanisms of cost containment could be taken up more widely.

Most local efforts to hold down prices focus on medicines the state buys on its own, principally for state employees/retirees or Medicaid recipients. But the initiatives in California, like the programs in Maine and Ohio that inspired them, offer the prospects of cut-price drugs to a much broader swath of residents.

DC's measure is also important, but in a different way, as it is tantamount to direct price control. Lawmakers in other states and cities have focused instead on purchasing strategies, such as expediting personal imports from Canada or banding together to form purchasing pools. Referencing to foreign prices, widely used in other parts of the world, also poses a significant threat. Australia is especially problematic in this respect. It might be a 'high income' country, but its pharmaceutical prices are considered low for a developed market.

Should PhRMA's legal challenge to DC fail, one possible outcome is that the District's pharmacies might be forced out of business by companies refusing to market their drugs there. After all, it is relatively easy for consumers to cross into neighboring Maryland or Virginia, where many of the city's workers live. The political implications of withdrawing from such a high profile market would be considerable though.

Another scenario is a long series of lawsuits on whether prices are excessive or not. This would amount to a 'litigation tax' on industry, PhRMA believes. But any prosecutions brought under the Act would require more transparency on foreign wholesale prices than is normally the case. Quite possibly, the Act's bark could be worse than its bite.

There are many lessons that should be learnt from the industry's experience of fighting price controls in Europe, Australia, Canada and beyond. How PhRMA plays its cards will be critical to the future.

PriceSpective is an international firm of pricing strategy experts and has knowledge of initiatives by US states to curtail drug costs and specific expertise on minimizing the risk of geographic referencing by pricing authorities.

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