1. Abstract

Proposed California legislation seeks to reduce prescription drug costs enabling the purchase of medicines from Canada, where they are less expensive, a highly controversial strategy known as reimportation. Opponents cite concerns for patient safety and the threat to biomedical innovation. Supporters assert that reimportation is necessary in the face of prohibitively high prices in the US that restrict access to lifesaving medications.

2. Purpose of health policy or idea

Proposed legislation introduced in the California State Legislature aims to lower the cost of prescription drugs in California by enabling private consumers and state agencies to purchase US-manufactured drugs from Canada, a strategy known as reimportation (the industry term for when US manufactures products are exported, but then brought back to the US for sale). Purchasing drugs from Canada is advantageous because Canadian price controls and a favorable exchange rate make them 30%-60% cheaper than when they are purchased in the US. Reimportation is a highly controversial strategy, however. Opponents (including the biomedical industry, the federal government and the state board of pharmacy) cite concerns for patient safety and the threat to biomedical innovation.

If passed as proposed, the bills would facilitate private purchasing and establish consumer protections by establishing a state-run website listing Canadian pharmacies certified as safe by the California board of pharmacies. Part of the proposed legislation would also require the state Department of General Services (DGS) (which purchases drugs for prisoners, state hospitals and state agencies) to set up a pilot program that considers Canadian sources when determining best prices for purchasing prescription drugs. Documentation prepared for the senate committee on the bills indicates that the DGS could save $23 million annually if it purchased 5 widely used drugs from Canada.

Directly affected by the legislation would be consumers, particularly seniors and other heavy users of prescription drugs, state agencies and recipients of state health services, the biomedical industry, and California pharmacies. More broadly, the state’s market size and the importance of its biomedical industry make it an important bellwether of the future of the prescription drug costs debate.

Main objectives

Reduce prescription drug costs for consumers, private insurers and state agencies by enabling them to import the medicines from Canada, where they are less expensive.
Type of incentives
Cost savings for consumers, insurers, and the state.

3. Characteristics of this policy

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<thead>
<tr>
<th>Degree of Innovation</th>
<th>traditional</th>
<th>innovative</th>
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<tr>
<td>Degree of Controversy</td>
<td>consensual</td>
<td>highly controversial</td>
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<td>Structural or Systemic Impact</td>
<td>marginal</td>
<td>fundamental</td>
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<td>Public Visibility</td>
<td>very low</td>
<td>very high</td>
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<td>Transferability</td>
<td>strongly system-dependent</td>
<td>system-neutral</td>
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4. Political and economic background

Several political and economic factors have influenced the development of these proposals, including rising costs associated with prescription drugs, and the nation-wide upswing in drug purchases from Canada.

In recent years, California has seen prescription drug costs occupy rapidly growing shares of shrinking state health program budgets. Between 1996 and 2003, the state DGS expenditures on prescription drugs rose 354 percent (from $40 million to $176 million). As pressure mounts to reduce state expenditures to control the state's budget crisis, prescription medications are a more and more attractive target for budget cutters. The rising cost of medications is by no means a problem limited to state agencies; private insurers, hospitals and consumers (particularly seniors) have also been struggling with rising prescription drug costs.

Faced with prohibitively high prescription drug costs, private individuals and state and local governments around the country have been beginning to look to Canada as a way to cut costs; In the private sector, an estimated 1 million Americans already purchase drugs from Canadian online pharmacies, with or without state assistance or regulation. At least 7 states, including Minnesota, New Hampshire and Springfield, Massachusetts, have enacted schemes to purchase drugs from Canada or to make it easier for their residents to do so, and more are seriously pressuring the federal government to sanction the method. The issue of drug reimportation has grown increasingly prominent on the national agenda in recent months, as consumer spending on health skyrockets, driven mainly by prescription drug costs, and more and more people turn to alternative sources for discount drugs.

Although the Federal government feels pressure from consumers to do something about prescription drug costs, it is also under intense pressure from the pharmaceutical industry to reject drug reimportation (or any other form of price controls). The pressure from the pharmaceutical industry is backed up with a lot of money; the industry has made approximately $44 million in direct campaign contributions since 1999 (78% of which went to republicans, 22% to democrats), and spent at least $82 million (through their major trade organization PhRMA and other groups) to influence the 2000 and 2002 election campaigns. Apart from their influence in election politics, the pharmaceutical industry employs more than 600 lobbyists in Washington to influence national policymaking.

Up to this point, reimportation remains illegal under federal law; however, no state has yet been officially penalized by federal regulators (beyond a warning letter) for violation of the reimportation ban.
5. Purpose and process analysis

Origins of health policy idea

Bills dealing with prescription drug reimportation were introduced separately into the state legislature by senate president John Burton and Senator Deborah Ortiz, and in the assembly by assemblymen Dario Fromer as part of a broader package of bills dubbed "the affordable prescription drug act of 2004". Legislators Fromer and Ortiz each chair the health subcommittees of their respective houses, and Burton worked extensively with Fromer in a conference committee on the employer health insurance mandate bill (known as SB2, see previous survey "Employer Mandate for Health Insurance"). Through the health care legislation they have sponsored, all three have demonstrated a clear interest in promoting low-cost health care and prescription drugs for all Californians. As California's budget crisis, combined with the new governor's resistance to new taxes has meant deeper and deeper cuts in state health programs, lawmakers have been scrambling for new ways to cut costs and maintain services.

Senior groups, frustrated with the rising cost of prescription drugs, which are not covered by health insurance available to many seniors, have increasingly lobbied for the state to do something to increase access to essential medications. Senior groups have joined consumer and labor organizations in a coalition pushing for the reimportation strategy, and promises to be a vocal supporter of the bills throughout the legislative process.

Stakeholder positions

Stakeholder groups include:

- Health care consumers, particularly seniors and those who receive state health services: A coalition of seniors, labor (notably the California Labor Federation (AFL-CIO)), and consumers has formed behind the reimportation bills. Organizations representing seniors, who are some of the heaviest users of prescription drugs, have been especially vocal in their support of the reimportation bills (including AARP, Congress of California Seniors, California Commission on Aging, California Senior Legislature, Gray Panthers). Though usually suspicious of Democrat-sponsored initiatives, taxpayer watchdog groups have come out in support of this measure. As Spokesman Jerry Flannagan, the foundation for consumer and taxpayer rights put it (although he expressed concerns that the package was a political ploy by Democrats to hold on to seats during this election year) "these are proposals that do have the potential to save money for the state and for patients"

- California's biomedical industry: The biomedical industry has come out strongly against the reimportation of drugs from Canada. The California Health Care Institute, representing pharmaceutical companies, biotechnology companies and academic research institutions asserts that using imperfect price controls imposed by the Canadian government will lower prices now but at the cost of stifling new innovation, and that imported drugs may pose a safety risk to consumers. Members of the industry have a strong lobbying presence in Sacramento, and the industry's size and strength in the state lends weight to their position; California boasts more than 2,500 biomedical companies and 87 universities and private non-profit research organizations, all engaged in biomedical research and development (R&D) in the state. The industry employs 225,000 in the state of California, with an average salary of $64,353. Biotechnology companies in California received $2.5 billion from partnerships with large pharmaceutical companies in 2000, and the state pulled in nearly $2.3 in funding from the National Institutes of Health (NIH) in 2000, more than any other state.

- Large Pharmaceutical Companies ("Big Pharma"): This powerful group strongly opposes reimportation and all forms of price controls on its products. Large pharmaceutical companies have a great deal of influence over national policymaking thanks to millions of dollars spent on campaign contributions, issue advertising and over 600 lobbyists in Washington DC. They will continue to pressure the federal government to block California's plan. Additionally, some companies have also threatened to cut off supply of drugs to Canadian Pharmacies
that sell to American consumers.

- **Health insurance companies and Managed Care Organizations:** Although rising prescription drug costs are clearly a concern for insurance companies, hospitals and managed care companies (large private insurers like Kaiser and Blue Shield have had to cut back their prescription drug benefits considerably recently to remain competitive in some California markets), they have not been particularly vocal in the debate, and when they have spoken out, they have tended to remain neutral. Public comments indicate that while they are interested in cutting costs, they are concerned with the safety and the legality of the reimported medications, and remain unconvinced that the reimported drugs will actually represent a large savings (especially those that have an exclusive deal with a pharmacy benefits manager).

- **State pharmacies and Pharmacy Benefit Managers:** The California board of pharmacy has come out strongly against drug reimportation, citing concerns about consumer safety. It is important to note that California pharmacies have a financial stake in this; they stand to lose revenue if purchasing drugs from Canada becomes common, both from lost business and because they will get fewer rebates from the pharmaceutical companies. The Board of Pharmacy has teamed up with federal regulators to launch a massive public information campaign opposing drug reimportation.

- **The state government, including legislators and the governor:** The state legislature is controlled by Democrats, who are traditionally strong advocates of affordable health care and whose constituents will expect them to support measures that will lower health care costs. The Governor has not yet taken an official stand on the reimportation bills. However, although he expresses concern over rising prescription drug costs, governor Schwarzenegger has expressed concerns over safety and legality issues, implying that he is not inclined to support reimportation in its current form. Given his administration's emphasis on job creation, the governor is likely to be sensitive to pressure from the biomedical industry. Additionally, the administration has tried to cultivate a close relationship with the federal government, and will likely be hesitant to damage that relationship by bringing the state into violation of federal law.

- **The federal government/federal regulators:** The federal government has taken a hard line against drug reimportation, citing concerns about counterfeit drugs and the potential to stifle biomedical innovation. This position is driven in large part by the well-funded lobbying efforts and targeted campaign contributions from the pharmaceutical industry. In California, federal regulators have launched a joint anti-reimportation public information campaign with the California board of pharmacy, and have indicated they will move to block the implementation of the legislation if it is passed.

- **Health Care Providers:** The California Medical Association (CMA), representing California physicians, has come out in favor of the bills. This goes against the American Medical Association (AMA), which has come out against national drug reimportation legislation, citing concerns for patient safety. The CMA is the largest state medical association and a member of AMA.

- **Canadian Pharmacies:** In general, Canadian pharmacies support reimportation, although they are nervous about potential repercussions from pharmaceutical industry or US federal regulators.

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**Influences in policy making and legislation**

As of April 2004, reimportation legislation had been introduced separately in both houses of the state legislature and had been approved by the health committees for each house. The bill must go through several more committees in each house before it is sent it to the floor for a vote. The state assembly committee had not yet ruled. In both houses, the bills must pass through several committees before they are passed to the floor for debate and a vote. Once a bill is passed in one house, it is referred to the other house, where the process is repeated. Differences between the two house versions of a bill are resolved in a joint committee, and the revised bill is returned to the two houses for another vote. Once both sides agree on a version of the legislation, then the bill goes onto the governor. The governor can veto the bill, sign it, or allow it to go into effect without signing it. The governor's veto power can be overridden by a 2/3 vote in both houses. Like most bills, the reimportation bills would go into effect January 1 of the year after they are approved.

Lobbyists are allowed to testify at committee hearings in both houses, can have their position recorded in the official
bill analysis, and can also lobby individual legislators. Because of their lobbying strength, the pharmaceutical and biomedical industry has been notoriously good at blocking bills it opposes. Therefore, while the legislation is still in its very early stages, the fact that it was indeed passed out of committee is a good sign for the bills supporters.

Because the passage of this legislation would bring the state into conflict with federal law, lobbyists may also focus their attention on federal regulators, who could block or limit the bills' implementation.

Legislative outcome

Adoption and implementation

If the legislation is passed as it stands now, the state board of pharmacy would be called upon to develop a method of certifying "safe" Canadian pharmacies, and to create a website to disseminate this information. State agencies would need to revise their purchasing contracts or procedures to include the possibility of using Canadian sources. Four main actors could influence the adoption and implementation of the legislation:

- **Federal regulators:** The federal government currently outlaws the importation of drugs from outside of the FDA's regulatory scope, and any plan for the state to purchase drugs from Canada would have to be cleared through some sort of waiver. Although some other states have implemented limited reimportation schemes without significant federal reprisals, the federal government has taken a hard line against reimportation. The FDA may also impose costly federal regulations on reimported products that offset the benefits of buying foreign medicines.

- **The state board of pharmacy:** The state board of pharmacy has been charged with developing a certification system for "safe" and "unsafe pharmacies. It is worth noting, however, that the board has a strong financial interest in limiting purchases from outside pharmacies, and also has strong ties to the pharmaceutical industry. These conflicts of interest have the potential to bias the foreign pharmacy certification process.

- **State agencies:** In order for reimportation plans to take effect, state agencies must decide it will be to their advantage to buy from Canada, and change their purchasing plans accordingly. Questions of ease of procurement, uncertainty if there will be a consistent and sufficient supply, and concerns about drug safety could all influence the agencies' uptake of the reimported drugs.

- **Pharmaceutical Companies:** Could cut of supply to Canadian pharmacies who do business with Californians, or could cut of sales to Canada altogether, halting the program. Can also pressure federal regulators to crack down on the state.

Implementation will affect consumers, taxpayers, state agencies, the biomedical industry, and California pharmacies, and may ultimately help shape the national debate on the cost of prescription drugs.

Monitoring and evaluation

The state budget process will provide a concrete method of determining how much money purchasing prescription medicines from outside sources is saving the state. Stakeholder groups will likely be monitoring the implementation process closely. However, as yet no integrated monitoring and evaluation method for the proposal has been established.
6. Expected outcome

Based on the growing number of individuals privately purchasing drugs from foreign sources, and the experiences of other states, it is safe to assume that if passed, purchases from Canadian pharmacies would increase. This has the potential to save consumers and the state millions each year. However, health risks from expired, sub-potent, or counterfeit drugs may increase.

Because the population of the state of California alone is larger than that of Canada, Canadian pharmacies would need to negotiate larger purchases from US pharmaceutical companies to deal with increased demand. Pharmaceutical companies such as GlaxoSmithKline, Wyeth and AstraZeneca have already begun limiting shipments to Canadian pharmacies that sell drugs to American consumers, and Pfizer has indicated that they would limit overseas sales to quantities sufficient for domestic consumption in the purchasing country. This could endanger the supply of low-cost drugs for Canada and other countries, including those in the developing world. Thinking more broadly about the economics of global research and development, the high prices US consumers pay in effect “subsidize” R&D for the rest of the world. The industry asserts that if prices go down in the US, the difference must be made up for from somewhere. Opponents respond that the pharmaceutical industry’s profit margins are already higher than any other industry, and that corporations should not put profits before health.

The concerns of the California biomedical industry over the threats to innovation and R&D funding may be somewhat assuaged by a package of state tax incentives aimed at pharmaceutical innovation that is currently working its way through the legislature. If the state passes these bills, industry groups may be more inclined to cooperate on the drug reimportation issue.

The federal government may also take regulatory action against California or Foreign sources supplying the state as they did in the case of the Canadian pharmacy supplying drugs for Springfield, Massachusetts's public employees. They could also begin prosecuting state agencies or large health plans that illegally purchase the drugs from foreign sources. It is also possible that federal regulators will go after individual consumers who engage in the practice, although they have indicated that this is not a priority. As national anger grows over the high cost paid by US consumers for prescription drugs, the stance of the federal government towards reimportation may soften, making it easier for the California reimportation bills to take effect.

On the state government level, because the Governor Schwartzneger will likely have veto power, and has made a close working partnership with the federal government a priority of his administration, the federal government may also be able to encourage the governor to block the passage of the bill. Schwartzneger pro-business and pro-job creation platform also means he will likely be strongly influenced by the lobbying efforts of the powerful biomedical industry.

California is one of the national leaders in biomedical innovation - the state is developing 1/3 of all new medicines for HIV, for example, and receives more federal grants for biomedical research than any other state. Like the rest of the country, the state has an aging population, increasing numbers of uninsured, and faces escalating prescription drug costs. Much of the world's pharmaceutical development occurs in California, however, the high costs of prescription medications sold in the country mean that these drugs are out of reach for many Californians. It is clear that something must be done to solve this problem of access while continuing to support biomedical innovation. Ultimately, the debate over prescription drug reimportation in California will help to shape and drive the national debate over the prohibitively high costs of prescriptions vs. patient safety and the protection of biomedical innovation in the United States and health around the world.

7. References

Sources of Information