2004 SPECIAL REPORT

Colorado Department of Regulatory Agencies
Office of Policy and Research

Importing Prescription Drugs from Foreign Countries: Federal Preemption Prohibits State-Sanctioned Regulation

January 21, 2004

STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES
Office of the Executive Director

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Bill Owens
Governor

January 21, 2004

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado Department of Regulatory Agencies has completed its evaluation of the issues surrounding the importation of pharmaceuticals from foreign countries into Colorado. This report constitutes my office's written analysis of the situation and offers three recommendations for the General Assembly to consider as it debates this issue.

Sincerely,

Richard F. O'Donnell
Executive Director

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Background

Introduction

The Department of Regulatory Agencies (DORA) received a legislative query concerning the need to regulate certain businesses commonly known as "store front pharmacies," or facilitators. In general terms, in exchange for a commission, facilitators help individuals in purchasing prescription drugs from foreign sources, including Canada, Mexico and the United Kingdom. Because importation of prescription drugs is illegal under federal law, Colorado's ability to regulate foreign importers and facilitators is preempted.

While there may be compelling arguments on the relative safety of prescription drugs from foreign pharmacies, under federal law, it remains illegal to import prescription drugs into the United States from any foreign source.[1] That point could not be any clearer. Congress recently affirmed this ban when it opted not to include a provision in the Medicare prescription drug coverage law that would authorize the importation of prescription drugs from Canada. Because of this federal ban, there is very little that Colorado can do regarding this issue that does not contravene federal law.

The Need for Prescription Drug Coverage Drives the Importation of Prescription Drugs

Between 1995 and 2000, annual prescription drug spending in the United States doubled, reaching a total of approximately $122 billion.[2] Between 1998 and 2000, retail drug prices increased at a rate of 9.2 percent per year.[3] In 2001, however, spending increased by 17.1 percent, bringing the average retail price of a prescription in Colorado to $47.99.[4] In that same year, 26 percent of Colorado's senior citizens paid more than $100 per month on prescription drugs.[5]

Increasing spending on prescription drugs accounted for 27 percent of the increase in overall healthcare spending in 2000.[6] Prescription drug spending now accounts for approximately 10 percent of total healthcare spending in the United States.[7]

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[1] The FDA personal-use import policy permits the importation of non-FDA approved prescription drugs by Americans if those prescription drugs are not available in the U.S. and the supply is for ninety days or less.
[2] "Federal Policies Affecting the Cost and Availability of New Pharmaceuticals," by Michael E. Gluck, Ph.D. for the Kaiser Family Foundation (July 2002) at 1.
[3] Id. at 4.
[4] "AARP Colorado Member Opinion Survey: Prescription Drugs," by the American Association of Retired Persons (Dec. 2002) at 1.
[5] Id. at 4.
[6] "Prescription Drug Expenditures in 2001: Another Year of Escalating Costs," a report by the National Institute for Health Care Management Research and Educational Foundation (Revised May 2002) at 2.
[7] Id.

Not surprisingly, these increases have hit the uninsured and the underinsured, including many senior citizens, the hardest. Although the Colorado Division of Insurance does not track the number of uninsured Coloradans, it estimates that between 15 and 18 percent of Coloradans lack health insurance. However, the number of Coloradans lacking prescription drug coverage is likely higher because prescription drug coverage is not a mandatory benefit under Colorado law and until just weeks ago was not provided as part of Medicare under federal law.

The increasing costs of prescription drugs coupled with increasing numbers of people without prescription drug coverage have led some people to seek out more affordable alternatives. For the most part, this has involved purchasing prescription drugs from pharmacies in Canada, Mexico and other nations, where the governments of such nations control the prices of prescription drugs.

Since Canada imposes price controls on prescription drugs, the prices are frequently much less than the price of identical drugs sold in the United States. As a result, a multitude of means has arisen to assist Americans in importing these less expensive prescription drugs from Canada. In some cases, Americans obtain legitimate prescriptions from their U.S.-based physicians and then travel to Canada, where they meet with properly licensed Canadian physicians who rewrite the prescriptions. These prescriptions are then taken to a properly licensed Canadian pharmacy where they are filled, often at a savings of between 20 and 80 percent compared to the cost of the same drug in the United States.

In November 2003, DORA staff compared U.S. prices to Canadian prices for a random sampling of brand name prescription drugs. Generic drugs were not examined in this sampling because generic drugs are typically more expensive in Canada, thus very few Americans purchase them from Canadian pharmacies. While prices for the selected drugs vary from pharmacy to pharmacy, Appendix A demonstrates that overall, Canadian prices are, on average, 43 percent lower than those of the United States.

While some Americans travel to Canada to obtain inexpensive prescription drugs, others interact with Canadian pharmacies through Internet web sites. Some of these pharmacies require a prescription by a U.S. physician, while others do not. Some claim to be located in Canada in order to convey a greater sense of legitimacy and safety, but are actually located in developing nations where the drugs may or may not be what they claim to be. There is little federal and state regulators can do to stop this worldwide Internet flood of activity without a substantial increase in financial resources and cooperation from foreign governments.

Still other consumers get their prescriptions filled with the assistance of facilitators, better known as “store-front operators.” These organizations typically establish a physical presence where an individual can take a legitimate prescription. The organization may require the individual to complete a medical questionnaire. The prescription, medical questionnaire and the payment are then forwarded to a Canadian pharmacy, where the order is filled and the drugs are shipped directly to the U.S. consumer. Facilitator compensation takes the form of a sales commission.

While no one knows how many U.S. citizens utilize one or more of these mechanisms, estimates range from a low of 1 million[8] to a high of 10 million,[9] representing an estimated $700 million worth of prescription drugs each year out of total U.S. sales of $132.4 billion.[10] According to a December 2002 survey of AARP's Colorado members, 36 percent of respondents have either ordered prescription drugs via the Internet or have traveled to Canada or Mexico to fill their prescriptions.[11]

What, then, can or should Colorado do? While the federal ban severely restricts what the states may do, Colorado nevertheless has a direct interest in protecting its citizens. Therefore, this special report summarizes some of the issues and arguments involved in this complicated issue and offers several recommendations as to what Colorado ought to do.

Methodology

In researching this special report, DORA performed a literature search, reviewed Colorado and federal laws, contacted and interviewed interested parties and stakeholders, including, but not limited to, representatives of the pharmaceutical industry, Canadian regulators and professional associations, Colorado professional associations, Colorado pharmacies, owners and operators of various import facilitators, consumer groups, and many others.

Are Foreign Drug Supplies Safe?

Canada as a Case Study

Because the general consensus is that Canada has the regulatory requirements most similar to the Food and Drug Administration (FDA), this review will use Canada as the focus of discussion regarding the safety of foreign sources. If Canada does not pass muster, it is generally assumed that no other country will meet the FDA's certification requirements.

[8] "Judge OKs Shutdown of Canada Drug Firm," *The New York Times* (Nov. 7, 2003). Downloaded from www.nytimes.com/aponline/business/AP-Canada-Drugs.html on Nov. 7, 2003; "Canada Rx Crackdown Not Easy," *CBSNews.com* (Nov. 10, 2003). Downloaded from www.cbsnews.com/stories/2003/11/10/health/printable582643.shtml on Nov. 10, 2003..

[9] "Push for drug reimportation gains steam," by Joel B. Finkelstein, *American Medical News* (Oct. 13, 2003). Downloaded from www.ama-assn.org/amednews/2003/10/13/gvsal1013.htm; "Millions of Americans Look Outside U.S. for Drugs," by Mary Pat Flaherty and Gilbert M. Gaul, *The Washington Post*, Oct. 23, 2003, p. A01.

[10] "Canada is a Discount Pharmacy for Americans," by Gilbert M. Gaul and Mary Pat Flaherty, *The Washington Post*, Oct. 23, 2003, p. A17.

[11] "AARP Colorado Member Opinion Survey," *supra* at 5.

The federal government in Canada, through Health Canada, approves drugs for sale in Canada, just as the FDA does in the United States. While the approval systems in the two countries are not identical, they are similar enough to be considered, more or less, equivalent.[12] This means that drugs approved for use in Canada may be as safe as those that are approved by the FDA for use in the United States.[13]

The Canadian provinces, like U.S. states, are charged with regulating pharmacists and pharmacies. A study prepared by the State of Illinois found that "while there are differences in the details of how the pharmacy profession is regulated, the standards of protecting the public health and safety are substantially equivalent."[14] The same study went on to state:

> The manufacturing, storage, and distribution practices required by Canadian law appear to be as rigorous as those governing the practices of pharmacies in . . . the United States generally.[15]

It is therefore reasonable to conclude that Health Canada-approved prescription drugs are just as safe as FDA-approved prescription drugs. The FDA disagrees given that it has declined to certify the safety of importation and actively fights attempts at commercial importation. Under the Medication Equity and Drug Savings Act of 2000, the Secretary of the U.S. Department of Health & Human Services (HHS) is authorized to certify the safety of foreign prescription drug supplies. Two successive secretaries of HHS—Donna Shalala under President Bill Clinton and Tommy Thompson under President Bush—have declined to issue a certification for Canadian prescription drugs.

The FDA recently examined 1,153 imported prescription drug products with the Bureau of Customs and Border Protection.[16] That examination found that 88% of the prescription drugs examined were unapproved, and many of those prescription drugs could pose "clear safety risks to consumers."[17] Roughly 15.8% of the prescription drugs entered the U.S. from Canada.[18]

Because Colorado does not possess any expertise in certifying the overall safety of prescription drugs, there is no way that Colorado can contradict the position of the FDA and tell its citizens that Canadian and other foreign sources of prescription drugs are safe.

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[12] "Federal Regulation of Pharmaceuticals in the United States and Canada," 21 *Loy.L.A. Int'l & Comp. L.J.* 215, 230 (May 1999).
[13] "Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies," by Ram Kamath, Pharm.D., and Scott McKibbin, *Office of the Special Advocate for Prescription Drugs, Illinois Department of Central Management Services* (Oct. 27, 2003), pp. 2 and 11; "Federal Regulation of Pharmaceuticals in the United States and Canada," 21 *Loy.L.A. Int'l & Comp. L.J.* 215, 230 (May 1999).
[14] Kamath and McKibbin, *supra* at 11.
[15] Id. at 18.
[16] "CanaRX Illegally Supplying Prescription Drugs; Company Violated U.S. Law, Puts Americans at Risk," U.S. Food and Drug Administration, www.fda.gov/bbs/topics/NEWS/2003/NEW00973.html (Nov. 6, 2003).
[17] Id.
[18] Id.

Some assert that the Canadian drug supply is vulnerable to infiltration by counterfeit and adulterated drugs that pose health risks because they could contain dangerous additives or sub or super-potent active ingredients. However, such arguments fail to recognize that the regulated U.S. market is, itself, subject to infiltration by counterfeit and adulterated drugs.

For example, in June of 2002, the Food and Drug Administration issued a drug warning after it was discovered that a large number of adulterated dosages of Procrit had hit the U.S. market.[19] Among other uses, Procrit is an injection drug used to primarily treat anemia associated with chemotherapy.[20] The concentration of active ingredient in the adulterated Procrit had been watered down twenty times lower than expected.[21] Patients had taken dosages of the adulterated Procrit.[22] While a physical reaction may not have occurred in those patients that took the adulterated Procrit, the watered-down dosage did impact the treatment of their illness by potentially rendering treatment up to that point insignificant as compared to a full dosage of Procrit.[23]

Economically, the U.S. prescription drug sales total $132.4 billion as compared to total sales of $6.2 billion in Canada.[24] Opening the enormous U.S. market to any foreign source will provide a secondary legitimate means through which to send counterfeit or adulterated prescription drugs to the United States. This added avenue of access to the U.S. market would inevitably lead to an increase in the number of counterfeit or adulterated prescription drugs entering the United States. Because the federal government already has a difficult time stopping the infiltration of counterfeit and adulterated prescription drugs from entering the U.S., opening the border to Canada will only further taint the U.S. prescription drug supply.

Pharmaceutical companies are also working to limit the amount of counterfeit and adulterated prescription drugs entering the United States. Johnson & Johnson recently announced that it was no longer going to sell prescription drugs to U.S. wholesalers that also bought Johnson & Johnson prescription drugs from other sources.[25] Traditionally, counterfeiters have used these "shadowy" secondary sources to "slip knockoffs into the nation's supply of medical products."[26] Other pharmaceutical companies have followed Johnson & Johnson's lead, including Pfizer and Eli Lilly & Company.[27] As the remaining pharmaceutical companies adopt the same policy, the prevalence of counterfeit and adulterated prescription drugs in the U.S. should decrease. Importation would undermine those actions.

[19] FDA MedWatch at http://www.fda.gov/medwatch/SAFETY/2002/procrit.htm.
[20] Id.
[21] Id.
[22] Id.
[23] Id.
[24] IMS Health at http://open.imshealth.com/download/dec2002pdf*.
[25] "New J&J Policy Aims to Thwart Counterfeits," Scott Hensley, *Wall Street Journal* (Dec. 11, 2003).
[26] Id.
[27] "Pfizer Acts to Halt Counterfeit Drugs, Following J&J," *Wall Street Journal* (Dec. 19, 2003).

In addition, other actions are making it harder to import prescription drugs (including counterfeit and adulterated drugs) to the United States. Pfizer recently toughened its position regarding Canadian drug retailers. Specifically, Pfizer sent a letter on January 12, 2004, advising drug retailers in Canada that they would need to have Pfizer's authorization in order to conduct transactions with the authorized drug wholesalers.[28] Pfizer's authorization is dependent upon those drug retailers promising not to send prescription drugs to U.S. consumers.[29] Similarly, the National Association of Boards of Pharmacy is pushing a plan that would require background checks on individuals applying to be wholesalers and would require a far more detailed chain of custody documentation requirement than exists today.[30]

Market Forces

Several factors account for the increased cost of prescription drugs in the United States. Because the U.S. is a free-market economy, it does not impose price controls. Since many other countries do impose price controls, U.S. consumers are subsidizing the price-controlled consumption of countries like Canada and France. Under U.S. patent law, pharmaceutical companies do not have to fear government-sanctioned disregard for U.S. patents. In other countries, if the pharmaceutical companies resisted price controls by refusing to supply a particular country with prescription drugs, that country would simply ignore the U.S. patents and resort to generic production of the drugs. Hence, pharmaceutical companies typically must relent on prices or risk devaluation of their patents.

In addition, allowing importation from countries that institute price controls undermines the free market in the U.S. and indirectly institutes price controls in the United States. While not nearly as severe as pharmaceutical companies' state, importation also will negatively undermine the financial ability of pharmaceutical companies to invest in the research and development that leads to the life-saving prescription drugs that allow more and more Americans to live longer and healthier lives and avoid hospitalization – and expensive hospital bills – through the pharmacological treatment of disease and illness.[31]

A second factor that contributes to the price differential is the differences in currency. Currently, the Canadian currency provides a very favorable exchange rate for Americans buying products, including prescription drugs, from Canada. Even if other countries did not use price controls, prescription drugs would be cheaper in Canada due solely to the currency imbalance.

[28] "Pfizer Pressures Canadian Sellers of Drugs to U.S.," *Wall Street Journal* (January 14, 2004).
[29] Id.
[30] "Drug Wholesalers Face State Efforts To Tighten Rules," *Wall Street Journal* (January 8, 2004).
[31] While many dispute the true costs, the estimated cost of developing a single new prescription drug range from $801 million to $1.7 billion. "Cost of Developing a New Drug Increases to About $1.7 Billion," by Peter Landers, *Wall Street Journal* (Dec. 8, 2003). Moreover, for the timeframe of 2000-2002, only one out of every thirteen drugs that reach the animal testing level made it to the market, which is a decrease from one out of every eight for the 1995-2000 timeframe. Id.

A third market force that contributes to the price of prescription drugs in the U.S. is that pharmaceutical companies engage in aggressive direct-to-consumer marketing. Most other countries, including Canada, do not permit direct-to-consumer marketing by pharmaceutical companies. In the U.S., such advertising is considered protected under the First Amendment. While exact figures can be hard to verify, few dispute that pharmaceutical companies spend a meaningful amount of money on direct-to-consumer advertising, which does impact the price of prescription drugs.

A final reason for increased prices of prescription drugs in the U.S. is the cost of litigation and the level of litigiousness in the U.S. as compared to other developed countries. In a recent report from The Manhattan Institute's Center for Legal Policy, it was noted that total tort costs annually exceed $200 billion and are expected to exceed $3.6 trillion over the next ten years.[32] These figures exclude the tobacco settlement, most contract and securities litigation, most punitive damages and legal fees generated in non-tort matters.[33] As a comparison, over the last thirty years, while the consumer price index grew 1.1% and the gross domestic product grew 5.0% annually, tort costs grew at an annual rate of 9.1%.[34] After growing at an astonishing rate of 14.4% in 2001, tort costs came in at 13.3% in 2002 and reached $233 billion, which translates into a per person "tax" of $809.[35] This litigation "tax" is passed on to consumers in the form of higher prices.

For example, Wyeth (formerly American Home Products) is presently engaged in the long-running battle over the use of the diet drug combination Fen-Phen. The litigation includes a class action and over seventy thousand individual claims.[36] As of today, Wyeth has reserved $16.6 billion[37] to be used to pay the litigation costs and compensation to those truly injured by the use of Fen-Phen and the far greater number whose injuries are far more tenuous.[38] One doctor is currently being sued under RICO for allegedly falsely certifying Fen-Phen claims when it was discovered that her practice consisted of doing echocardiograms for 25 plaintiff's firms for 12 hours a day, five days a week, which in one eleven month period earned her over $3.2 million.[39]

[32] "Trail Lawyers, Inc.: A Report on the Lawsuit Industry in America 2003," The Manhattan Institute's Center for Legal Policy (2003).
[33] Id.
[34] Id.
[35] "U.S. Tort Costs: 2003 Update: Trends and Findings on the Costs of the U.S. Tort System (Executive Summary)," Tillinghast-Towers Perrin, p.2 (2003).
[36] "Woman asks that award in Fen-Phen case be reduced," *The Sacramento Bee* (Dec. 11, 2003).
[37] "Drugmaker's quarterly earnings mixed," *Philadelphia Inquirer* (Oct. 23, 2003).
[38] "Tough Questions Are Raised On Fen-Phen Compensation," *The New York Times* (Oct. 7, 2003).
[39] "Doctor answers fen-phen lawsuit," Dan Margolies, *The Kansas City Star* (Dec. 5, 2003). In fact, U.S. District Judge Harvey Bartle III, upon reviewing the medical claims, stated that the doctor's practice "resembled a mass production line that would have been the envy of Henry Ford." Id. Judge Bartle also noted that the doctor "never met with the claimants, never reviewed their medical records, and largely relied on the law firms to provide the medical history." "RICO Suit Filed in Fen-Phen Dispute," *The Legal Intelligencer* (Sept. 22, 2003).

While many can debate the extent of the negative impact (such an amount certainly wouldn't be positive or cost-neutral), Wyeth's tort costs on Fen-Phen run in the billions, and negatively undermine its ability to invest in new research and development. As a result, the prices of its other prescription drugs are impacted.

Given the sheer number of lawsuits (legitimate and otherwise) against pharmaceutical companies, it is not surprising that the prices of their products are increasing.

Existing Resources Available to Coloradans

A number of resources are available to Coloradans who lack prescription drug coverage to purchase prescription drugs in the United States. They include both public and private sector programs. Brief descriptions of a few are included here.

Public Sector Resources

Medicare

Congress recently passed a new Medicare prescription drug benefit. On December 8, 2003, President Bush signed the legislation into law. Beginning in mid-2004 and continuing through 2005, Medicare enrollees will be able to purchase, at an estimated cost of $35 per year, prescription drug discount cards, which are expected to save cardholders between 15 and 25 percent off of retail drug prices.[40]

Beginning in 2006, the federal government will subsidize a prescription drug benefit, which will be administered by private insurers. Monthly premiums are anticipated to run approximately $35 per month. After satisfying a $250 annual deductible, the program would pay 75 percent of an enrollee's drug costs up to $2,250 each year. There would be no prescription drug coverage for costs between $2,250 and $3,600, meaning the enrollee would pay all of these costs out-of-pocket. The program would then cover 95 percent of costs exceeding $3,600.[41]

The new program also has special subsidies for low-income enrollees. The monthly premiums, deductibles and coverage gaps will be waived for enrollees with annual income that is less than $12,123 and with less than $6,000 in fluid assets.[42]

Medigap

Medicare beneficiaries may purchase "Medigap" coverage from private insurers. Such policies typically entail premium payments of between $200 and $300 per month. Policyholders then pay 50 percent of the cost of their prescription drug costs. Benefits are capped at either $1,250 or $3,000 per year, depending upon the plan selected. Additionally, Medigap policies may have high annual deductibles.

[40] "Lawmakers ready to pass landmark Medicare legislation," by David Espo, *The Rocky Mountain News* (Nov. 24, 2003), p.21A.
[41] "Details of Medicare bill to provide prescription coverage," *The Rocky Mountain News* (Nov. 25, 2003), p. 23A.
[42] Id.

Under Medicare's new prescription drug benefit, individuals must choose between drug coverage provided by Medicare and that provided by Medigap policies. Medicare enrollees will not be able to obtain supplemental drug coverage to assist with Medicare's coverage gaps if they are enrolled in Medicare's drug program.[43]

Medicaid

Medicaid is a partially federally funded healthcare assistance program administered in Colorado by the Department of Health Care Policy and Financing (HCPF). Depending upon the level of Medicaid benefits awarded, Medicaid may provide prescription drug benefits either free of charge or at steeply discounted rates. For example, a beneficiary may be required to pay a co-payment of $0.75 for generic prescription drugs or $3.00 for brand name prescription drugs.[44]

Eligibility is generally based on income and assets. In very general terms, full Medicaid benefits may be awarded if income is less than between $500 and $600 per month and assets held, excluding a primary residence and certain life insurance policies, amount to less than $2,000 or $3,000.[45]

Private Sector Resources

In addition to the above resources, private sector resources have been created to assist citizens in their search for affordable prescription drugs.

Rx Assist

Operated from St. Anthony's Hospital, Rx Assist is a free telephone counseling service that helps individuals determine whether they qualify for programs that offer lower priced or free prescription drugs. Rx Assist was created in cooperation with Saint Anthony's Hospital, Rose Community Foundation, Health One Alliance and the Denver Regional Council of Governments.

The role of this program is valuable to Colorado because the success of the Rx Assist mission may impact hospital admissions. Although empirical evidence is lacking, some healthcare professionals estimate that approximately 30 percent of hospital admissions occur because of individuals not taking medications properly, including not taking prescribed drugs. Nonetheless, it is reasonable to conclude that this program should have some positive impact on medication non-compliance.

[43] "New Medicare Bill Bars Extra Insurance for Drugs," by Robert Pear, *The New York Times* (Dec. 7, 2003).
[44] As downloaded from www.chcpf.state.co.us/MedicaidEligibility/brochure.htm on Nov. 24, 2003.
[45] As downloaded from www.chcpf.state.co.us/MedicaidEligibility/EligibilityChart.htm on Nov. 24, 2003.

In addition to connecting patients with affordable prescription drugs, Rx Assist helps patients deal with the often-cumbersome bureaucracy of the pharmaceutical industry. Many programs sponsored by pharmacy companies can be complex and paperwork intensive. Further, participants found that pharmaceutical companies change forms without notice and reject old forms without communication to the participant. The personal assistance provided by Rx Assist staff enables patients to successfully acquire needed prescription drugs.

Various Programs Sponsored by Individual Pharmaceuticals Manufacturers

Most pharmaceutical manufacturers have plans to assist the poor and indigent in obtaining prescription drugs. Although qualifications vary from manufacturer to manufacturer, in general, individuals must have income less than 200 percent of the federal poverty level (FPL). In 2003, the FPL for a single individual was $8,980 per year, and $12,120 for a couple.[46] Depending upon the manufacturer and the patient's particular set of circumstances, the drugs may be sold to the patient at a discount or provided free of charge.

Complications with these programs involve varying qualifications, considerable amounts of paperwork and the requirement that the patient know which manufacturer makes a particular drug so that the patient can apply to the proper manufacturer. This is particularly troublesome for patients on multiple medications. Additionally, some manufacturers require the prescribing physician to be more involved in the process than others. Such involvement may include completing forms and physically receiving the drugs for distribution to the patient.

Together Rx

Partially in response to the problems inherent in the programs sponsored by individual pharmaceutical manufacturers, eight such manufacturers, together with the Pharmaceutical Research and Manufacturers Association, developed the Together Rx plan.

The Together Rx's Internet web page claims to have saved more than one million senior citizens more than $228 million[47] by offering discounts of between 20 and 40 percent off retail[48] on approximately 181 different drugs.[49]

Unfortunately, Together Rx is only available to individuals who are enrolled in Medicare, have an annual income of less than $28,000 for singles or $38,000 for couples, and who lack prescription drug coverage (both public and private).[50] Additionally, discounts apply only to the drugs manufactured by the eight manufacturers participating in the program and the level of discount varies by drug and pharmacy. There is no cost to the consumer to join the Together Rx program.

[46] 68 Fed. Reg. 6456-6458 (2003).
[47] As downloaded from www.togetherrx.com on Nov. 20, 2003.
[48] As downloaded from www.togetherrx.com/about.html on Nov. 20, 2003.
[49] As downloaded from www.togetherrx.com/druglist.html on Nov. 20, 2003.
[50] As downloaded from www.togetherrx.com/about.html on Nov. 20, 2003.

State and Local Government Action

Given that it is impossible to separate the political from the prudent, it is naïve to believe that many state and local actions to import prescription drugs do not involve the political calculation that senior citizens vote and want less expensive drugs, or that budget shortfalls can be made up by importing less-expensive prescription drugs. Unless a state or local government possesses the resources and expertise to certify the safety of imported prescription drugs to the same degree that the FDA certifies the U.S. pharmaceutical drug supply, any attempt to import prescription drugs is fraught with potential liability.[51]

For example, any state or local government that violates a mandatory directive of federal law loses all immunity for claims arising under that action.[52] As a result, that government entity is liable for all damages.[53]

While Colorado fully supports the concept of federalism, the federal government has wholly pre-empted the regulation of the pharmaceutical drug industry. Equally important is the exclusive role the federal government plays in international trade issues. Simply because a state or local government dislikes the federal government's position on a particular issue does not permit that government entity to ignore the law. Such selective respect for the rule of law by state and local governments undermines that acting government's own legitimacy at enforcing its own laws.

For example, other than respect for the rule of law, what stops a county or city government in Illinois from deciding that certain Illinois state laws are not worthy of being followed? Do government entities really want to create an environment in which each government entity gets to pick and choose which laws it wants to respect and which laws it wants to ignore? After all, if access to cheaper prescription drugs justifies disregarding the rule of law, than so should countless other items, including access to cheaper medical care, access to cheaper food, access to cheaper shelter, access to cheaper clothing and the list goes on and on.

Regardless, despite attempts to reap political or financial gain from importing prescription drugs from Canada, state and local governments are facing increasing practical difficulties in starting such programs. Recently, the Canadian International Pharmacy Association, the largest representative of Canadian pharmacy importers, announced that its twenty-seven members would not provide prescription drugs for state and local government programs.[54]

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[51] States and local governments that engage in the importation of prescription drugs could face private legal actions if imported prescription drugs harm consumers. "States to Help Citizens Import Canadian Drugs," *Wall Street Journal* (Dec. 18, 2003).

[52] "The Granite State May Be In For Expensive Litigation," Jeffrey Axelrod, *The Weirs Times* (January 8, 2004).

[53] Id.

[54] "Canada Cools to U.S. Drug Flow," *Wall Street Journal* (Dec. 26, 2003).

Even more ominous is the upcoming decision by the Canadian Medical Protective Association—the entity that provides malpractice insurance to Canadian doctors—to decline coverage for doctors who are sued over Internet prescription drug transactions in Canada.[55] The ban already applies to U.S.-based lawsuits.[56] Hence, Canadian doctors who rewrite U.S. prescriptions will be unable to procure malpractice insurance, which is a key requirement of many Canadian provinces for a doctor to be licensed.[57]

With increasing pressure being brought by the federal government, the likelihood of state or local action becomes more perilous.

Noted below are brief discussions of a few of state and local government plans.

Maine

Enacted in 2000, the Maine Rx program provides discounted prescription drugs to those that enroll. Under the program, Maine negotiated rebates and other discounts with drug manufacturers to fund the reduced price for drugs offered to the program's participants. If a drug manufacturer does not enter into a rebate agreement with the state, that manufacturer's Medicaid sales are subject to a prior authorization procedure.

Thus, Maine is experimenting with a way in which to provide affordable prescription drugs to its citizens without resorting to foreign pharmacies.

Illinois

In October 2003, the governor of Illinois requested that the Food and Drug Administration (FDA) grant Illinois the legal ability to purchase prescription drugs for its state employees and retirees from select Canadian pharmacies. In making this request, Illinois prepared an 85-page report outlining the safeguards the state was proposing, a finding that Canadian pharmaceuticals and pharmacies were safe, and the estimated cost savings to the State of Illinois.[58]

On November 6, 2003, the FDA denied Illinois' request.

Springfield, Massachusetts

Unlike the State of Illinois, the City of Springfield, Massachusetts, did not seek FDA approval to obtain prescription drugs for its employees and retirees from Canadian pharmacies. Rather, it established a relationship with a Canadian pharmacy and offered the plan to its approximately 9,000 employees and retirees. The FDA is planning to shut down the operation.[59]

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[55] "Insurer won't cover doctors for Net drug lawsuits," *Winnipeg Free Press* (January 6, 2004).
[56] Id.
[57] Id.
[58] Kamath and McKibbin, *supra*.
[59] "Boston to defy rules on drug imports," *Financial Times* (Dec. 10, 2003).

Analysis and Recommendations

In exploring whether and what Colorado can or should do regarding the importation of prescription drugs from foreign sources, several options presented themselves. However, for the reasons discussed below, the Department of Regulatory Agencies (DORA) concludes that the recommendations made herein represent the best course of action for Colorado consumers.

In conducting this review, Colorado's statutory sunrise criteria have been applied as well as an analytical benchmark. While this review is not a statutorily mandated sunrise review, in creating the sunrise criteria, the General Assembly created a meaningful and appropriate guide for determining whether the government should distort the market through regulation.

First and foremost, it is imperative to remember that, with limited exceptions, federal law prohibits the importation of drugs into the United States. That the Food and Drug Administration (FDA) has thus far adhered to a strategy of selective enforcement is irrelevant. Anything that Colorado or any other governmental entity does in contravention of this federal law demonstrates disregard for the rule of law, a fundamental premise upon which the American legal and social systems are based. In all likelihood, such action would eventually result in expensive court battles between the federal and state or local governments.

Secondly, one of the primary roles of government is to protect the health, safety and welfare of the people. While claims that the Canadian drug supply is awash with counterfeit drugs may be exaggerated, the fact remains that counterfeit drugs do enter foreign markets, just as they enter the U.S. market. The difference is that in the United States, the FDA and pharmaceutical companies can be pressured by the American people and the U.S. government to focus their inspection and enforcement efforts on reducing the amount of counterfeit drugs circulating in the U.S. market. The American people and the U.S. government, however, have limited power to influence the policy directions of other countries. In other words, the U.S. has no control over whether and how many counterfeit drugs enter foreign systems, which may ultimately end up in the hands of U.S. consumers.

In conducting the research for this report, very few parties suggested that Colorado follow the examples established by Springfield, Massachusetts or the State of Illinois. However, some have suggested that Colorado regulate foreign pharmacies that export into Colorado, regulate the storefront facilitators that operate in Colorado, or criminalize, under state law, the importation of prescription drugs from abroad. This section analyzes the various regulatory options.

Create a Registration Requirement for Foreign Pharmacies and Facilitators

Currently, Colorado law requires U.S.-based pharmacies located outside of Colorado that ship drugs to consumers in Colorado to register with the Colorado Board of Pharmacy (Pharmacy Board). [60] But for references in this law to the "state" in which the pharmacy is licensed, located, or both, this statutory provision could provide the grounds for the Pharmacy Board to register foreign pharmacies that export into Colorado. To include foreign pharmacies in this requirement would require a simple statutory change, replacing "state" with "jurisdiction."

However, this, too, could create more problems than it would solve. Registering foreign pharmacies in Colorado would be an explicit attempt to assist consumers in violating the federal ban on imports. It would also send a conflicting message to Coloradans – under federal law it is illegal to import drugs from foreign countries, but the State of Colorado regulates foreign pharmacies that export drugs into Colorado. This would give foreign Internet or mail order pharmacies an air of legitimacy.

Additionally, it would be difficult, if not impossible, as a practical matter, for the Pharmacy Board to regulate and discipline a foreign-licensed pharmacy. If the foreign pharmacy chose to ignore disciplinary action, the Pharmacy Board lacks the resources to go into a foreign court to enforce any such order. For example, none of the Assistant Attorney Generals assigned to DORA are licensed to practice law in Canada. Other jurisdictional hurdles exist such as the force of law that a Colorado action would have in Canada and the ability of consumers to seek redress against foreign entities.

A more complicated matter is that of the foreign pharmacy that refuses to register with the Pharmacy Board. How could the Pharmacy Board enforce an injunction against a foreign pharmacy when the Pharmacy Board does not even know where that pharmacy is physically located? The Internet affords mail order pharmacies the luxury of anonymity. Additionally, the number of Internet pharmacies is almost impossible to discern. Thus, a requirement that foreign pharmacies register with the Pharmacy Board would impose upon the Pharmacy Board a regulatory task that would be impossible to enforce.

For the very same reasons noted above, giving the Pharmacy Board cease and desist power would not solve this problem. Instead, it would result in the Pharmacy Board being mired down with complaints by competitors to shut down importers and facilitators at the expense of time spent monitoring those pharmacies currently regulated by the Pharmacy Board. Without jurisdiction over those entities and without a substantial increase in resources to try to enforce cease and desist orders in a foreign country, the power would constitute a classic case of all bark and no bite. Moreover, given that the Attorney General's Office already possesses adequate resources under the Colorado Consumer Protection Act to pursue cases, adding another layer of regulatory power is simply not justified.

[60] § 12-22-130(1)(b), C.R.S.

Furthermore, if Colorado regulated foreign pharmacies at all, then foreign pharmacies that are not properly registered with the Pharmacy Board could easily claim to the public, via their websites, for example, that they were properly registered, thus creating a false sense of security on the part of the Colorado consumer. Such pharmacies could easily sell counterfeit or adulterated drugs to Coloradans under the false color of law. In other words, by providing a registration system intended to protect Coloradans, Colorado would open the door to bad actors fraudulently using the existence of a regulatory system as a means to lure senior citizens into using their bogus sites. Today, since no foreign pharmacy can be licensed, it is easy for consumers to be made aware that all foreign pharmacies are unlicensed. Hence, regulation could actually be used to inflict great harm, both physically and financially, on Coloradans.

As far as facilitators or storefront operators are concerned, those entities willfully flout federal law and the regulation of them is entirely inconsistent with the federal ban. While philosophical and political opposition to a law is a hallmark of our country, commercially profiting from violating the law is not.[61] Failing to have one's view prevail through the political process does not therefore endow that person with a commercial license to ignore the law—no matter how "noble" their alleged reasoning may be.

Importantly, facilitators go take great lengths to claim that they are not pharmacies so as to evade the existing regulatory requirements of U.S.-based pharmacies. If it were found that facilitators are pharmacies, then they would be subject to the same legal requirements as Colorado pharmacies, including the requirements prohibiting importation under federal law.

Nevertheless, eight or so facilitators are now conducting business in Colorado in contravention of federal law. The FDA recently secured a court injunction against Rx Depot, one of the larger facilitators of Canadian importation.[62] The legal underpinnings of that injunction would apply with equal force to Colorado facilitators.

Create Criminal Penalties in Colorado Law

At the other end of the spectrum of possible options is the criminalization, at the state level, of foreign pharmacies that export into Colorado, of the storefront facilitators that assist them, or both. The primary idea here is to make it a felony for any person to assist another person to import prescription drugs into Colorado from another country. This would seem to necessitate making it a felony under state law to actually import such drugs, for how could it be a felony to facilitate an otherwise legal act? Therefore, the law may have to render both the Colorado consumer and the storefront facilitators guilty of felonies.

[61] Commercial exploitation of the arbitrage between U.S. and Canadian prescription drug prices is not the type of civil disobedience used during the Civil Rights Movement to effectuate political and societal change.

[62] U.S. v. Rx Depot, Inc., Case No. 03-CV-0616-EA(M) (N.D. Okla. November 6, 2003).

If such a state law referred to the federal ban on imports, it may constitute an unlawful delegation of legislative authority. While this doctrine is typically invoked downwards, i.e., from the General Assembly to a state agency, the logic holds that it can also be invoked upwards, i.e., from the General Assembly to the U.S. Congress. The theory upon which this doctrine rests holds that the state legislature cannot delegate to another body what the law of Colorado shall be. For example, the General Assembly cannot impose a code of ethics upon a profession simply by adopting by reference the code of ethics of a professional association. This is because the professional association could change its code of ethics, and thus change Colorado law without General Assembly action. This is not permissible.

Given the present situation, the federal government regulates prescription drugs and currently prohibits the importation of prescription drugs. The wisdom of this prohibition is not for Colorado to decide, it is the federal government's. If the General Assembly were simply to pass a law stating that it is felony under Colorado law to facilitate the violation of the federal statute, what would happen if the U.S. Congress repeals the ban? Logic holds that this is the same type of unlawful delegation of legislative authority.

If the above analysis were correct, then the General Assembly would have to make it a felony under state law to import drugs from another country. This would be a difficult mandate to enforce. The state's courts are already overburdened and it does not seem likely that the state's district attorneys would prosecute cases against senior citizens for importing affordable prescription drugs unless and until someone is harmed.

But why should Colorado pass laws that so closely mirror federal laws? Does not such action resemble an indirect unfunded mandate? The federal government has a ban in place that, for one reason or another, is not being aggressively enforced. Why should Colorado pass a law enabling the state to, in essence, enforce the federal ban if the federal government does not see fit to aggressively enforce it? Presumably, the federal ban was enacted to protect Americans. Through failing to aggressively enforce the ban, the federal government has, in essence, shifted the burden of enforcement to the states. Without funds to enforce such laws, it becomes an unfunded mandate.

The federal government, not the states, is in the ideal position to address this issue. The importation of prescription drugs into the U.S. involves issues of international trade and macroeconomics that directly impact the nation's healthcare delivery system. Healthcare costs are rising across the board, in Colorado and across the nation. Any attempt by Colorado to address one segment of the system will, likely, have little real effect. Only a comprehensive approach to the issue of healthcare will help to resolve the motivation to resort to foreign pharmacies.

In fact, both the FDA and the Speaker of the House Dennis Hastert have heightened their rhetoric recently to address this issue.[63] Speaker Hastert urged the U.S. to make changes that would force Canada to discontinue the use of price controls.[64] FDA Commissioner Mark McClellan, on a trip to Ottawa, told reporters that countries that used price controls were not paying their fair share of pharmaceutical drug research and development.[65] As the pressure continues to mount at the federal level, Congress and the President may have to take affirmative steps to end the use of price controls by other countries or permit importation.

In the end, the importation of prescription drugs from foreign pharmacies is a federal issue that must be addressed by the federal government. And, indeed, the U.S. Congress this year debated, voted on and chose keep the ban on the importation of prescription drugs from Canada. However, because the FDA has thus far refused to aggressively enforce the federal ban, the several states, including Colorado, must protect their citizens and offer those citizens an avenue for addressing legitimate complaints when they are harmed. With this in mind, DORA proposes implementation of the recommendations that follow.

Recommendation 1 – DORA should forward all complaints it receives regarding prescription drugs dispensed by a foreign pharmacy and facilitator to the Colorado Attorney General's Office, the appropriate federal authorities in the United States, and to the licensing authority for the jurisdiction in which that pharmacy is located.

For reasons discussed above, there is very little, if any, direct action that the Pharmacy Board can take to halt the importation of prescription drugs from abroad. However, that is not to say that there is nothing DORA can do to assist Coloradans who are harmed by imported prescription drugs.

Since DORA is the state agency most people would contact in the event they received adulterated, sub or super-potent prescription drugs, it seems only logical for DORA to take the lead in assisting such people. Toward this end, DORA should forward complaints it receives that involve foreign pharmacies and facilitators to the FDA, the U.S. Attorney, or both, as well as to the licensing authority for the jurisdiction in which the foreign pharmacy is located.

Additionally, DORA should forward complaints involving consumer harm as a result of imported prescription drugs to the Colorado Attorney General's Office (AGO). Certain provisions of the Colorado Consumer Protection Act (CCPA), which the AGO is charged with enforcing, are applicable to such cases as discussed below, and so, the AGO should pursue such cases vigorously.

[63] "Canada Cools to U.S. Drug Flow," *Wall Street Journal* (Dec. 26, 2003).
[64] Id.
[65] Id.

In this manner, DORA and Colorado consumers can help to alert government officials, regardless of nationality, of problem pharmacies so that proper measures can be taken to rectify any such problems.

Recommendation 2 – In cases of harm to a consumer in Colorado caused by a prescription drug dispensed by a foreign pharmacy and facilitator, the Colorardo Attorney General should pursue all remedies available under the Colorado Consumer Protection Act.

In addition to pursuing complaints referred by DORA, the AGO should also accept complaints directly from consumers involving imported prescription drugs and pursue such cases, as may be appropriate, under the CCPA. The CCPA is intentionally broad so that the AGO can adequately protect consumers on a variety of issues and on a variety of activities.

Under the CCPA, the AGO is authorized to seek redress in situations in which fraudulent or misleading statements have been made.[66] If an importer or facilitator claimed that importation was legal and sent a prescription drug to a Coloradan that was counterfeit, adulterated, in incorrect dosage or otherwise not proper, certainly that importer or facilitator would be subject to the reach of the CCPA. For example, the AGO recently filed a lawsuit against Invesco mutual fund company based upon false representations as to the characteristics, uses and benefits of its goods and services and for failure to disclose material information concerning its goods and services.[67] Because prescription drugs are sent with a label and medical data, all statements made on those documents would subject the violator to jurisdiction under the CCPA.

The civil penalties and damages provisions of the CCPA are formidable. They should be utilized, to the greatest extent possible, against those who cause harm to Coloradans by way of adulterated prescription drugs, regardless of the origin of those drugs.

Recommendation 3 – DORA should develop and launch an educational campaign to inform Coloradans on how to safely and legally purchase Internet and mail-order prescription drugs.

It is important for a state entity charged with regulating the profession and outlets that dispense prescription drugs to inform citizens that importing prescription drugs from foreign sources is illegal. Additionally, buying prescription drugs from an Internet site or mail order entity may contain additional risks not present at a brick and mortar establishment licensed by state regulators.

[66] C.R.S. 6-1-105 *et seq*.
[67] State of Colorado v. Invesco Funds Group, Inc., 03-CV-9199 (Dec. 2, 2003).

In reality, however, Coloradans will very likely continue to buy prescription drugs using Internet and mail order entities from within the U.S. and from outside of the U.S. Since the sole purpose of state regulation of pharmacies and pharmacists is to protect the public, DORA should undertake to educate Coloradans as to how to legally purchase prescription drugs over the Internet or by mail in a manner that is as safe as possible. It is imperative that this educational campaign also acknowledges that there is no way to guaranty the safety of any prescription drug purchased over the Internet or by mail from a foreign country.

At a minimum, individuals purchasing prescription drugs over the Internet or by mail order should ensure that the following criteria are met by the entity. Given that most Internet or mail order transactions will be finalized by use of a credit card, consumers should take extra precautions to make sure that the entity they are dealing with is legitimate.

Individuals should first identify the pharmacy filling the prescription by physical address and license number;

Individuals should verify with the pharmacy's local authorities that the pharmacy is duly licensed in that jurisdiction;

Individuals should only purchase prescription drugs from pharmacies that require a prescription from the patient's physician and verify with the physician that the prescription is legitimate;

Individuals should only purchase prescription drugs from pharmacies that obtain a detailed medical history of the individual and allow the individual access to the actual pharmacist filling the prescription for the purpose of medication counseling and drug information;

Individuals should only purchase prescription drugs from pharmacies that properly label medications including the name of the patient, the name of the pharmacy, the name of the physician, the name of the medication, the strength of the medication, the directions for use, the amount of medication dispensed and remaining quantity and the date the medication was dispensed;

Individuals should only purchase prescription drugs from pharmacies located in jurisdictions that provide the individual with the same legal rights they possess in Colorado;

Individuals should only purchase prescription drugs from pharmacies that retain a detailed chain of custody for the prescription drugs they stock;

Individuals should only purchase prescription drugs from pharmacies that do not sell narcotics or other medications that require special handling like refrigeration;

Individuals should only purchase prescription drugs from pharmacies that have a registered agent in Colorado so that consumers can easily serve legal actions on those entities;

Individuals should only purchase prescription drugs from pharmacies that are registered with the Colorado Board of Pharmacy;

Individuals should only purchase prescription drugs from pharmacies that sell prescription drugs approved by the FDA;

Individuals should only purchase prescription drugs from pharmacies that have a licensed pharmacist as the pharmacist of record; and

Individuals should only purchase prescription drugs from pharmacies that provide detailed directions and medical information similar to what individuals receive from Colorado brick and mortar pharmacies.

Appendix A - U.S. – Canadian Price Comparisons for Brand Name Prescription Drugs

Drug	Dosage	Number of Tablets	U.S.	Canadian	Difference	Percentage Saved
Advair	50 mcg	60	$214.99	$127.55	$87	41%
Allegra	D	30	$42.99	$14.86	$28	65%
Amaryl	1mg	60	$23.99	$49.64	-$26	-107%
Antivert	25mg	100	$70.99	$35.18	$36	50%
Cardizem	90mg	100	$116.99	$63.60	$53	46%
Celebrex	100mg	60	$94.99	$41.82	$53	56%
Cipro	750mg	20	$119.99	$89.64	$30	25%
Claritin	10mg	100	$319.97	$72.41	$248	77%
Clarinex	5mg	30	$70.99	$38.11	$33	46%
Flomax	0.4mg	60	$121.99	$56.07	$66	54%
Flonase	0.05%	120	$64.99	$31.25	$34	52%
Imitrex	20mg	6	$160.00	$129.57	$30	19%
Lipitor	20mg	30	$95.99	$56.66	$39	41%
Luvox	50mg	30	$94.99	$27.37	$68	71%
Mavik	1mg	60	$66.99	$50.87	$16	24%
Monistat	400mg	3	$44.99	$25.42	$20	43%
Naprosyn	250mg	100	$96.99	$51.04	$46	47%
Nexium	40mg	30	$119.99	$66.74	$53	44%
Ortho Tri-Cyclen		28	$34.99	$15.27	$20	56%
Paxil	20mg	30	$86.99	$49.80	$37	43%
Procardia	30mg	30	$40.99	$29.94	$11	27%
Propecia	1mg	30	$50.99	$36.98	$14	27%
Prevacid	15mg	30	$125.99	$55.43	$71	56%
Prozac	20mg	30	$95.99	$51.34	$45	47%
Requip	2mg	100	$136.99	$119.04	$18	13%
Retin-A	0.10%	15gm	$41.99	$19.85	$22	53%
Robaxin	50mg	60	$57.99	$37.42	$21	35%
Sansert s	2mg	60	$173.99	$46.28	$128	73%
Sectral	200mg	60	$105.69	$32.06	$74	70%
Tambocor	100mg	100	$290.99	$110.64	$180	62%
Tamoxifen	10mg	60	$59.99	$20.49	$40	66%
Vioxx	12.5mg	30	$85.99	$36.20	$50	58%
Zantac	150mg	60	$109.99	$75.16	$35	32%
Zestril	5mg	60	$73.99	$38.52	$35	48%
Zocor	10mg	30	$65.99	$51.18	$15	22%
Zyrtec	5mg	30	$61.99	$27.37	$35	56%
Averages			$101.23	$52.24		43%

Source: Data downloaded from www.rxdiscountguides.com on November 26, 2003. Canadian prices used in this comparison constitute the lowest available Canadian price.

Appendix B - Major Contacts Made In the Course of the 2004 Special Report Concerning Importing Prescription Drugs from Foreign Sources

AARP
Canadian pharmacy and pharmacist regulators
Canadian Internet pharmacies that exports to Colorado
Colorado Attorney General's Office
Colorado Department of Health Care Policy and Financing
Colorado Department of Public Health and Environment
Colorado District Attorneys Council
Colorado Division of Insurance
Colorado Medical Society
Colorado Pharmacists Society
Consumer Advocates
Denver/Boulder Better Business Bureau
Denver District Attorney's Office
Colorado Office of Legislative Legal Services
Pharmaceutical Research and Manufacturers of America
Representatives from several health insurance carriers
Representatives from several pharmaceutical manufacturers
Representatives from several store front facilitators
Rx Assist
St. Anthony's Hospital
State Long-Term Care Ombudsmen
U.S. Attorney's Office