

STATEMENT OF JOHN M. RECTOR
BEFORE THE HOUSE COMMITTEE ON GOVERNMENT REFORM

March 18, 2004

Mr. Chairman, Members of the Committee

I am John M. Rector. I serve as Senior Vice Present of Government Affairs and General Counsel for the National Community Pharmacists Association (NCPA), formerly the National Association of Retail Druggists.

I want to thank you for inviting us to testify on the Internet Pharmacy Consumer Protection Act, H.R.3880.

The National Community Pharmacists Association (NCPA), founded in 1898, represents the professional and proprietary interests of the nation's community pharmacists, including the owners of 25,000 pharmacies. Independent pharmacists serve 18 million persons daily. NCPA has long been acknowledged as the sole advocate for this vital component of the free enterprise system. For decades we have been the only national pharmacy association with universal state association membership, including those of the Committee's members.

Our members function in the market in a variety of forms. They do business as single stores ranging from apothecaries to full line high volume pharmacies; as multiple location entities (e.g. 100 pharmacies) and as franchises such as the 1200 pharmacies involved with the Medicine Shoppes franchise. Whatever the form of business entity, however, independent pharmacists are the decision makers for this wide variety of NCPA member companies.

As owners, managers and employees of independent pharmacies, our members are committed to legislative and regulatory initiatives designed to protect the public and to provide the pharmacist a level playing field and a fair chance to compete. We appreciate the opportunity to assist the Committee in assessing the regulation of Internet pharmacies and pharmacists.

First and foremost we are guided by the premise, universally upheld by the federal courts, that the regulation of the practice of pharmacy by pharmacists and other learned professions rests exclusively with the respective states. This authority includes the registration of a pharmacist to practice pharmacy. In recent years the agencies delegated to exercise the state authority, typically the State Board of Pharmacy, appointed by the Governor, have struggled to provide consumers' equitable protection when pharmacy is practiced interstate via the US mail or by private mail order companies.

NCPA sees Internet pharmacy as a possible vehicle for good patient education and care if the proper safeguards are in place. However, if controls are not in place or not enforced these enterprises create serious problems. Consequently, the Internet pharmacies raise major issues and concerns for those trying to assure the quality and care that patients have a right to expect.

In our view the core concept that must be kept in mind is that Internet pharmacy is unregulated mail order pharmacy. While the ordering process may be different from the typical mail order scheme, the professional, regulatory, and shipping aspects are the same. Therefore, NCPA's long-standing position on unregulated mail order is relevant. NCPA's March 2004 Statement of Positions states:

Internet Pharmacies

NCPA encourages the equitable application of existing authority to level the playing field with regard to regulating interstate, Internet, and mail order pharmacy as they relate to patient safety and care. NCPA reaffirms its position that the states already have the *sole* authority to license and register pharmacies and pharmacists who practice pharmacy in the consumer's state.

Unregulated Mail Order Drug Programs

Mail order drug programs represent a serious threat to public health. It is not possible for mail order drug vendors, which lack face-to-face contact with patients, to comprehensively monitor their patients' health status, gather information on the full spectrum of their prescription and nonprescription drug use patterns, or adequately assess their understanding and compliance with drug therapy.

NCPA questions the integrity of a drug distribution system that relies exclusively on the mails and in which drugs are dispensed in excessive volume, over long distances, often exposed to extreme temperatures or humidity, delayed, and otherwise compromised. NCPA supports legislative and regulatory actions that apply professional and consumer protection standards to mail order vendors, and urges appropriate officials to investigate the practice and subject mail order drug vendors to appropriate state and federal consumer protection laws, including state pharmacy practice acts.

NCPA urges the National Association of Boards of Pharmacy and its member state boards of pharmacy to adopt parallel equitable protection for patients who are presently exposed to mail order pharmacists and pharmacies unregulated in their states.

The association further supports the elimination of any federal prescription drug coverage favoring mail order pharmacy, and asserts that the government should require companies providing drugs to federal employees to abide by the laws of the states of the beneficiaries receiving the drugs. In addition, the association supports the enactment of legislation and appropriate regulations designating all prescription drugs as poisons or dangerous substances, thus prohibiting the mailing of such substances, via either the

postal service or private carriers, to consumers, as is currently the case with other dangerous substances.

NCPA has developed model legislation for states to use in their efforts to regulate out-of-state mail order pharmacies and pharmacists.

The integrity of the current drug distribution system is being undermined by foreign, unregulated mail order pharmacies and pharmacists; by the acquisition and distribution of prescription drugs without a prescription via the Internet and U.S. Postal Service; and by the gross abuse of “personal use” exemptions for prescription drugs at our borders.

Therefore, the White House should develop a comprehensive, coordinated multi-agency action plan to protect the health and safety of Americans, and to prevent further erosion of the U.S. prescription drug distribution system, including the prosecution of those operating unregulated mail order companies, those selling prescription drugs without a prescription on the Internet, and those abusing personal use exemptions as a guise to import unapproved and misbranded prescription drugs.

It is noteworthy that “pharmacies” do not practice pharmacy and it is the conduct of pharmacists who elect to dispense in a resident patient’s state that must be addressed.

Another way of approaching this issue is to ask: “Why should the resident pharmacist abide by the laws and regulations of the resident patient’s state if the non-resident pharmacist, in competition with them, is permitted to violate such laws and regulations, including practicing without a resident state’s pharmacist license?”

The advent of mail order pharmacy marketed via the Internet has only served to further challenge state efforts to equitably protect consumers. There are opportunities to help control illegal interstate activities by Internet pharmacies and pharmacists while fully respecting the exclusive authority of the states to regulate the practice of pharmacy.

NCPA enthusiastically endorses H.R.3880. Requiring the internet pharmacy website to display information regarding the business, the physicians and the pharmacists associated with it, as well as the licensure of physicians and pharmacists could enhance collaboration between federal and state authorities. Further, such disclosure would assist inquiring consumers in making a better informed decision about whether or not to utilize the internet pharmacy.

Requiring a patient to actually be examined by the prescribing physician is essential to assuring the appropriate care for the patient and will facilitate compliance with the patient's state laws regulating physicians who prescribe and pharmacists who dispense prescription drugs to the patient.

Providing the states with new enforcement authority similar to the Federal Telemarketing Sales Act, permitting state Attorneys General access to federal injunctive relief to enforce state laws regulating the licensure of resident and non-resident pharmacies and pharmacists, will in our view especially assist efforts to curb the illegitimate online conduct of pharmacies and pharmacists.

Generally we are not satisfied with the state and federal monitoring and law enforcement regarding mail order pharmacies. Although recently the volume of illegal Canadian drug mail order imports has received special isolated attention from such authorities, it is estimated that Americans buy that amount of prescription drugs from domestic mail order businesses, including that facilitated by the internet, every two weeks. (See Attachment A - FDA Drug Scrutiny Rapped as Uneven, *Boston Globe* September 16, 2003 article. See Attachment B – US Justice Department's release regarding intervention in major pharmacy benefit manager (PBM) mail

order scandal case and also see Attachment C - resolution on U.S. mail order prescription drugs was unanimously approved by the NCPA's House of Delegates at our 105th Annual Convention in Seattle, Washington, on October 22, 2003).

Also, we support the priority application of current laws (e.g. RICO and the Prescription Drug Marketing Act) by the Treasury, Health & Human Services, Justice Departments and other agencies, and the vigorous investigation and appropriate prosecution of the so called "rogue" Internet pharmacies, whether they are doing business in the US or through "offshore" mail order imports.

Whatever additional steps are adopted it is essential that patient care provided by properly licensed pharmacies and pharmacists, engaged in lawful conduct, not be the targets of investigations or regulations.

In conclusion, the legislation, H.R.3880, will help deter unlawful use of the Internet and consequently consumers are far more likely to receive lawfully prescribed prescription drugs and related pharmacists services from legitimate, properly licensed pharmacies and trustworthy appropriately licensed pharmacists.

We look forward to assisting the Committee as it addresses the regulations of Internet pharmacies and pharmacists.

The Boston Globe

FDA DRUG SCRUTINY RAPPED AS UNEVEN

Author(s): Christopher Rowland, Globe Staff **Date:** September 16, 2003 **Page:** A1 **Section:** National/Foreign

The Food and Drug Administration is serious about monitoring the safety of mail-order drug shipments in the United States - if they come from Canada.

Last month, the agency conducted an unusual sting operation targeting the City of Springfield, which is importing lower-priced drugs from Canada for city workers to reduce the spiraling cost of drugs bought in the United States. In an elaborate undercover operation, the FDA received at room temperature a single order of insulin that should have been chilled. The agency publicized the sting nationally to illustrate what it described as the dangers of ordering drugs by Internet from Canada. But the FDA takes a hands-off approach to enforcing the much greater volume of prescription shipments from US Internet mail-order pharmacies, where increasing numbers of Americans get their drugs. In fact, FDA officials said they can't recall ever conducting a domestic sting operation targeting the quality of insulin or other drug shipments. Critics said the agency is in the pocket of US drug makers, which have vigorously tried to shut down Canadian imports.

"I'm very concerned that they are selectively enforcing here," said Springfield Mayor Michael Albano, who is heading to Washington for meetings today with FDA officials to make his case. "They're doing the pharmaceutical companies' bidding to try and stop the momentum."

Though rising, Canadian drug imports totaled just \$700 million last year. In comparison, Americans buy that amount of drugs every 10 days from domestic mail-order prescription businesses, and the level is growing fast.

Meanwhile, there are concerns that the lack of FDA oversight of US shipments is a problem. According to a study using dummy packages with temperature sensors sent to 32 states, one in four mail-order prescription deliveries in the United States is likely to be exposed to excessive heat while en route to the consumer. In some cases, especially with biologic drugs, excessive heat can diminish the drugs' effectiveness.

The study was conducted by US Pharmacopeia, a Rockville, Md., nonprofit group that sets national standards for pharmacies. The group has encountered industry resistance to spending on new technology to ensure safer deliveries.

"I have never, ever had insulin arrive cool in 13 years of buying it" through domestic mail order, said diabetes patient Tom Boyer of San Francisco. He throws the lukewarm cold packs that arrive with his 90-day insulin supplies into the freezer. When they get cold again, he uses them to soothe a sore knee. US Representative Bernard Sanders, Independent of Vermont, who advocates legislation to allow the importation of low-cost Canadian drugs, said the Springfield sting and lack of US enforcement are evidence that the FDA is helping drug companies protect higher drug prices paid by American consumers.

"The FDA is working for the pharmaceutical industry, which contributes huge amounts of money to the Republican Party and the president," Sanders said.

The FDA declined to respond specifically to charges that the agency favors industry.

"Our policy is based on promoting the safety of the American people," said Brad Stone, an agency spokesman in Washington. William Hubbard, the FDA's associate commissioner for policy and planning, said the Springfield sting was necessary because there are no other mechanisms to hold Canadian companies accountable.

Hubbard said the FDA "absolutely" has the jurisdiction to regulate the safety of domestic mail-order shipments. But he said enforcement at the state level ensures that consumers are protected.

"No American pharmacist is going to give you hot insulin," he said. "He's going to be subject to licensure, subject to inspection, subject to a complaint from a patient. His business is going to be at risk. This guy in Canada has nothing at risk."

The Springfield municipal program has been a focus of the FDA since Albano unveiled it in July.

Importing prescription drugs from Canada is illegal, yet the FDA has declined to enforce the prohibition for individual consumers. The purchases have increased over the last four years as Americans desperate to reduce their medicine costs have found discounts as low as 50 to 80 percent on brand-name drugs north of the border, a result of Canadian government price controls. The US House has passed a bill that would make Canadian sales in the United States legal. The proposal is hotly opposed by the FDA and industry, which say American consumers could be exposed to counterfeit, expired, or improperly stored medicine from Canada.

It was against this backdrop that the FDA, using an assumed name and address, took action last month against Springfield's supplier of Canadian drugs, CanaRx Services Inc., based in Windsor, Ontario. The FDA said the sting resulted in a room-temperature batch of insulin that should have been delivered refrigerated. Hubbard said the package was not insulated but declined to release other details. In the United States, some diabetics say insulin ordered from domestic mail-order companies often shows up at their doorstep at room temperature.

Concord author Philip Luber said he tried mail-order insulin for his daughter in 1999. The insulin that arrived via Federal Express, he said, was not refrigerated and arrived lukewarm. After his daughter began injecting the new batch, her glucose levels did not fall sufficiently, evidence, he believes, that the insulin had been degraded by extreme heat during shipment. Luber persuaded his insurance company to allow him to purchase the insulin at a local drugstore instead.

"The packages they were using were called insulated packages. It had layers of something in it, bubble-wrap or other insulation," he said. "But if you stick any kind of package in a hot truck for a couple of days in the middle of August, it doesn't matter."

For at least the past five years, US drug companies, wholesalers, and mail-order pharmacies have joined forces to oppose a set of proposed national prescription-shipping standards that would include the use of temperature sensors in packaging to tell consumers if their mail-order prescriptions had been exposed to extreme heat or cold. Without such sensors, proponents say, patients have no way of knowing if the drugs arriving on their doorstep were baked in a truck in the Arizona desert or frozen solid in the belly of a cargo plane.

"The concern has always been that when a mail-order pharmacy ships, it's being sent to the consumer under uncontrolled conditions," said Eric C. Sheinin, vice president for standards development at US Pharmacopeia, the standard-setting group.

US mail-order companies are generally regulated by individual state boards of pharmacy following US Pharmacopeia guidelines.

The FDA's Hubbard said the agency's rules establish US Pharmacopeia as the standard-setting entity for the operation of pharmacies, including national-scale pharmacies that ship across state lines. But US Pharmacopeia said it has no shipping standards, which has been a source of concern among some US Pharmacopeia officials. A 1997 study by the organization, in which test packages were shipped to 32 states, demonstrated that 26.1 percent of mail-order drugs were exposed to excessive heat of 104 degrees or more, well above the tolerance for insulin, for example. A 1995 study found that temperatures in St. Louis mailboxes reached 136 degrees.

Manufacturing guidelines for insulin say it should be stored in a refrigerator, although it can be kept safely at room temperature for up to 28 days. It loses effectiveness when it is exposed to greater than body temperature. The problem for mail-order consumers is that there is no way to tell by looking at the product if it has been heated beyond tolerable levels. Freezing insulin renders it almost completely ineffective, but there are telltale signs of freezing, such as a cloudy appearance.

The National Community Pharmacists Association has called on the federal government for greater regulation of Internet mail-order pharmacies, to no avail, said John M. Rector, the association's general counsel.

US Pharmacopeia has repeatedly proposed national guidelines to safeguard drugs in shipment, including the insertion of temperature sensors into packages of sensitive prescriptions like insulin and synthetic hormones. Those proposals have been defeated by "push-back from industry," which holds seats on the US Pharmacopeia governing bodies, Sheinin said. The organization's leadership plans to unveil a fresh set of proposals within two weeks.

The FDA's director of pharmacy affairs, Tom J. McGinnis, said the FDA would enforce whatever standard US Pharmacopeia adopts. Thus far, he said, the agency has not seen the need for independent action.

"FDA looked at this issue in the past, at least 10 years ago, when mail-order pharmacies started getting big," he said, "and we didn't see any degradation of strength, quality, and purity at that time."

The Pharmaceutical Care Management Association, which represents mail-order pharmacies, and the largest mail-order pharmacy, Medco Health Solutions Inc., declined to comment on US Pharmacopeia's proposals for temperature sensors. In the past, according to copies of industry newsletters, mail-order pharmacies, wholesalers, and drug manufacturers have said that requiring sensors would present an unfair regulatory burden, raise handling costs, and increase the likelihood that consumers would return drugs to mail-order retailers.

"Mail-order pharmacy sources are already appropriately regulated by state boards of pharmacy," said Tim Brogan, a spokesman for the Pharmaceutical Care Management Association.

Medco Health Solutions, a subsidiary of drug maker Merck & Co., said mail-order pharmacists take great pains to make sure drugs arrive in good shape. Medco spokeswoman Ann Smith cited several measures including overnight or expedited shipping, iced or gel-packed insulated containers, and follow-up calls to an insured patient to see if the package arrived on time.

"We believe that our protocols are extremely rigorous," she said.

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**UNITED STATES ATTORNEY'S OFFICE
NEWS RELEASE**

**U.S. FILES COMPLAINT IN INTERVENTION IN TWO
"WHISTLEBLOWER" ACTIONS AGAINST MEDCO HEALTH SOLUTIONS
Alleged Violations Include Cancelling, Deleting, or Destroying Patient Prescriptions
To Meet Contract Turnaround Requirements, Creating False Records about Calls to Physicians,
Shorting Prescription Orders, Making False Statements to Patients, And Switching Patients To
New Drugs Without Physician Authorization**

September 29, 2003 - PHILADELPHIA - United States Attorney Patrick L. Meehan announced today the filing of the Government's [complaint](#) in intervention in two "whistleblower" actions brought under the federal False Claims Act and state False Claims Acts against **Medco Health Solutions, Inc. ("Medco")**. This action follows the notice of intervention filed in the pending actions on June 23, 2003.

In these actions, [USA ex rel. Hunt and Gauger v. Medco](#) and [USA ex rel. Piacentile v. Medco](#), the "whistleblowers" or "relators" alleged that Medco submitted and caused the submission of false claims to the United States, that Medco made false statements and prepared false records in support of false claims, and that Medco made false statements to reduce its liability for penalties to the United States. These violations, according to the complaints, arose out of Medco's contract with the Blue Cross and Blue Shield Association to provide mail order prescription drug benefits to federal employees, retirees, and their families.

"The conduct alleged in the complaint is a financial fraud on employee health benefits programs funded in whole or in part by the United States. Moreover, it is a fraud on the patients who rely upon Medco mail order pharmacies for their prescriptions, and on the judgment and professionalism of the licensed pharmacist which safeguards their health," said Meehan. "Patients who use mail order pharmacies have paid for and should receive the same professional quality and commitment that they receive from their neighborhood pharmacist. Pressure by an employer to reduce costs and increase profits must never be allowed to coerce pharmacists into ignoring their duties to patients. Getting the proper medication in the hands of patients as quickly and efficiently as possible should be the mission of any pharmacy benefit manager. However, these allegations suggest that, somewhere along the line, the focus became the profit instead of the patient."

The Complaint filed today alleges that Medco engaged in the following conduct:

- 1) Cancelling, deleting and destroying patients' mail order prescriptions so that Medco could avoid penalties for its repeated delays in filling and mailing patient prescriptions;
- 2) Mailing prescriptions to patients with less than the number of pills ordered and paid for ("shorting"), and charging both patients and health plans as if they had dispensed the full amount;

- 3) Creating false records showing that physicians had been contacted to discuss the proper drug, or the proper dosage or dispensing instructions, when no such contact had been made;
- 4) Creating false records showing that physicians had been contacted to discuss the risk of adverse drug interactions for a patient, when no such contact had been made;
- 5) Intimidating and coercing pharmacists in order to certify new prescriptions for filling without direct contact with the treating physician, when the professional judgment of the pharmacist was that a call was required;
- 6) Making false statements to patients that mail order prescriptions had not been received, when in fact the prescription had been received and then cancelled in order to appear to meet contractually required turnaround times;
- 7) Billing the United States and patients for prescriptions not authorized by law to be filled;
- 8) Making false statements to the United States during the investigation of Medco's illegal conduct;
- 9) Changing prescriptions based upon misleading or false information provided to treating physicians;
- 10) Making false statements to the Blue Cross Blue Shield Association about compliance with contract requirements that prescriptions be mailed within so many days of receipt;
- 11) Inducing physicians to authorize switching of prescriptions from lower to higher cost medications while representing that the switch was for the purpose of reducing prescription costs for the health program;
- 12) Favoring Merck drugs over other manufacturer's drugs in switching programs, even when the Merck drugs were more expensive;
- 13) Failing to comply with state laws requiring appropriate drug utilization review by a pharmacist and consultation with the treating physician where there is a potential for harmful interaction among drugs prescribed for a patient;
- 14) Fabricating records of calls by pharmacists to physicians;
- 15) Failing to call physicians for clarification, as required by governing law, when the prescription received by the pharmacist is ambiguous.

The Government's Notice of Intervention was limited to Count 1 of the Hunt/Gauger complaint, and Counts 1 and 2 of the Piacentile complaint. The decision by the Department of Justice to intervene in a case does not necessarily mean that it endorses, adopts, or agrees with every factual allegation or legal conclusion in the relators' complaint. Copies of the Government's Complaint in Intervention, the Government's notice of intervention, and each relator's complaint are available on the U.S. Attorney Web site, www.usdoj.gov/usao/pae.

Under the False Claims Act, a "whistleblower," known as a "relator," files a complaint on behalf of the United States "under seal," that is, with the

District Court in files not available to the defendant or the public. After investigation, the United States must decide whether to intervene and participate in the prosecution of the action with the relators' counsel, or to decline to participate and permit the relators' counsel to prosecute the action alone. The relator retains the right to prosecute declined claims or parties. The case is unsealed by the court at the time of the intervention or declination.

It is customary for the United States, upon intervention in a pending qui tam action, to prepare, file and serve its own complaint after the date of intervention. This amended complaint sets forth the factual allegations that the United States is prepared to adopt and allege against the defendants as the result of its investigation. In whistleblower actions in which the United States intervenes, the United States may adopt some or all of the relators' factual allegations. The United States' complaint may assert additional claims under statutes other than the False Claims Act, or the common law which the relators are not entitled to assert. The United States may also assert claims under the False Claims Act or other laws against individuals or entities not named in the relators' complaints.

These qui tam actions, both filed in the United States District Court for the Eastern District of Pennsylvania, have been consolidated and assigned to Senior Judge Clarence Newcomer.

In this case, as in all civil False Claims cases, the claims made in the complaints are allegations only. The defendants have a right to a jury trial on each of the claims, and the United States must prove each of the claims by a preponderance of the evidence. Each of the defendants has the right to present evidence on its behalf, and to cross-examine witnesses called by the United States and the relators.

The notice of intervention follows an extensive investigation of the factual allegations and evidentiary support provided by the relators. This investigation was conducted by the United States Attorney's Office, Eastern District of Pennsylvania, together with the Office of Inspector General of the Office of Personnel Management, The Office of Inspector General of the Department of Health and Human Services, and the Defense Criminal Investigative Service. State Attorneys General are also examining related issues in coordination with the Department of Justice.

The handling of this case by the United States Attorney's Office is primarily assigned to James G. Sheehan , Associate United States Attorney.

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RESOLUTION #4

U.S. Mail Order Prescription Drugs

WHEREAS, the national debate about illegal prescription imports has highlighted the lack of appropriate regulation of U.S. domestic mailers of prescription drugs and of the pharmacists and non-pharmacists responsible for such mailings; and

WHEREAS, the U.S. Food and Drug Administration and others have recently acknowledged the lack of monitoring investigation of U.S. mail order drugs, which surpasses the volume of illegal Canadian prescriptions every 10 days; and

WHEREAS, the pharmacy benefit managers disingenuously claim both that they do not practice pharmacy and that their pharmacists are the only pharmacists that provide worthwhile services; and

WHEREAS, the U.S. government in United States of America vs. Medco (9/29/03) claims that the poster child of unregulated U.S. mail order prescriptions and mail order pharmacists has engaged in systematic abuse of consumers, especially federal employees, including military personnel and their families;

BE IT RESOLVED THAT NCPA revise its model mail order state regulation bill and request appropriate state authorities to

enforce current law and enact appropriate new laws, if necessary, to ensure that patients exposed to mail order prescriptions have the benefit of the relief and remedies available to non-mail order consumers of prescription drugs.