2006

The State Legislators Desktop Reference to Prescription Drug Policy

Institute For Policy Innovation

IPI

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After three or four years of very tight budgets, states are starting to see a steady increase in revenues. While they aren't all out of the rough yet, prospects are brightening, state coffers are rising and pressure to find savings by reducing access to needed health care is declining.

That is good news for consumers. In an effort to cut spending, many states restricted access to prescription drugs by creating preferred drug lists (PDLs) or imposing a new tax on drug manufacturers, known as a "supplemental rebate." Some states joined bulk purchasing pools in order to obtain larger manufacturer discounts.

And, even in the face of strong Food and Drug Administration (FDA) warnings that their actions were illegal and unsafe, several states devised ways to help state employees, seniors and low-income citizens through unsafe (and unsuccessful) foreign drug importation schemes.

In addition, the Medicare Modernization Act of 2003, the federal legislation that created a new prescription drug benefit for Medicare beneficiaries (Part D), went into effect on Jan. 1, 2006. The availability of the new drug benefit should reduce the need for states to provide access to medications for lower-income seniors who had no prescription drug coverage.

There are also several Medicaid reform proposals on the table. The National Governors Association wants to increase the current Medicaid rebate (which is part of federal law and different than the supplemental rebate mentioned above) from 15.1 percent to 19 percent. More states are expanding their Medicaid programs to cover more people, in part to access the federal matching grant to states, but also so they can receive more money in rebates and supplemental rebates from the drug industry.

And some states, as well as Washington, D.C., are proposing direct price controls.

Legislators need to be prudent stewards of taxpayers' dollars, but they also must ensure that vulnerable populations receive appropriate care. This Desktop Reference will help state legislators identify effective actions that may save the state money without reducing access to needed medicines.

Merrill Matthews, Ph.D.
Peter J. Pitts

Medicaid Restrictive Formularies

Explanation

A restrictive formulary is a limited list of medications, also referred to as a "preferred drug list," or PDL. Medications not on the list would not be covered by a state Medicaid program unless a physician specifically requested permission to prescribe it and the state granted that permission. PDLs seek to steer patients and their doctors toward lower-priced drugs in the hope of saving state money.

Issues

Since the early 1990s, federal law has allowed states to "prior authorize" drugs in the Medicaid program, a process that requires doctors to get approval before dispensing drugs. But that option was intended to be very limited, primarily to prevent fraud and abuse. Recently, states have broadened the scope of their interpretation of the law in an effort to limit access to several commonly prescribed drugs. That's where the formularies come in. The goal is to discourage doctors from using expensive medications by imposing on them the burden of additional government paperwork (i.e., the doctor has to get prior approval).

However, most of the increase in spending on drugs has come from increased utilization, not higher prices. Only about 11 percent of total health care spending is

for prescription drugs. The fastest-growing component of health care spending — more than one-third — is for hospitals, and for Medicaid long-term care services, which continue to strain state budgets.

Spending on pharmaceuticals can save health care dollars while saving and improving the quality of lives. For example, Columbia University economist Frank Lichtenberg has estimated that every dollar shifted from older to newer drugs saves about $7 in other health care costs. And research has shown that restricting access to medications can increase overall health care costs by increasing the number of hospital, emergency room and physician visits. A survey by Project Patient Care and Harris Interactive estimates that in 2001 alone, formulary restrictions caused 1.1 million Americans to experience negative health outcomes and 1.9 million to experience side effects.

Restrictive formularies can also decrease patient access to appropriate care. In fact, a group of patients filed a class-action suit against the state of Florida claiming that the state was denying them access to needed drugs as guaranteed under the federal agreement that created the Medicaid rebate program. The state settled with the patients out of court, agreeing to a provision that, while imposing some limitations, still ensured patient access. Ironically, most states in the 1990s legislated against HMOs' attempts to control costs by controlling access to care; yet states that impose restrictive formularies are doing the same thing.

There are many other access-restriction programs that have a similar effect. "Step therapy" (or "fail first") programs start patients on a lower-cost medication, then move them up to more expensive therapies if the cheaper ones fail. "Therapeutic interchange" allows substitution of a less-expensive drug that has been determined, usually by a committee, to have the same therapeutic effect. "Prior authorization" programs require a physician to first get permission from the state before prescribing a drug not on the PDL.

Positive Steps

The Center for Medicare and Medicaid Services' (CMS) guidance on PDLs says, "When implementing PDLs, we urge states to be mindful of patients who are stabilized or previously prescribed, non-preferred medications . . . [W]e further urge states to consider the impact on beneficiaries of sudden changes in therapy as a result of a state's implementation of a PDL."

States considering restrictive formularies are trying to save money, but there are better ways to save.

One way is to focus on outcomes. Disease management programs, in which a health care professional educates patients and coordinates their care and support, are promising. Such programs are reducing costs and improving patient outcomes by targeting the most expensive users who suffer from one or more chronic conditions such as asthma, congestive heart failure, diabetes, coronary artery disease and/or depression.

(See the Disease Management Association of America [www.dmaa.org]).

Another way is to focus on patients using many prescriptions and to carefully evaluate the treatment of these "high utilizers," which in extreme cases may be using 20 or more prescriptions in a six-month period. While this number of medications may be appropriate for some individuals, there is an increased potential for drug therapy problems, such as drug interactions, that will necessitate closer review. Such a review would intend to prevent these problems and minimize duplicative therapy.

States could consider implementing "maximum allowable cost" (MAC) programs, which limit payments for brand name drugs when generic copies are available. For example, a state can preclude Medicaid from paying more than 150 percent of the cost of the cheapest generic copy. This approach does not limit access to drugs and still lowers costs.

States also should expand efforts to eliminate both intentional and unintentional Medicaid fraud. Some recipients who should be dropped from the program, usually because their incomes increase, remain on the rolls. If they are covered by an employer plan, the state Medicaid program can recover inappropriate payments from the new insurer. Reducing fraud is politically popular and saves money without reducing patients' access to needed care.

The best way to ensure the fairness of decisions about which drugs are chosen for the formulary is to require that all meetings and records be open to the public. This way, all interested parties can see why the committee decided on one drug over another and what research and testimony were used to make those decisions. This process also allows for company and public input. Decisions should be made so that clinical and cost considerations are clearly understood. Clinically inferior drugs should not be sold to the public as superior products in order to meet cost goals.

Finally, any new drug should be available to all patients unless and until the committee decides otherwise. If the committee is going to err, it should err on the side of access and availability.

Importation

Explanation

Importation is the practice of bringing prescription drugs into the United States, but avoiding the FDA's processes for ensuring safety. Though this practice is often referred to as "reimportation" — because there is a common, though false, assumption that the imported drugs were originally made by U.S. drug manufacturers and sold and shipped to other countries — the drugs are, in fact, imported and not reimported.

Issues

It is against the law to import drugs into this country unless it is done by a medication's manufacturer. However, the FDA typically does not enforce rules against U.S. citizens returning from abroad with a small amount of medication intended for personal use (see http://www.fda.gov/ora/import/pipinfo.htm).

But that doesn't mean it's legal; for practical and political reasons the law has not been rigidly enforced. So elected officials who encourage or help the poor, seniors or government employees buy prescription drugs from Canada or other countries are helping those Americans break the law, and may be breaking the law themselves by facilitating the acquisitions.

The Food and Drug Administration opposes importation, saying it does not have the ability to ensure the

safety of those drugs. Congress has given the secretary of the Department of Health and Human Services the authority to permit importation whenever the secretary can ensure the drugs are safe and would save Americans money, but neither the current secretary nor past secretaries (both Democrat and Republican) have reached that conclusion. Moreover, 11 former FDA commissioners have sent a letter to Congress opposing importation, considering it a threat to public health.

While there have been mayors, state legislators, governors and even members of Congress who tried to facilitate the purchase of foreign drugs over the Internet, despite the fact that such actions are explicitly illegal, that political trend is fading. There have been too many stories in the press exposing the worldwide explosion of counterfeit drugs — including in Canada — and the harm those drugs (or counterfeits) can cause. When politicians thought importing drugs from Canada and other countries appeared to be a way to get safe drugs at a lower price, many supported taking that step. Now that it is clear the drugs may be diluted, expired, compromised or counterfeit, importation doesn't look good at any price.

Furthermore, expanding importation would not save Americans money, as noted in a report from the U.S. Congressional Budget Office ("Would Prescription Drug Importation Reduce U.S. Drug Spending?" *CBO Economic and Budget Issue Brief*, at http://www.cbo.gov). Indeed, widespread drug importation would force prices up in other countries. Canada represents 2.6 percent

of the global prescription drug market, while the U.S. represents about 53 percent. This means that Canada has a very limited supply of prescription drugs relative to the U.S., and would never be able to meet the demands of the American market. If it tries, shortages will develop in Canada driving up the price for Canadians and Americans.

Members of the Canadian parliament have recognized this problem and introduced legislation to limit the cross-border sale of drugs.

Although some states and a few U.S. cities tried to facilitate importation, those programs are not doing well. Gov. Rod Blagojevich of Illinois, one of the more aggressive pro-importation politicians, has had numerous problems and snafus with his plan and, according to *American Medical News* (published by the American Medical Association), "Physicians say they no longer advise patients" to use the governor's program.

Positive Steps

There are a number of options available for states wanting to help low-income people gain access to affordable prescription drugs. To begin with, most drug manufacturers and the drug industry have programs to provide low-income patients with access to prescription drugs free or at greatly discounted prices. States should help promote information about these and other programs to expand awareness of what is available and how to access the programs.

Maryland has taken some positive steps toward increasing access to prescription drugs by creating a new program that could be a model for other states to follow: the Maryland Medbank. This program, partially funded by a state appropriation, is a clearinghouse that provides Marylanders with information about existing programs (www.medbankmd.org).

According to Medbank, the program has provided $90 million worth of free medicine and processed 327,000 prescriptions for 31,650 patients (through June 2005). The typical Medbank patient has a monthly income of $1,300, or 175 percent of the federal poverty level (FPL). Thus the state has played a leading role in educating consumers about available programs that help them get prescription drugs at little or no cost.

But states can do more. For example, New York took an innovative step to promote price transparency by posting on the state's Web site the prices of the 25 most popular drugs from pharmacies in all 62 counties. The prices are taken from the state-mandated Drug Retail Price List, which requires all state pharmacies to list the prices of the 150 most popular medications. There can be significant price breaks, depending on which pharmacy a person chooses. New York has demonstrated that patients need not cross borders to find affordable drugs. They may only have to go across town.

Drug Price Controls

Explanation

Using price controls as a tool of economic policy has been widely discredited, so much so that very few politicians have seriously proposed price controls as a way to bring down the cost of a product or service.

However, price controls are making a comeback with respect to prescription drugs. There are several proposals on the table. Some are blatant attempts at imposing a government-set price, others are more subtle. Some price control proposals are even touted as a free market solution to bring down prices.

But price controls have never worked. They dramatically distort the market and either force the poorest to pay higher prices than they otherwise would or they dry up the supply of the product or service.

Issues

There is a growing recognition that importing prescription drugs from other countries is not only illegal, but the rapid rise of counterfeit, subpotent and mishandled drugs outside of the U.S. threatens the health of those who take them. As a result, some politicians are looking for other options that will allow them to tell their constituents they have brought down drug prices.

Directly imposing price controls — rather than the indirect method of importing the price controls of

other countries — appears to be one option. And politicians are looking for models to follow.

The Veterans Administration is often cited as a model that would ensure the states get lower prices because the VA depends on voluntary agreements. But the process isn't actually voluntary; the government dictates what it will pay. The "voluntary" part is that individual drug companies can decide whether they will accept or reject the price. Because the VA is a very small program, agreeing to an artificially low price does not cause major financial disruptions, so the drug companies have generally participated.

But it isn't a voluntary pricing system any more than the way the government reimburses hospitals under Medicare Part A or physicians under Medicare Part B. Both of those programs use price controls, and they have widely distorted the health care market by shifting costs to private sector payers, such as insurers, which increase premiums to cover the claims.

In addition, the city of Washington, D.C., has passed legislation that would impose price controls on drugs sold within the city.

Such attempts are based on a fundamental misperception. The prices charged by drug manufacturers are not the final price passed on to the consumer. There may be one or more middlemen that handle the drugs before they reach the retail outlet, usually a pharmacy. Imposing price controls on the manufacturer doesn't

necessarily mean that part or all of the reduced price will be passed on to the consumer. For example, most insured people with drug coverage fall under pharmacy benefit managers (PBMs). Those organizations often negotiate deep discounts or receive company rebates on certain drugs. That is part of their business model. Only a portion, if any, of that discount may be passed on to the retail pharmacy outlet. In fact, the retail customer might not see any of the discount.

Ironically, the largest markups for the end user — the patients — are usually on generic drugs. Several news stories over the past few years have found huge markups in the generic products, much higher than for brand name drugs.

The point is that the pharmaceutical distribution network is very complex. Imposing price controls in one place may have little or no impact on final prices.

Positive Steps

The goal of price controls is to reduce spending. But states have several options to shortsighted and ultimately unsuccessful attempts to control prescription drug prices. First, legislators need to recognize that prescription drug prices can vary significantly from pharmacy to pharmacy. And the fact that it is difficult for consumers to compare prices at different pharmacies exacerbates the problem.

New York has taken several aggressive steps to promote prescription drug price transparency. First there is the

aforementioned state-mandated Drug Retail Price List, which requires all state pharmacies to list the prices of the 150 most popular medications. And New York City published "Prescription Drug Prices All Over the Map" in 2004, which provides the highest and lowest price of five popular brand name prescription drugs in five boroughs. The study found differences of up to 40 percent.

States also can purvey information. Most states have drug assistance programs, and pharmaceutical manufacturers have numerous plans for seniors and the poor. Often, however, eligible patients do not know what is available or how to enroll. As indicated in an earlier section, Maryland has taken positive steps toward providing better access to prescription drugs through a new program that could be a model for other states: the Maryland Medbank. Partially funded by a state appropriation, Medbank is a clearinghouse for information about existing programs (www.medbankmd.org).

Through June of 2005, Medbank had provided $90 million worth of free medicine and processed 327,000 prescriptions for 31,650 patients. The typical Medbank patient earns $1,300 a month, which is 175 percent of the federal poverty level (FPL). Maryland's innovative approach has played a leading role in educating consumers about available programs that help them get prescription drugs at little or no cost.

States can and should provide information about the new prescription drug benefit. Millions of seniors will

want to join the new Medicare drug benefit, and they have lots of options, so many that critics have been complaining that seniors are confused. Whether they are or not, it certainly makes sense for the state to help Medicare beneficiaries wade through their options.

Tort Reform

Explanation

The United States has become the most litigious society in history. The Towers Perrin Tillinghast annual report pegs U.S. tort system costs at about $246 billion in 2003, a 5.4 percent increase over 2002 — which is very good news since the costs in 2002 were a 13.4 percent jump over the year before. However, medical malpractice costs have grown at an average of 11.8 percent per year since 1975 and cost nearly $27 billion in 2003.

Some efforts at reforming the tort system have been successful. Building on these reforms could produce billions of dollars in savings throughout the health care system.

Issues

Many states are facing huge problems in their medical liability systems, and many have seen physicians refuse to practice because they could no longer afford their malpractice premiums.

In addition, liability concerns can keep valuable products off the market creating huge social costs. These losses are most acute in medical research and development. Companies are wary of developing vaccines, and the number of companies doing research on contraceptive devices has declined from 13 to 2 because of the fear of liability.

States that have adopted the appropriate malpractice reforms have experienced substantial savings. A study by Daniel Kessler and Mark McClellan found that "malpractice reforms that directly reduce provider liability pressure lead to reductions of 5 to 9 percent in medical expenditures without substantial effects on mortality or medical complications."

A Stanford University study estimated that uniform adoption of such legal reforms would reduce health care costs by $50 billion with no serious adverse consequences to the nation's health.

Positive Steps

State legislators should consider capping punitive (not economic) damages. California's model of a $250,000 cap on noneconomic damages has worked very well. (For more information, see the American Legislative Exchange Council's [ALEC] model legislation.) For example, in 2003 Texas enacted sweeping and comprehensive tort reform that included California-style noneconomic damage caps of $250,000. Medical malpractice insurance rate hikes were eliminated for 2004 premiums and are even declining for some doctors. In addition, in 2004 Mississippi made significant strides that included many of the best aspects of the California and Texas reforms.

Alternatively, states could redirect punitive damages to someone or some group other than the plaintiff and the plaintiff's attorney. For example, diverted punitive

damages could help to fund the state's provision of prescription drugs to low-income families or its coverage of the uninsured.

A less-comprehensive but still helpful approach would be to exempt drug manufacturers from liability when a doctor has prescribed a properly labeled FDA-approved drug. The FDA approves drugs for safety and efficacy. Manufacturers should not be subject to lawsuits if patients ignore labels or a doctor's instructions.

Direct-to-Consumer Advertising

Explanation

In 1997 the FDA reduced the restrictions imposed on direct-to-consumer (DTC) advertising by pharmaceutical companies, which in turn led to a significant increase in drug advertising in print and broadcast media.

Issues

Some critics claim that advertising has caused prescription drug prices to skyrocket and encourages excessive, even unnecessary drug use. Proponents argue that the ads educate consumers about health issues and the values of the products.

What critics either fail to understand or fail to acknowledge is that advertising empowers patients and may lower prices. This is as true of prescription drugs as it is of groceries, automobiles and computers.

Because direct-to-consumer advertising helps raise awareness of health issues, it can lead to physician visits and diagnoses of previously undisclosed conditions. *Prevention* magazine reported in 2002 that more than 61 million Americans talked to their doctors about a medical condition they had seen advertised, and 25 million talked to their doctor for the first time about a medical condition. According to a 2003 FDA survey,

88 percent of responding physicians said patients inquiring about a drug had a disease the drug treated.

Responding to an ad for one drug may also lead patients to receive treatment for another, previously undiagnosed, disease. According to PhRMA, of 1 million men who visited their doctors as a result of advertising for Viagra, 30,000 turned out to have untreated diabetes, 140,000 had untreated blood pressure, and 50,000 had untreated heart disease.

Of course, seeing an advertisement does not mean that consumers will get the prescription that was advertised. Physicians have to write a prescription first, and research indicates that unnecessary prescriptions are quite rare. One survey showed that among consumers who saw a specific advertisement, only 13 percent received a prescription as a result. According to FDA research, physicians are not being pressured by their patients into writing inappropriate prescriptions due to direct-to-consumer advertising.

Positive Steps

The states' primary concern over DTC advertising is whether it is increasing utilization among populations whose prescriptions are subsidized with state money, primarily Medicaid and other public health program recipients and state employees.

If there is concern that DTC advertising encourages drug overuse or abuse, legislators could commission a study by an outside group, the health department or

another state agency to see if patients are receiving appropriate care. However, the FDA recently did this for the second time nationwide and found that DTC advertising encourages patients with medical conditions to seek needed treatment, that very little abuse occurs and that most doctors are comfortable with patients' drug inquiries. These findings are important because two of the biggest problems facing Medicaid populations are awareness and compliance. By advertising, the manufacturers actually heighten public awareness about certain illnesses that can and should be treated. And the ads implicitly serve as reminders that patients already on medications should take them.

Some state legislators have considered restricting drug advertisements in their states. But this action surely would be unenforceable because some ads are part of national programming. They also likely would be unconstitutional and doubtless would run counter to existing state laws.

Instead, a state could sponsor its own ad encouraging those concerned about a medical condition to see their doctor. The ad could refer the audience to a Web site or a phone number that provides information about available programs and services. The point is not to fight advertising and the media, but to use them to enhance the state's message.

Supplemental Rebates

Explanation

Under federal law, pharmaceutical companies participating in Medicaid rebate 11 percent for generic drugs and 15.1 percent for branded drugs to state Medicaid agencies. In exchange, Medicaid was supposed to allow broad coverage of manufacturers' products, although states can exert some restrictions to control spending. Now, some states facing budget pressures are requiring or considering additional — "supplemental" — rebates. Only by paying these additional rebates could firms assure that their products appeared on the Medicaid formulary, the list of approved drugs for that state's Medicaid recipients.

Issues

Pharmaceuticals account for an average of 10 cents of every dollar of Medicaid spending on health care. And, under federal law, pharmaceutical companies already pay states a rebate of almost one-sixth of the cost of providing prescription medicines to Medicaid patients. The Congressional Budget Office estimated that, under the 1990 law, collections would be $1.9 billion over five years; collections were $4.7 billion in 2001 alone.

Supplemental rebates are essentially a new tax on drug companies under another name. Requiring supplemental rebates can effectively limit the selection of medi-

cines available to low-income patients (through the use of preferred drug lists), which can lead to increases in total costs if patients are substituting hospital or institutional care for drug therapy. Studies show that restrictions have led to more hospitalizations, emergency room visits and physician visits.

Finally, all supplemental rebates collected by states must be shared with the federal government at the same rate as the federal Medicaid matching grant. Thus a dollar in supplemental rebates means, on average, only 43 cents in savings for states.

Positive Steps

Since supplemental rebates are a new tax on drug manufacturers, legislators can take a strong anti-new-tax stand by challenging those who support supplemental rebates.

States also could let competition drive drug costs down by giving Medicaid participants a defined contribution as Nevada has done for its low-income seniors who are not qualified for Medicaid. Claims costs in Nevada were running only a little more than $40 per person per month, plus overhead and administrative fees. Thus it provides a very affordable alternative while retaining access to needed medications.

Purchasing Coalitions

Explanation

An attempt by several states to join together in the hope of getting large group discounts when buying prescription drugs.

Issues

The Centers for Medicare and Medicaid Services (CMS) has approved a multi-state purchasing pool that includes Michigan, Vermont, New Hampshire, Nevada, Alaska, Minnesota and Hawaii. Other states are also looking to form or join a pool.

The states' goal is to "negotiate" greater savings from drug manufacturers. There is nothing wrong in theory with states joining together in voluntary arrangements to negotiate discounts. That's just relying on economies of scale. In practice, however, the key mechanism for extracting greater discounts or supplemental rebates is through the threat of access restrictions, not economies of scale.

Thus, what is touted as using the market to negotiate discounts is little more than an attempt to create a monopsony (i.e., a market where there is only one buyer; the flip side of a monopoly). Indeed, a large enough pool could significantly influence the direction of both the research and development of new products. Thus, the wants and desires of those making up the approval committee could carry more weight in deciding

which diseases and new drugs are most important, rather than making those decisions based on what patients need or what research-based companies think are promising therapies.

Positive Steps

The Centers for Medicare and Medicaid Services has released guidance to state Medicaid directors (SMDL #04-006) for states wanting to join a purchasing pool. It is clear that CMS wants to balance states' desire to "achieve cost savings while at the same time protecting the interests of Medicaid beneficiaries and promoting competition."

If a state wants to enhance its buying power by joining with other states, negotiations should be free of coercion. Using the threat of limiting the poor's access to certain drugs is an unethical, and probably illegal, bargaining chip.

In addition, the negotiations should be decentralized as much as possible. Investing some type of committee with the power to make decisions about which drugs will and will not be available to a population of millions of people would be an invitation for all types of interest groups to become involved, politicizing the entire process.

If a committee is formed, the best way to limit political influences is to ensure that all records are open. This way, the public can see why the committee decided on one drug over another and what research and testimony

were used to make those decisions. In addition, CMS recommends that states "annually evaluate and issue a public report on the aggregate cost savings associated with their participation to determine whether expenditures in other Medicaid areas, such as hospitalizations or physician services, have increased as a result of the implementation of a multi-state pooling agreement."

Finally, any new drug should be available to all patients unless and until the committee decides otherwise. If the committee is going to err, it should err on the side of access and availability.

Counterfeit Drugs

Explanation

Some city, state and federal legislators have introduced bills that would allow for drug importation from certain nations within the European Union. They believe that if they can limit imported drugs to certain specified and approved countries, they will minimize or eliminate the threat of counterfeit medicines reaching U.S. consumers.

Issues

The problem is that U.S. officials cannot cherry-pick drugs from just one or two of the 25 European Union nations, e.g., Great Britain or France. That's because EU law prohibits such trade limitations. According to the Treaty of Rome, parallel trade is completely legal, and Articles 30 and 36 prohibit manufacturers from managing their European supply chains.

Dangerous counterfeit drugs are passing through Canada into the medicine cabinets of America from places such as Cyprus, Thailand, Portugal, Costa Rica, China, India, Pakistan, Iran and Belize. Global Internet drug dealers are using the façade of the Canadian maple leaf to lull unsuspecting Americans into thinking they're getting a bargain.

The World Health Organization (WHO) estimates that 8 percent to 10 percent of the global medicine supply chain is counterfeit — rising to 25 percent or

higher in some countries. The largest counterfeit market with close proximity to the EU free trade zone is Russia, where the generally accepted estimate is that 12 percent of drugs are counterfeit. Now that the Baltic nations of Latvia, Lithuania and Estonia have joined the European Union, WHO has warned that an increase in the risks of counterfeits entering the EU supply chain is "obvious."

Last year 140 million individual drug packages were parallel imported throughout the European Union — and a wholesaler repackaged each and every one. This means that, literally, European prescription drug arbitragers opened 140 million packets of drugs, removed their contents and repackaged them for sale in other European nations. But these "parallel traders" are in the moneymaking business, not the safety business. And mistakes happen. For example:

- New labels may incorrectly state the dosage strength;
- The new label may say the box contains tablets, but inside are capsules;
- The expiration date and batch numbers on the medicine boxes may not match the actual batch and dates of expiration of the medicines inside; and,
- Patient information materials are often in the wrong language or are out of date.

This means that drugs purchased from a British pharmacy by an unknowing American consumer could come from European Union nations such as Greece, Latvia, Poland, Malta, Cyprus or Estonia. In fact, parallel traded medicines account for about 20 percent (one in five) of all prescriptions filled by British pharmacies. In the EU there is no requirement to record the batch numbers of parallel imported medicines, so if a batch of medicines originally intended for sale in Greece is recalled, tracing where the entire batch has gone (for example, from Athens to London through Canada and then to Indianapolis) is impossible.

Positive Steps

Modern electronic technology is rapidly approaching the state at which it can reliably and affordably provide much greater assurances that a drug product was manufactured safely and distributed under conditions that did not compromise its potency. The FDA has concluded that this approach is a much more reliable direction for assuring the legitimacy of a drug than paper record-keeping requirements, which are more likely to be incomplete or falsified.

Notes

About the Authors

Merrill Matthews Jr., Ph.D., is a resident scholar with the Institute for Policy Innovation (IPI) and director of the Council for Affordable Health Insurance. He is past president of the Health Economics Roundtable for the National Association for Business Economics and health policy advisor for the American Legislative Exchange Council. Dr. Matthews served for 10 years as the medical ethicist for the University of Texas Southwestern Medical Center's Institutional Review Board for Human Experimentation.

Peter J. Pitts is director of the Center of Medicines in the Public Interest, a senior fellow for health care studies at the Pacific Research Institute and senior vice president for health affairs at Manning, Selvage & Lee.

Institute for Policy Innovation

1660 S. Stemmons Frwy. Suite 475

Lewisville, Texas 75067

Phone - (972) 874-5139

Fax - (972) 874-5144

www.ipi.org