

Specialty Drugs and Pharmacies

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by Devon M. Herrick

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Patients benefit enormously from safe and effective drug therapies. Highly advanced specialty drugs and biological agents are increasingly used to treat rare diseases and disorders for which there were no treatments only a few years ago. Advanced drug therapies are very expensive, and often require special handling and extensive patient monitoring.



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Executive Summary

Yet, many states have enacted regulations and ill-conceived public policies that force health plans to utilize drug providers who are unqualified to administer these exacting therapies. Not only do such policies boost patients' costs, they also compromise safety and invite fraudulent providers who jeopardize the effectiveness of specialty drug therapies.

The Importance of Specialty Drugs. Specialty drugs are not a therapeutic class or an official designation of the U.S. Food and Drug Administration (FDA). Rather, the term describes some of the latest high-tech, costly drugs, which may require careful handling within the supply chain.

The cost of specialty drug therapies ranges from tens of thousands of dollars to hundreds of thousands annually. Specialty drugs comprise only about 1 percent of prescriptions. Yet spending on these drugs is about one-fourth of prescription drug spending. Up to 40 percent of the drugs currently under development are specialty drugs.

Where Do Patients Get Their Specialty Drugs? Specialty drugs require a level of experience and expertise that most drugstores simply do not possess. Stocking and dispensing specialty drugs often involves handling biological agents that are very fragile — often requiring complex distribution channels. For instance, many biological agents require sophisticated logistical planning — including climate-controlled shipping and meticulous storage — with specific protocols and documentation.

Specialty pharmacies are more highly involved in patient care than drugstores that merely dispense drugs. Patients who receive specialty drugs and biological agents require extensive monitoring, risk evaluation, mitigation strategies for side effects and diagnostic support by a physician.

Physicians are in a position to evaluate the expertise and capabilities of the specialty pharmacy providers their patients patronize. In a recent survey, two-thirds of the physicians agreed that “some” traditional pharmacies are competent to handle and dispense specialty medications, but three-fourths also agreed that “most” pharmacies do not possess the expertise and capability to manage complex drugs.

Building Efficient Specialty Networks. Many specialty drugs have no

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close substitutes, rendering efforts to control costs by encouraging generic substitution largely ineffective. Plan sponsors also carefully manage distribution options, which may include weighing the merits of group purchasing organizations and special pharmacy outlets. As more health plans gain new members due to Affordable Care Act mandates, and more specialty drug therapies enter the market, plan sponsors are increasingly relying on narrow networks and formulary management. Due to these specialty medications' high cost, health plans must carefully manage the procurement and dispensing of these drugs.

Overregulation of Health and Drug Plans. As preferred networks and exclusive pharmacy providers have become more common, so too have the calls for lawmakers to enact laws that restrict the ability of drug plans to partner with exclusive specialty networks. As a result, the losing bidders and firms who are locked out of the preferred networks argue for the increased regulation of drug plans in order to gain access to patients on specialty drugs. In other words, special interests want Congress and state legislatures to reduce the ability of drug plans to effectively negotiate for lower prices. Opponents of this practice argue that "open" pharmacy networks offer enrollees more choices and more convenience, and promote competition.

Although these regulations supposedly benefit consumers and promote competition, they actually weaken health plans' ability to safely and efficiently manage prescription drug benefits. Tightly controlled pharmacy networks also allow better tracking by manufacturers of drugs that require specific or complex dosing and lab monitoring, which the FDA sometimes requires as a condition of drug approval. FDA monitoring requirements favor tightly controlled networks for safety reasons. Moreover, the Federal Trade Commission (FTC) agrees narrow networks are an effective means of cost control, where as any willing provider laws could raise cost for

consumers.

State and federal laws can interfere with negotiations between drug plans, drug makers and pharmacies. Such consumer protection laws are actually costly to taxpayers, employers and patients. Nearly two-thirds of the states have some type of *any willing provider* or freedom-of-choice regulations that apply to drug plans. Nearly one-fourth of states have regulations specific to drug plans.

These regulations can inhibit drug plans from establishing the most efficient preferred network for specialty drugs and make it more difficult to ensure the integrity of their networks. The larger the universe of entities that drug plans are legally required to reimburse for specialty drugs, the greater the likelihood one of these firms could cut corners with drugs that have been mishandled, mislabeled — or are counterfeit.

Because specialty drugs are extremely costly, unethical medical (and drug) providers trying to boost their profit margins have a financial incentive to ignore warning signs that a product is suspect. Counterfeit versions of the cancer drug Avastin were able to enter the U.S. drug supply chain in 2012 mostly due to greed. According to an analysis by the *Wall Street Journal*, 400-milligram vials of Avastin were sold by an unknown (unauthorized) supplier for a \$500 discount. This discount was enough to entice numerous providers to purchase the drugs, which later turned out to be counterfeit.

Restricting the ability of health plans to ensure safety, verify quality and hold down costs threatens patients' safety and consumers' wallets. Congress and state legislatures should avoid the well-meaning, but ill-conceived regulations intended to protect consumers, which often have the opposite result. A better way to ensure desirable outcomes is to promote a competitive environment free of market distortions that favor one party over another.

About the Author

Devon M. Herrick is a senior fellow with the National Center for Policy Analysis. He concentrates on such health care issues as Internet-based medicine, health insurance and the uninsured, and pharmaceutical drug issues. His research interests also include managed care, patient empowerment, medical privacy and technology-related issues. Herrick is past Chair of the Health Economics Roundtable of the National Association for Business Economics.

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Introduction

Patients benefit enormously from safe and effective drug therapies. Drug therapy is the most efficient method to treat most ailments — often substituting for more expensive hospital and surgical treatments. By almost any measure, the prescription medications Americans take are a bargain compared to the alternatives.

Increasingly, highly advanced specialty drugs and biological agents are treating rare diseases and disorders that had no treatment (or relatively ineffective treatments) only a few years ago. Some examples of conditions treated with specialty drugs include: cancer, multiple sclerosis, HIV, hepatitis C, rheumatoid arthritis and infertility.¹

These advanced drug therapies are very expensive, and often require special handling and extensive patient monitoring. Yet, many states have regulations that force health plans to utilize drug providers who are not qualified to administer these exacting therapies. Such policies boost patients' costs, compromise safety and invite fraudulent providers who jeopardize the effectiveness of specialty drug therapies.

Drugs and Biologics

Drug therapy is becoming more pervasive in the practice of medicine. As newer therapies are developed, highly advanced *specialty drugs* are increasingly supplanting conventional drug therapies.

The Importance of Drug Therapy. Spending on prescription drugs has grown tremendously over

the past two decades. Americans spend nearly \$300 billion dollars on prescription drug therapies annually.² This is a significant increase from the \$40 billion spent on prescription drugs in 1990.³ But don't be fooled; drug therapy is a bargain — comprising only about 10 percent of total medical expenditures. By contrast, expenditures on physician services account for twice as much as drugs, and inpatient hospital care accounts for three times the cost of drug spending. [See Figure I.]

More than six in 10 Americans take a prescription drug in any given year — including 90 percent of all seniors.⁴ The bulk of drugs consumed are generally prescribed

“Specialty drugs are expensive and often require special handling and extensive patient monitoring.”

for chronic conditions. For instance, a mere handful of therapeutic drug classes account for two-thirds of seniors' drug spending.⁵ Indeed, drug spending on the top five therapeutic drug classes for all adults accounted for about half of all prescription drugs purchased.⁶ Broader use of prescription drugs for chronic conditions could improve health status and reduce medical costs by avoiding expensive emergency room visits, costly complications and hospitalizations.

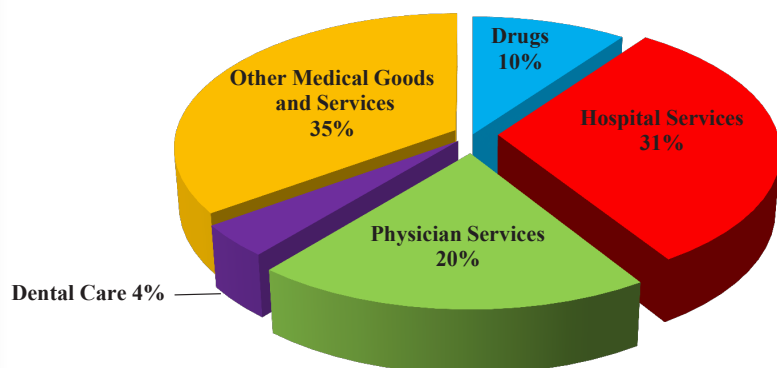
The Importance of Specialty Drugs. *Specialty drug* is not a therapeutic class or an official designation of the U.S. Food and Drug Administration (FDA). Rather, the term describes some of the latest high-tech therapies, which may require careful handling within the supply chain. These drugs include drugs for rare diseases and large-molecule biologics made from proteins (essentially derived from organic substances or living organisms). These drugs typically treat medical conditions that are life-threatening, chronic and often somewhat rare.⁷ Specialty drugs are often (but not always) administered by a physician in a clinical setting rather than taken with a glass of water at home. [See the sidebar “Physicians and Specialty Care.”]

The cost of specialty drug therapies ranges from tens of thousands of dollars to hundreds of thousands annually. A drug regimen using a specialty drug can easily approach \$15,000 per year; the most expensive therapy reportedly costs \$750,000 per year.⁸ Specialty drugs comprised only about 1 percent of prescriptions in 2012, yet spending on these drugs was about one-fourth of prescription drug spending.⁹ [See Figure II.]

The biggest selling class of therapeutic agents are typically specialty drugs that oncologists use to treat cancer.¹⁰ In 2011, oncology drugs made up about one-third of the total spending on specialty pharmaceuticals, accounting for \$30.6 billion. Another 15 percent of specialty drug spending is for autoimmune disorders, rheumatoid arthritis and Crohn's disease. HIV and multiple sclerosis account for about 12 percent and 8 percent of specialty

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Figure I
Drug Spending as a Proportion of All Health Care Expenditure
(2008)



Source: "National Health Expenditures by Type of Service and Source of Funds, CY 1960-2011," Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services, page last modified January 9, 2013. Available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/NHE2011.zip>.

drug spending, respectively.¹¹

Growth of Specialty Drugs

Spending on specialty drugs is growing faster than conventional drug therapies. Traditional pharmacy spending grew at an annual rate of 2.75 percent from 2008 to 2011. During the same period, specialty pharmacy spending grew nearly three times faster — averaging 7.5 percent annually.

In 2011, expenditures on specialty pharmacy were \$92 billion.¹² The actuarial consultancy Milliman expects this to increase to \$235 billion by 2018.¹³ In just a few short years — before the end of the decade — specialty drug therapies could grow to nearly half of all drug expenditures.¹⁴ Specialty pharmacy per-unit costs are rising about seven

times as fast as overall pharmacy costs.¹⁵ Of the top 10 drugs in terms of annual revenue, only three were specialty drugs in 2010. This may rise to seven of the top 10 by 2016.¹⁶

Specialty drugs also comprise a significant portion of the new drugs in the development stage. A little over two decades ago, about 10 specialty drugs were available; today there are more than 300. Nearly two-thirds of drug expenditures on new drugs in 2012 was for specialty pharmaceuticals. About 60 percent of recent drug approvals by the FDA were specialty drugs. [See Figure III.] Drug experts expect spending on specialty drugs to gradually displace traditional drug therapies as the major component of drug spending.

Where Do Patients Get Their Specialty Drugs?

A specialty pharmacy doesn't resemble the drugstore most consumers have come to know. The traditional pharmacy stocks drugs, counts tablets, and places them in a bottle labeled with the doctor's instructions. A pharmacist then performs a cursory questionnaire to make sure the patient understands the doctor's orders, and answers any questions. The pharmacy software automatically checks for known contraindications. The process is relatively straightforward, and follow up is generally left up to the physician. By contrast, the services of a specialty pharmacy are much more complex. [See: "The Role of Drug Plans in Managing Complex Conditions."]

Problem: Fragile Drugs.

Specialty drugs require a level of experience and expertise that most drugstores simply do not possess. Stocking and dispensing specialty drugs often involves handling biological agents that are very fragile — often requiring complex distribution channels. For instance, many biological agents require sophisticated logistical planning — including climate-controlled shipping and meticulous storage — with specific protocols and documentation. The specifics vary from one therapy to another, but a simple variation in room temperature may damage certain medications. Patient safety is a consideration — as is the cost of damaging a specialty drug that is administered to a patient.

Problem: Patient Monitoring.

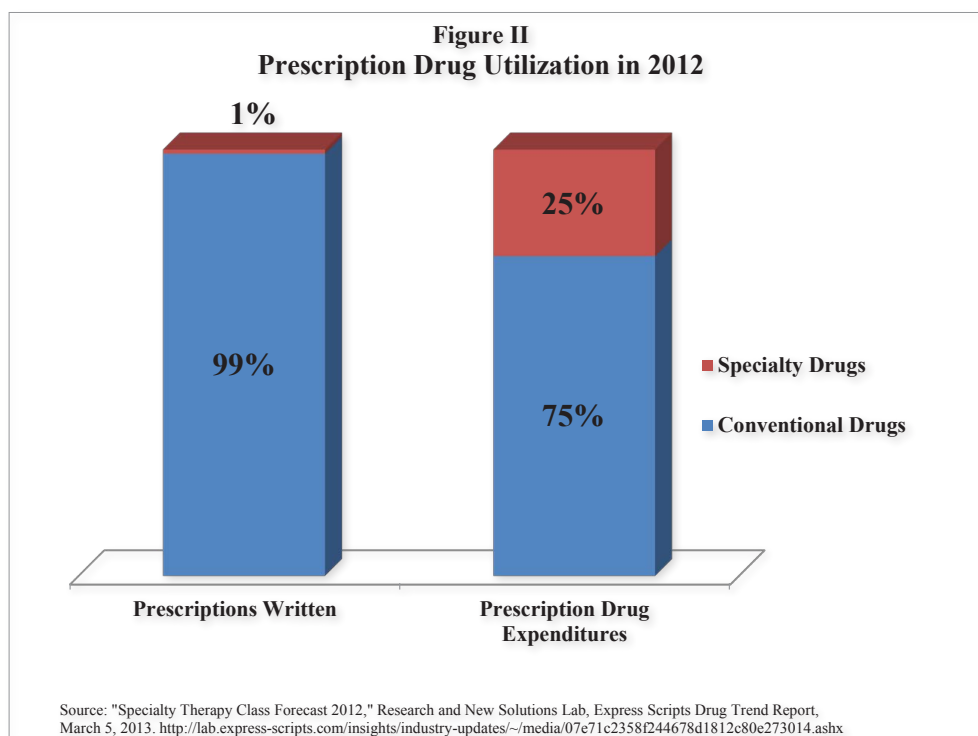
Specialty pharmacies are often referred to as "high touch" pharmacy services. These are more highly involved in patient care than

drugstores that merely dispense a drug. Patients who receive specialty drugs and biological agents require extensive monitoring, risk evaluation, mitigation strategies for side effects and diagnostic support by a physician.

Problem: High Costs. Due to these specialty medications' high cost, health plans must carefully manage the procurement and dispensing of these drugs. Health plans are increasingly becoming more involved with the delivery of specialty pharmacy services.²⁵ Many drug plans restrict or limit their specialty pharmacies to those most qualified, or who have agreed to charge competitive prices. In addition, many drug plans also rely on copayments (57 percent) and coinsurance (38 percent). A few are even considering higher levels of cost sharing.²⁶

As the table illustrates, the cost of a single specialty drug prescription may run in the thousands of dollars. Chronic conditions and those that require treatments for an extended period can cost tens of thousands per year.²⁷

When a new market segment displaces an old one, existing stakeholders in the legacy market understandably want to adapt to their changing environment. This is especially true if the growth market is lucrative. Because of the vast amounts of money involved in drug therapy, a diverse assortment of new and old competitors are jockeying for position and vying to enter the field of specialty pharmacy.³¹ These market participants include not just traditional retail (chain) drug stores, but also infusion providers (clinics specializing in intravenous



therapies), hub vendors (specialized middlemen), therapy-based service providers (clinics specializing in specific diseases), group purchasing organizations and so forth.³² Small, independent (community) pharmacies are also teaming up and organizing their own networks in order to break into the market for specialty drugs.³³

Building Efficient Specialty Networks. Many specialty drugs have no close substitutes, rendering efforts to control costs by encouraging generic substitution or using tiered formularies largely ineffective. Some health plans have boosted cost-sharing for specialty drugs, but many plan sponsors fear that could actually raise costs by discouraging adherence to therapies.³⁴ Health plans also manage the high cost of specialty drugs by developing clinical protocols and medical management prerequisites (such as prior authorization) based on comparisons of patient outcomes

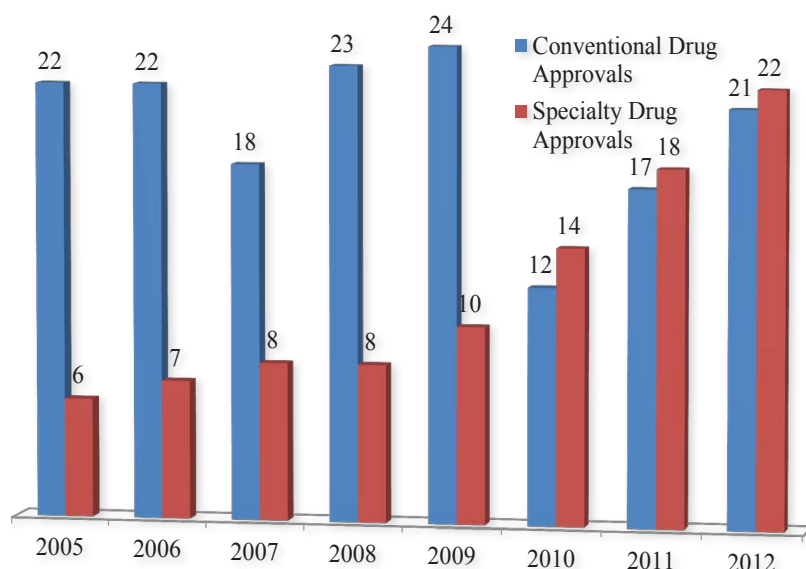
from therapies.

Plan sponsors also carefully manage distribution options, which may include weighing the merits of group purchasing organizations and special pharmacy outlets.³⁵ As more health plans gain new members due to Affordable Care Act mandates, and more specialty drug therapies enter the market, plan sponsors are increasingly relying on narrow networks and formulary management.³⁶

Health plans negotiate lower prices and ensure better monitoring by contracting with exclusive specialty pharmacy networks.³⁷ Health plans can then negotiate lower drug prices and dispensing and administrative fees by offering pharmacy networks the opportunity to compete to become one of their exclusive network drug providers.³⁸ Opponents of this practice argue that "open" pharmacy networks offer enrollees more choices

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Figure III
Share of Drug Approvals



Source: "Medical Cost Trend: Behind the Numbers, 2014," PricewaterhouseCoopers Health Research Institute, June 2013, Figure 6.

and more convenience, and promote competition. However, Pharmacy Benefit Managers (PBMs) and drug plans counter that the individual pharmacies in exclusive networks agree to deeper discounts in return for the business.³⁹

Tightly controlled pharmacy networks also allow better tracking by manufacturers of drugs that require specific or complex dosing and lab monitoring, which the FDA sometimes requires as a condition of drug approval.⁴⁰ FDA monitoring requirements favor tightly controlled networks for safety reasons. Moreover, the Federal Trade Commission (FTC) favors narrow networks as a reasonable means of cost control. After the Centers for Medicare and Medicaid Services (CMS) proposed regulations for Medicare Part D drug plans that would prevent plan sponsors from using *preferred networks* (where

seniors would find lower costs), the FTC again warned the CMS in a comment letter that such regulations would drive up costs for taxpayers and consumers, saying:⁴¹

"The proposed any willing pharmacy provisions threaten the effectiveness of selective contracting with pharmacies as a tool for lowering costs. Requiring prescription drug plans to contract with any willing pharmacy would reduce the ability of plans to obtain price discounts based on the prospect of increased patient volume and thus impair the ability of prescription drug plans to negotiate the best prices with pharmacies. Evidence suggests that prescription drug prices are likely to rise if Prescription Drug Plans ("PDPs") are less able to assemble selective pharmacy networks."

Problem: Overregulation of Health and Drug Plans. As

preferred networks and exclusive pharmacy providers have become more common, so too have the calls for lawmakers to enact laws that restrict the ability of drug plans to partner with exclusive specialty networks. As a result, the losing bidders and firms who are locked out of the preferred networks argue for the increased regulation of drug plans in order to gain access to patients on specialty drugs. In other words, special interests want Congress and state legislatures to reduce the ability of drug plans to effectively negotiate for lower prices. Though these regulations are often claimed to benefit consumers and promote competition, they actually weaken health plans' ability to safely and efficiently manage prescription drug benefits. Trade associations for the excluded drug providers argue that expanded networks benefit patients. However, the parties that benefit the most from expanded networks are inefficient pharmacies that charge higher prices. Drug plan administrators say that unfettered competition will result in lower drug costs and greater efficiency. As one analyst concluded, "...the case for PBM regulations appears weak. The market for PBM services is highly competitive..."⁴²

State and federal laws can interfere with negotiations between drug plans, drug makers and pharmacies. Such consumer protection laws are actually costly to taxpayers, employers and patients.⁴³ Nearly two-thirds of the states have some type of *any willing provider* or freedom-of-choice regulations that apply to drug plans.⁴⁴ Nearly one-fourth of states have passed regulations specific to

drug plans.⁴⁵ Similarly, freedom-of-choice laws allow enrollees to fill a prescription at almost any pharmacy willing to abide by networks' contract terms, rather than requiring them to fill prescriptions at selected pharmacies, or use the drug plans' mail-order pharmacy.

When drug plans create pharmacy networks they negotiate for the lowest possible prices. Negotiated prices are the result of bargaining power — the ability of the drug plan to deny business to a firm if their bid isn't favorable.⁴⁶ Bargaining power also strengthens the ability of drug plans to demand quality-enhancing safeguards and patient protections. Unfortunately, any-willing-provider and freedom-of-choice laws reduce the drug plans' power to bargain for lower prices or better quality. This

occurs because any-willing-provider laws prevent health plan sponsors from selectively negotiating and contracting with pharmacies to create exclusive networks.⁴⁷ The Federal Trade Commission notes that these laws reduce bargaining power, which leads to higher drug prices and higher premiums.⁴⁸ The laws also protect less-efficient drug suppliers from competitive bidding to win the right to be included in a preferred network. Thus, any-willing-provider and freedom-of-choice laws typically benefit local pharmacies rather than consumers.⁴⁹

Laws that restrict PBMs from building exclusive networks increase the number of pharmacies for which claims must be adjudicated and paid, boosting administrative costs about 43 percent.⁵⁰ When plans are forced to

reimburse any drugstore that submits a claim, fraud becomes a possibility. Fraudulent drug stores might buy stolen identities or collaborate with dishonest enrollees to file claims for drugs not dispensed.⁵¹ Thus, the freedom to assemble and operate an exclusive provider network not only saves money on drugs, it also reduces overhead and aids in fraud control. [See the section below on *What is the Risk?*]

For health plan enrollees, there are trade-offs between cost and convenience.⁵² Smaller networks may require consumers to patronize a pharmacy a few miles out of their way, or force patients to fill prescriptions at a pharmacy other than one conveniently located inside their local grocery store. When properly designed, however, limited networks

Physicians and Specialty Care

Americans see their doctors more than a billion times each year.¹⁸ About two-thirds of visits to physicians' offices result in a prescription.¹⁹ An estimated 3.8 billion retail prescriptions were filled in 2011 — about 12 per person in the United States, on average.²⁰ As the use of advanced medications becomes more commonplace, physicians increasingly shoulder the added responsibilities that accompany prescribing and managing patients on specialty drug therapies.

In a recent survey, all of the physician specialists surveyed reported their practice treats patients using specialty drug therapy.²¹ Although their patients obtain their drugs from a variety of sources, about half (48 percent) obtain their medications either at a specialty pharmacy, an outpatient clinic or directly from their physician's office. Physicians who have patients on specialty drug regimens can knowledgeably evaluate the expertise and capabilities of the pharmacy providers their patients patronize. Two-thirds of physicians surveyed reported working with specialty pharmacies to obtain drug therapies for their patients. Although two-thirds of the physicians agreed that "some" traditional pharmacies are competent to handle and dispense specialty medication, three-fourths agree that "most" pharmacies do not possess the expertise and capability to manage complex drugs.²²

Cancer treatments are the most common specialty drug therapies prescribed to patients. One survey counted about 352 oncology drugs currently in development.²³ Doctors often treat autoimmune disorders such as rheumatoid arthritis and Crohn's disease with specialty drugs as well. Other conditions are multiple sclerosis, hepatitis C and HIV.²⁴ These conditions may be either life threatening or highly debilitating, and patients with these conditions must be closely monitored and their medications carefully handled.

Average Specialty Drug Prescription Health Plan Claim

Condition Treated	2012	2013
Inflammatory Conditions	\$2,212.73	\$2,551.10
Multiple Sclerosis	\$3,583.85	\$4,137.23
Cancer	\$3,682.32	\$4,023.18
HIV	\$947.56	\$1,029.45
Growth Deficiency	\$3,146.71	\$3,540.27
Miscellaneous Disorders		\$8,278.92
Respiratory Conditions	\$3,344.83	\$3,759.59
Anticoagulants	\$985.18	\$957.79
Transplant	\$286.34	\$292.64
Pulmonary Hypertension	\$3,748.39	\$3,759.14

Source: Express Scripts Drug Trends Report, 2012 and 2013.

counterfeit.⁵⁵ Unrestricted, broad pharmacy networks made it much easier for unscrupulous suppliers to sell counterfeit drugs on the gray market to providers willing to ignore warning signs in return for a lower price. As a pharmaceutical supply chain consultant Adam Fein explained:⁵⁶

“The supply chain for a specialty drug with a limited network is straightforward:

manufacturer→authorized distributor→medical practice. ANYTHING outside of that channel is diversion. In this case, the medical practices purchased from a non-authorized distributor, which had illegally imported the product from a non-authorized source (i.e., not the manufacturer), and so on. This process requires economically-motivated medical practices at the end of the supply chain.”

In other words, without providers willing to look the other way to obtain an expensive drug at bargain basement prices, there would be few opportunities for counterfeit drugs to enter the U.S. drug supply chain. Yet, they do.

A Canadian Internet pharmacy, CanadaDrugs.com, had a role in shipping fake cancer therapies to the United States. Canada Drugs mostly sold conventional drugs to American consumers, who were looking for prescription medications priced lower than they could buy domestically. After American drug makers cut off shipments to foreign-based “Internet” pharmacies, firms like Canada Drugs had to look elsewhere

provide lower prices and convenient access.

In May 2013, a consortium of more than 500 pharmacies filed suit in federal court to force the CMS to prohibit the use of exclusive pharmacy networks within the Medicare Part D drug program.⁵³ This regulation would have prohibited health and drug plans from creating *preferred networks*, including specialty pharmacy networks. And, in January 2014, CMS itself proposed a rule change that would have prohibited preferred networks.⁵⁴ But due to immense stakeholder pressure, the proposed rule was tabled.

What Is the Risk?

Specialty drug makers track their product shipments very carefully to ensure proper handling, and to prevent counterfeit drugs from making their way undetected onto pharmacy shelves. Regulations that prohibit drug plans from establishing preferred network providers for

specialty drugs make it more difficult to ensure the integrity of their networks. The larger the universe of entities that drug plans are legally required to reimburse for specialty drugs, the greater the likelihood that one of these firms could cut corners with drugs that have been mishandled, mislabeled — or are counterfeit.

Because specialty drugs are extremely costly, unethical medical (and drug) providers trying to boost their profit margin have a financial incentive to ignore warning signs that a product is suspect. Counterfeit versions of the cancer drug Avastin were able to enter the U.S. drug supply chain in 2012 mostly due to greed. According to analysis by the *Wall Street Journal*, 400-milligram vials of Avastin were sold by an unknown (unauthorized) supplier for \$1,995 — a 25 percent discount. A \$500 discount was enough to entice numerous providers to purchase the drugs, which later turned out to be

around the world for inventory. In the process they inadvertently supplied counterfeit drugs to American pharmacies and clinics who were willing to procure discounted drugs of unknown provenance with few questions asked.

In April 2012, federal authorities discovered that counterfeit versions of Avastin had entered the supply chain through a supplier controlled by Canada Drugs.⁵⁷ Seventy-six physicians in 22 states had unknowingly administered fake cancer drugs that entered the United States through a series of shady, gray market suppliers. The drugs were a complete fake — containing no active ingredient.⁵⁸

The FDA identified other bogus suppliers of the counterfeit Avastin.⁵⁹ For instance:

- Less than a year after uncovering the Canada Drug scam, the FDA warned doctors and clinics that another counterfeit version of Avastin — this time a similar but non-FDA approved drug made in Turkey, called Altuzan, was being misbranded as Avastin.⁶⁰
- In 2013, more than 1,200 Canadian cancer patients were jolted by the news that they had received diluted doses of chemotherapy.⁶¹
- In 2014, vials of the breast cancer drug, Herceptin, thought

to have been stolen in Italy, were discovered across Europe after medical personnel noticed the vials showed evidence of tampering. The vials either didn't contain the active ingredient or the drugs were diluted.⁶²

Counterfeit drugs are a huge and growing problem around the world. Counterfeits appear almost identical to real products — making detection all but impossible. One expert estimates that the counterfeit drug market is growing by 20 percent annually.⁶³ About half of drug expenditures worldwide are on American patients. This makes the U.S. drug market lucrative for drug

The Role of Drug Plans in Managing Complex Conditions

Health plans that provide drug benefits face enormous challenges. Drug prices often vary from one pharmacy to the next. Multiple drugs, with vastly different costs, may occupy the same therapeutic class. Plan sponsors must negotiate drug prices and dispensing fees with pharmacy networks, process claims and then reimburse for prescriptions filled by enrollees.²⁸ Rather than undertake the difficult task of implementing a drug plan themselves, health plan sponsors often employ firms that specialize in designing and managing drug benefits. These firms are called Pharmacy Benefit Managers (PBMs). Drug plan sponsors — including insurers, employers, Medicare Part D drug plans and many state Medicaid programs — hire PBMs because they can manage drug plans more efficiently than health plans. PBMs can also negotiate lower prices from drug manufacturers because they have multiple clients and, therefore, possess far more bargaining power than individual firms.

A health plan responsible for reimbursing health care providers has incentives to carefully manage chronic diseases, to analyze the effectiveness of the drugs and to track patient compliance.²⁹ Drug plans also check for drug interactions and inappropriate or duplicate prescriptions. Finally, drug plans assemble pharmacy networks, negotiate prices with drug makers, process payments and contract with mail-order pharmacies.³⁰

Enrollees in most drug plans obtain their drugs at local pharmacies or by mail order. But this is rarely the case with patients prescribed a specialty drug. Many specialty drugs are injectable, and are procured by a patient's doctor specifically for administration to that patient. In addition, specialty drugs require handling, storage by specialty pharmacies and patient monitoring. In some instances, specialty drugs are reimbursed as a medical benefit through the health plan rather than as a drug benefit through a drug plan.

counterfeiters.

Conclusion

Drug therapy can often successfully replace more expensive hospitalizations and surgical treatments. Increasingly, expensive specialty drugs are being used to treat complex illnesses that had few effective treatments in years past. However, restricting the ability of health plans to ensure safety, verify quality and hold down costs threatens patients' safety and consumers' wallets. Congress and state legislatures should avoid well-meaning, but ill-conceived regulations intended to protect

consumers, but which often have the opposite result. A better way to ensure desirable outcomes is to promote a competitive environment free of market distortions that favor one party over another.

Society is always better off when prices, profitability and services delivered are determined in a free market environment. Policymakers should authorize a process of competitive bidding among drug plan stakeholders in an atmosphere free of perverse regulations.

Open Networks: What Could Go Wrong?

What can go wrong when health plans are not allowed to restrict their networks to pharmacies they trust? Plenty! In a shocking case that occurred more than a decade ago, Kansas City pharmacist Robert Courtney was caught drastically diluting cancer drugs and other premixed intravenous (IV) drugs to boost his profit margin.⁶⁴ He diluted approximately 72 different kinds of drugs used to treat a variety of conditions. In addition to shortchanging patients on the amount of active ingredients in their prescriptions, Courtney also purchased drugs from illegal "gray market" sources and sometimes billed for products different than the drug dispensed.⁶⁵

Over the course of a dozen years beginning in 1990, he is thought to have diluted up to 98,000 prescriptions administered to 4,200 patients. When accusations reached authorities that his wholesale drug orders were lower than the volume of retail prescriptions his pharmacy filled, the FBI investigated. Of six prescriptions ordered on behalf of the FBI in the summer of 2001, all were diluted — ranging from less than half (39 percent) of the ordered dosage to only 17 percent of the prescribed dose. An attorney representing his victims estimated that each patient whose oncology regimen was diluted earned Courtney about \$50,000 in income. By the time he was caught, Courtney reportedly amassed a fortune worth an estimated \$18.7 million over the course of only a dozen years.⁶⁶

Endnotes

- ¹ Kevin Alder, “The Evolution of the Specialty Pharmacy Effectively Partnering for Persistence,” *PM360*, February 14, 2014. Available at <http://www.pm360online.com/the-evolution-of-the-specialty-pharmacy-effectively-partnering-for-persistence/>.
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The NCPA is a nonprofit, nonpartisan organization established in 1983. Its aim is to examine public policies in areas that have a significant impact on the lives of all Americans — retirement, health care, education, taxes, the economy, the environment — and to propose innovative, market-driven solutions. The NCPA seeks to unleash the power of ideas for positive change by identifying, encouraging and aggressively marketing the best scholarly research.

Health Care Policy.

The NCPA is probably best known for developing the concept of Health Savings Accounts (HSAs), previously known as Medical Savings Accounts (MSAs). NCPA President John C. Goodman is widely acknowledged (*Wall Street Journal*, WebMD and the *National Journal*) as the “Father of HSAs.” NCPA research, public education and briefings for members of Congress and the White House staff helped lead Congress to approve a pilot MSA program for small businesses and the self-employed in 1996 and to vote in 1997 to allow Medicare beneficiaries to have MSAs. In 2003, as part of Medicare reform, Congress and the President made HSAs available to all nonseniors, potentially revolutionizing the entire health care industry. HSAs now are potentially available to 250 million nonelderly Americans.

The NCPA outlined the concept of using federal tax credits to encourage private health insurance and helped formulate bipartisan proposals in both the Senate and the House. The NCPA and BlueCross BlueShield of Texas developed a plan to use money that federal, state and local governments now spend on indigent health care to help the poor purchase health insurance. The SPN Medicaid Exchange, an initiative of the NCPA for the State Policy Network, is identifying and sharing the best ideas for health care reform with researchers and policymakers in every state.

**NCPA President
John C. Goodman is called
the “Father of HSAs” by
The Wall Street Journal, WebMD
and the *National Journal*.**

Taxes & Economic Growth.

The NCPA helped shape the pro-growth approach to tax policy during the 1990s. A package of tax cuts designed by the NCPA and the U.S. Chamber of Commerce in 1991 became the core of the Contract with America in 1994. Three of the five proposals (capital gains tax cut, Roth IRA and eliminating the Social Security earnings penalty) became law. A fourth proposal — rolling back the tax on Social Security benefits — passed the House of Representatives in summer 2002. The NCPA’s proposal for an across-the-board tax cut became the centerpiece of President Bush’s tax cut proposals.

NCPA research demonstrates the benefits of shifting the tax burden on work and productive investment to consumption. An NCPA study by Boston University economist Laurence Kotlikoff analyzed three versions of a consumption tax: a flat tax, a value-added tax and a national sales tax. Based on this work, Dr. Goodman wrote a full-page editorial for *Forbes* (“A Kinder, Gentler Flat Tax”) advocating a version of the flat tax that is both progressive and fair.

A major NCPA study, “Wealth, Inheritance and the Estate Tax,” completely undermines the claim by proponents of the estate tax that it prevents the concentration of wealth in the hands of financial dynasties. Senate Majority Leader Bill Frist (R-TN) and Senator Jon Kyl (R-AZ) distributed a letter to their colleagues about the study. The NCPA recently won the Templeton Freedom Award for its study and report on Free Market Solutions. The report outlines an approach called Enterprise Programs that creates job opportunities for those who face the greatest challenges to employment.

Retirement Reform.

With a grant from the NCPA, economists at Texas A&M University developed a model to evaluate the future of Social Security and Medicare, working under the direction of Thomas R. Saving, who for years was one of two private-sector trustees of Social Security and Medicare.

The NCPA study, “Ten Steps to Baby Boomer Retirement,” shows that as 77 million baby boomers begin to retire, the nation’s institutions are totally unprepared. Promises made under Social Security, Medicare and Medicaid are inadequately funded. State and local institutions are not doing better — millions of government workers are discovering that their pensions are under-funded and local governments are retrenching on post-retirement health care promises.

Pension Reform.

Pension reforms signed into law include ideas to improve 401(k)s developed and proposed by the NCPA and the Brookings Institution. Among the NCPA/Brookings 401(k) reforms are automatic enrollment of employees into companies’ 401(k) plans, automatic contribution rate increases so that workers’ contributions grow with their wages, and better default investment options for workers who do not make an investment choice.

Environment & Energy.

The NCPA's E-Team is one of the largest collections of energy and environmental policy experts and scientists who believe that sound science, economic prosperity and protecting the environment are compatible. The team seeks to correct misinformation and promote sensible solutions to energy and environment problems. A pathbreaking 2001 NCPA study showed that the costs of the Kyoto agreement to reduce carbon emissions in developed countries would far exceed any benefits.

Educating the Next Generation.

The NCPA's Debate Central is the most comprehensive online site for free information for 400,000 U.S. high school debaters. In 2006, the site drew more than one million hits per month. Debate Central received the prestigious Templeton Freedom Prize for Student Outreach.

Promoting Ideas.

NCPA studies, ideas and experts are quoted frequently in news stories nationwide. Columns written by NCPA scholars appear regularly in national publications such as the *Wall Street Journal*, the *Washington Times*, *USA Today* and many other major-market daily newspapers, as well as on radio talk shows, on television public affairs programs, and in public policy newsletters. According to media figures from BurrellesLuce, more than 900,000 people daily read or hear about NCPA ideas and activities somewhere in the United States.

What Others Say About the NCPA



"The NCPA generates more analysis per dollar than any think tank in the country. It does an amazingly good job of going out and finding the right things and talking about them in intelligent ways."

Newt Gingrich, former Speaker of the U.S. House of Representatives



"We know what works. It's what the NCPA talks about: limited government, economic freedom; things like Health Savings Accounts. These things work, allowing people choices. We've seen how this created America."

John Stossel,
host of "Stossel," Fox Business Network



"I don't know of any organization in America that produces better ideas with less money than the NCPA."

Phil Gramm,
former U.S. Senator



"Thank you . . . for advocating such radical causes as balanced budgets, limited government and tax reform, and to be able to try and bring power back to the people."

Tommy Thompson,
former Secretary of Health and Human Services