INSIDE:
PBM Are Getting Picky: The Rise of Formulary Exclusions

PLUS: Q&A with Express Scripts
Chief Medical Officer
Steve Miller, MD, to Pharma: Just Talk to Us

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Pharmacy Steps Into the Limelight
By Peter Wehrwein

Only a tiny fraction of Americans could tell you what PBM stands for, and probably an even tinier number could tell you what PBMs do. Even people who work in health care are foggy about them. Steve Miller, MD, the chief medical officer for Express Scripts, jokes that he didn’t even know how to spell PBM when he took the job 10 years ago.

Times are changing. Express Scripts has been in the news with its coverage decisions, particularly with respect to hepatitis C drugs. Our cover story, by Robert Calandra, examines the clout of PBMs and what’s behind it. Part of the explanation is the power in numbers that has come with the consolidation of PBMs. In these data-drenched times, large numbers are more important than ever, especially in health care.

We went deep on PBMs this issue. Thomas Reinke has a piece about exclusionary formularies. And we pick Miller’s brain a little in a Q&A. He was a good interview: talkative, relatively unguarded, willing to share some details. Whatever you may think of Miller (and Express Scripts), he’s a force to be reckoned with.

But PBMs are not the only big story in pharmacy. The FDA has, at long last, approved the first biosimilar, and our story explores the obstacles ahead for these medications. Our biosimilar tip of the day: Keep your eye on interchangeability and how that plays out. We’ve also got a piece about orphan drugs by Krishna Patel in this issue. Her takeaway for formulary decision makers is to stick to the label and the guidelines.

Pharmacy sometimes gets overshadowed in American health care. Not now, though. It’s where the action is. And we’re looking forward to providing readers with insights about a crucial sector of the health care system, not just in this issue but in the many ahead.

VISIT US IN SAN DIEGO! Managed Care Publisher Maureen Dwyer Liberti will be attending the Academy of Managed Care Pharmacy’s 27th Annual Meeting & Expo from April 7 to 10. We’d love to see you at Booth 126.
TRACKING PHARMACY’S MANY MOVES

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Their ability to shape all aspects of the pharmacy marketplace keeps growing. Size and the specialty drug spend have turned them from mere middlemen to major players.

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He has been called “cost-fighting ninja” and someone pharma fears. He says he is just a concerned clinician worried about price and access.

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Patients are willing to pay nearly $67 for a product that improves sleep onset latency by 10 minutes, reduces wake time after sleep onset by 15 minutes, and improves total sleep time by an hour.

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The digital edition does not contain some of the advertising pages that appear in the print edition.
Narcolepsy is an often misdiagnosed,12-14 incurable,7,15 chronic and potentially disabling neurologic disorder,7-9 and is associated with high medical comorbidity burdens16 and reduced daily function.8,11 Narcolepsy has also been shown to have substantial socioeconomic burden3,6 resulting from increased healthcare resource utilization1,2 and lower work productivity2 relative to those without narcolepsy.

For more information about narcolepsy, please contact your Jazz Pharmaceuticals Account Manager.

References:
2. Wla KF, Black J, Chenkin RD, Flinnen NM, Witt EA. Resource use, productivity loss, and economic burden of narcolepsy: Results from the National Health and Wellness Survey. Poster presented at: Academy of Managed Care Pharmacy 2014 Nexus; October 7-10, 2014; Boston, MA. Poster G-16.
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Independence Blue Cross

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West Chester, Pa.

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Health Intelligence Partners
Chicago, Ill.

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Greenville, S.C.

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Professor and Director of the Center for Population Health
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Bloomberg School of Public Health
Baltimore, Md.
Getting the Most Out of Formularies Involves a Bit of Economic Training

For those who ever struggled with math, Dan Danielson, MS, RPh, of Premera Blue Cross, feels your pain. What Danielson doesn’t want, however, is for patients to feel any unnecessary pain if pharmacy directors at health plans exclude a medication from a formulary (or place it on a more expensive tier) because of faulty economic equations.

Danielson, who manages Premera’s value-based formulary, is scheduled to make a presentation at the annual meeting of the Academy of Managed Care Pharmacy (AMCP) in San Diego this month. The title: “Pharmaco-economic Modeling: Applying Value to Formulary Management.”

One of the challenges newly minted medical and pharmacy directors at health plans face is that, for the most part, they’ve gotten only a smattering of economic education. When it comes to weighing the costs and benefits of certain treatments, “the math gets pretty intense,” Danielson tells Managed Care. “They might not be able to do it, but they can understand it.”

Pharmacy directors need to be able to weigh the economic effects of their decisions in light of what’s taking place in the entire health care system, not just their budget. Here’s the thing—they can do it.

“Much of what they need to be good consumers of economic information, they already have—that is skills in medical literature evaluation and clinical common sense and healthy skepticism” says Danielson. “Most managed care leaders lack familiarity with the language used in health economics, which makes it hard to apply the skills they already have.”

Fortunately, they can be introduced to this new language for a small investment in time and money. Danielson cites courses offered by AMCP, the University of Washington, and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Danielson’s presentation (which he is giving along with John Watkins, PharmD, Premera’s formulary manager, and Kai Yeung, the insurer’s independent program reviewer) will feature case studies of how Premera handles the pharmacy management for its own employees.

They’ll discuss how Premera uses an incremental cost–benefit ratio to help define the economic implications in an environment in which breakthrough biologic medications (as well as advances in classic chemical-based drugs) guarantee that a blockbuster is always in the pipeline.

Last days getting harder for patients

Dying is hard and it might be getting harder despite the efforts to improve end-of-life care, says a study published in the Annals of Internal Medicine. The study looks at about 7,200 people, ages 51 or older, who died between 1998 and 2010, and asked a proxy (usually a family member) if the patient had one of these eight symptoms: pain, depression, periodic confusion, dyspnea, severe fatigue, incontinence, anorexia, or frequent vomiting.

Pain, depression, and periodic confusion grew at an alarming rate, say the Rand researchers who conducted the study. They point out that hospice may not be used enough. “Hospice is often ‘tacked on’ to this more intense late-life care: Although hospice use doubled from 2000 to 2009, the median stay is less than three weeks.”

Pain, depression, periodic confusion worsen at end of life

<table>
<thead>
<tr>
<th>Prevalence (%)</th>
<th>Whole population*</th>
<th>Whole population</th>
<th>CHF and/or chronic lung disease</th>
<th>CHF and/or chronic lung disease</th>
<th>Frailty</th>
<th>Frailty</th>
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<td>Pain</td>
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<td>1998</td>
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<td>2010</td>
<td>61</td>
<td>57</td>
<td>54</td>
<td>54</td>
<td>69</td>
<td>83</td>
</tr>
</tbody>
</table>

*Means the 7,200 people included in the study.
Danielson wants to show pharmacy directors how to review product dossiers and manufacturer-provided cost-effectiveness analyses. Does the model reflect what really happens in a provider's office? Do the quality-of-life implications, as described, make sense? Are there items left out, hidden, or inappropriately de-emphasized?

“What we're really talking about is how we at Premera put this together,” says Danielson. The team will discuss how they developed Premera’s approach to weighing treatments for hepatitis C. How they compared Incivek and Victrelis to the new kids on the block, Sovaldi and Olysio, and now how they’re comparing Sovaldi and Olysio to the even newer kids on the block, Harvoni and Viekira Pak.

“Our main purpose is to try to make value assessment less foreign to managed care leaders,” says Danielson.

Chronic Fatigue Gets New Name, Emphasis

Among many providers, chronic fatigue syndrome (CFS) gets no respect, but the Institute of Medicine (IOM) hopes that “systemic exertion intolerance disease” (SEID) will.

That’s the new name the IOM gives CFS—actually called myalgic encephalomyelitis/chronic disease syndrome (ME/CFS), because myalgic encephalomyelitis is the name used outside of the United States.

Why the name change? Because chronic fatigue syndrome perpetuates the belief among many physicians that the condition is psychogenic. Meanwhile, myalgic encephalomyelitis doesn’t work because there is a lack of evidence for encephalomyelitis, or brain inflammation, in many patients.

It is a real disease that needs to be cared for, says the 235-page report. IOM notes that SEID affects between 830,000 to 2.5 million Americans. The total economic costs range from $17 billion to $24 billion annually.

“Many health care providers are skeptical about the seriousness of ME/CFS, mistake it for a mental health condition, or consider it a figment of the patient’s imagination,” the IOM states.

That stops now—hopefully. The IOM wants to disseminate new diagnostic criteria to providers and the public. Here are some symptoms of SEID:

- An inability to throw oneself into occupational, educational, social, or personal activities with the same energy as before and that malaise persists for more than six months; profound fatigue of new or definite onset (not lifelong) and that is not the result of ongoing excessive exertion and is not substantially alleviated by rest
- Postexertional malaise, often described by patients as a crash or collapse after even minor physical or mental exertion
- Unrefreshing sleep
- Cognitive impairment and/or orthostatic intolerance

Other symptoms, such as gastrointestinal problems or sore throat, had been exhibited in SEID patients, but were not common enough to be included in the new diagnostic criteria.

The diagnosis is made if the patient exhibits these symptoms at least half the time, with moderate, substantial, or severe intensity. This is also not, the IOM says, a “diagnosis of exclusion” and could be applied to patients who have other conditions that could give them fatigue.

Often physicians attributed SEID to the poor physical conditions of their patients. The IOM, however, notes that some people who have come down with SEID are in great shape, and even some athletes are cut down by the disease.

The IOM warns against physicians doing the expensive testing for SEID that had been done in some studies, noting that many of those tests are onerous and not always available.

“It has therapeutic value but I prefer to prescribe it for recreational use.”
SEID. The amount of evidence available to understand subgroups of people with the disease is still limited. The IOM hopes its report will generate more studies, and it plans to revisit the issue in about five years.

**Too Many Americans Not Taking Their Meds**

Poverty rates and insurance coverage (or lack of it) heavily influence whether adults take their medications as prescribed, according to a study by the CDC’s National Center for Health Statistics.

Nearly 1 in 10 Americans do not adhere to the pharmaceutical regimen that best addresses their needs, according to government researchers.

About 6% of adults younger than 64 who had private insurance skipped medications to save money; for those covered by Medicaid the proportion was 10.4%; and for the uninsured, 14%. Researchers used data from the 2013 National Health Interview.

“Lack of health insurance coverage and poverty are recognized risk factors for not taking medications as prescribed due to cost,” the study states.

About 8% of adults do not take their drugs and 15% ask for something that costs less. In addition, 1.6% bought prescriptions from another country, and 4.3% used alternative medicines.

These trends are even greater among the most economically disadvantaged adults. For instance, among adults ages 18 to 64 with incomes of 139% of the federal poverty level (FPL) or lower—the cutoff in most states for Medicaid eligibility—the percentage who asked their doctors for a lower-cost medication to save money rose to more than 17%.

For adults 65 and older, the share who asked for a lower-cost medication increased from 15% among those making below 139% FPL to 21% among those with incomes from 139% to 250% FPL.

Adults 65 and older who are covered by private insurance were less likely than any other group to not take their medication as prescribed. Just 4% of that group are nonadherent.

**LETTER TO THE EDITOR**

In your February issue, Weiss et al. constructed an economic model to evaluate whether the use of a naloxone injector would be cost effective. Their conclusion, including the use of their sensitivity analysis, was that there was a net savings of dollars and lives. However, the study, written by the device/drug manufacturer, is flawed and biased. Its key assumptions that make the drug cost-effective are based completely on an unfounded assumption (the authors state no data exists to support it) that the utilization of resources, and lives lost, will be 75% of the control group.

The validity, and therefore usefulness of a model is dependent on the assumptions being reasonable and verifiable. The authors choose to consider nonbase case analyses by considering only cases when resource use decreases or overdose rates increase. Where was the analysis showing worst-case results?

If the authors reply to this letter, an analysis showing results that are not as favorable (i.e. what if hospital costs only decrease by 5%) as well as threshold analysis showing the point at which the item’s costs exceed the benefits, would be useful.

*Lorne Basskin, PharmD
Pharmacoeconomic consultant
Asheville, N.C.*

**Author’s Reply**

The authors thank Dr. Basskin for his response. Finding solutions to the public health crisis of morbidity and mortality from opioid overdose and the ensuing utilization of health care resources can only benefit from the participation of as many interested parties as possible.

The authors believe that this is the first analysis of its kind and agree with Dr. Basskin that a more robust base of data for the assumptions would be highly desirable. It should be noted that the assumptions on cost savings and overdose rates resulted in a net increase in costs when drug acquisition costs were taken into account. In the sensitivity analysis, the potential break even point (drug acquisition cost equal to resource cost savings) is based on both assumed rates of cost avoidance and overdose rates. Worst-case results (maximum incremental cost) are equal to the drug acquisition costs in Table 4, assuming no reduction in medical resource utilization. The model uses known costs of treating opioid poisoning and cardiovascular events.

The authors note that the lack of real-world data on cost savings is a limitation of the study and that further study is required to determine the extent of these savings. It is proven that use of naloxone in opioid overdose events saves lives and it is a safe assumption that early use will prevent a certain number of high cost events (e.g. respiratory depression events leading to cardiac arrest or hospitalization requiring intensive care).

Studies in the heroin-using population have demonstrated cost-effectiveness as a result of early intervention in the community setting.

Additionally, usability studies supporting the FDA-approved new indication and labeling for NAI (naloxone autoinjector) demonstrated that even individuals with limited to no training can administer NAI correctly.

Therefore, the increased likelihood of naloxone administration provided by NAI following an opioid overdose event will likely result in cost offsets as fewer patients would advance to more serious stages of opioid poisoning.

The cost of NAI, which was estimated based on a cohort of appropriate at-risk patients, must be balanced against these savings in health resource utilization.

*Richard C. Weiss, MS
Managed Solutions LLC
Mt. Freedom, N.J.*
The effect of people using alternative medicine or buying their drugs abroad is unknown, say researchers. They also note that differences in cost-saving strategies by insurance coverage may be interrelated with socioeconomic and other patient characteristics.

Transplant Study Runs Out of Data
A study about the benefits of organ transplantation made headlines recently when researchers calculated that such procedures added more than 2 million years of life over 25 years.

Researchers, who hailed from numerous universities, tracked about 530,000 organ transplant recipients between 1987 and 2012, and another 580,000 people who had been placed on waiting lists but never got an organ.

The study, which the authors rightly describe as immense, is not only unprecedented, it might not ever be duplicated because of public policy. The two sources for data were the United Network for Organ Sharing (UNOS) registry, and the Social Security Administration Death File, without which “our analysis would have been crippled by the significant number of patients lost to UNOS follow-up.”

On Jan. 1, 2013, the Social Security Administration stopped sharing its data with UNOS because of patient privacy concerns. Researchers hope that the study, which ended the day before (Dec. 31, 2012), shows just how essential the death file is “to the complete analysis of post-transplant survival.”

The study is not yet complete. Many of the organ recipients are still alive, so the life-years saved will be larger than 2 million.

This is certainly not an area of research to be abandoned, the authors argue. Just look at the number of life-years saved: kidney, 1.3 million; liver, about 460,000; heart, nearly 270,000; lung, about 65,000; pancreas-kidney, almost 80,000; pancreas, just under 15,000; intestine, about 4,500.

Heart transplant patients have seen a large increase in survival, partly because of the invention of artificial devices that improve the chance of survival for those on the waiting list.

Doctor Shortage Includes Specialists
There’s going to be a shortage of between 46,000 and 90,000 physicians by 2025, and much of that deficit will be seen in specialties, according to the Association of American Medical Colleges (AAMC). The demand for nonprimary care physicians—including psychiatrists, oncologists, neurologists, and others—will range from 28,200 to 63,700, according to the study. The projected shortage of primary care physicians has been much in the news in recent years, and the AAMC doesn’t do anything to squelch that concern. It estimates a shortfall of between 12,500 to 31,000 PCPs, according to data collected by the consulting company IHS.

The spreads represent the best- and worst-case scenarios, reflecting “comparisons of all the supply scenarios to all the demand scenarios, and uses the 25th to 75th percentiles of projected shortages across the comparisons.”

The lower-end projections partly reflect the growing numbers of advanced practice nurses and “the increased roles these clinicians are playing in patient care delivery.”

The AAMC wants Congress to allocate $1 billion more a year to fund 3,000 more medical residencies annually at teaching hospitals.

Briefly Noted
Hospitals could utilize primary care physicians (PCPs) as one way to give patients more personalized care, says a study in the New England Journal of Medicine. The PCPs would help alleviate the strain on hospitalists by visiting patients within 12 to 18 hours after admission. Maintaining stage 1 meaningful use standards can be expensive, which is why physician practices with inadequate funds have a difficult time getting government bonus money, according to a study in the Annals of Family Medicine. Rural practices, in particular, are struggling with meaningful use requirements.

More physician practices are using electronic medical records, coordinating with pharmacies, installing clinical decision-support processes, measuring quality of care, and allowing patients online access to their records—all elements of the patient-centered medical home. A study in Health Affairs says that the practices want to do a better job of caring for patients with chronic conditions.

— Frank Diamond

Managed Care Contributor Wins AHCJ Award
Richard Mark Kirkner has been a contributor to Managed Care since 2009 and, recently, he’s contributed an honor. The Association of Health Care Journalists has awarded Rich third place for Best Article—Trade Category. His article, “Rush to Robotic Surgery Outpaces Medical Evidence, Critics Say,” (Managed Care, May 2014; tinyurl.com/mcm-robotic) points out that there’s no clinical evidence that robotic surgery produces better outcomes. Rich, who resides in Phoenixville, Pa., has more than two decades of health care writing and editing experience.
Orphans knocking on the door

Of the 41 new molecular entities approved by the FDA last year, 17 (41%) were orphan drugs. There’s every indication that the trend will continue. That’s good news not only for the pharmaceutical companies but also for formulary decision makers at health insurers and PBMs.

An orphan drug treats a rare disease, which is defined in the statute that set up the orphan drug approval process as a condition that affects fewer than 200,000 Americans. About 6,800 rare diseases have been identified affecting a total of roughly 30 million people. That typically translates into only a few members in a health plan being affected by an orphan disease, and fewer still being treated with any particular orphan drug.

Number of approved new molecular entities with orphan designation

The number of orphan drugs entering the market is increasing for two basic reasons. The pharmaceutical industry has turned to niche conditions because the marketplace for medications that treat the common ones is crowded and under downward price pressure as a result of generics. Second, the incentives of the Orphan Drug Act—a minimum of seven years of market exclusivity, for example—are working.

How should formulary decision makers react to all these orphans on their doorstep? One thing they should not do is impose onerous restrictions that go beyond the label or guidelines for orphan drugs. The Arkansas Medicaid program tried to restrict access to ivacaftor (Kalydeco), the cystic fibrosis drug with an annual price of about $300,000. The program was forced to reverse its policy after front-page coverage in the Wall Street Journal and a patient lawsuit.

Payers are concerned, as they should be, about high-priced drugs like ivacaftor. But ivacaftor is indicated only for a small subset of cystic fibrosis patients (although the FDA has been broadening the indications).

To make sound formulary decisions, it is important to understand the disease, how many members have the diagnosis, and which of those members are appropriate candidates for the drug. Formulary decision makers need to strike the right balance between restricting access (e.g., prior authorization) and encouraging drug prescriptions. Many people with orphan conditions are high utilizers of health care. When orphan drugs have the potential to lower utilization and therefore cost, formulary decision makers should not only provide access but encourage providers to prescribe the drugs.

2014 orphan drug approvals

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<tr>
<th>Drug Name</th>
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<td>Beleodaq (belinostat)</td>
<td>Peripheral T-cell lymphoma</td>
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<td>Blinicyto (blinatumomab)</td>
<td>Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia</td>
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<tr>
<td>Cerdelga (eliglustat)</td>
<td>Type 1 form of Gaucher disease</td>
</tr>
<tr>
<td>Cyramza (ramucirumab)</td>
<td>Advanced stomach cancer/gastro-esophageal junction adenocarcinoma</td>
</tr>
<tr>
<td>Esbriet (pirefridone)</td>
<td>Idiopathic pulmonary fibrosis</td>
</tr>
<tr>
<td>Hetlioz (tasimelteon)</td>
<td>Non-24-hour sleep-wake disorder in totally blind individuals</td>
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<tr>
<td>Impavido (miltelisone)</td>
<td>Leishmaniasis</td>
</tr>
<tr>
<td>Keytruda (pembrolizumab)</td>
<td>Unresectable/advanced melanoma</td>
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<td>Lynparza (olaparib)</td>
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<td>Myalept (metoleptin)</td>
<td>Complications of leptin deficiency</td>
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<td>Northern (dorodopa)</td>
<td>Neurogenic orthostatic hypotension</td>
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<td>Ofev (nintedanib)</td>
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<td>Opdivo (nivolumab)</td>
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<td>Sylvest (situximab)</td>
<td>Multicentric Castleman’s disease (rare disorder similar to lymphoma)</td>
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<td>Vimizim (elosulfase alfa)</td>
<td>Mucopolysaccharidosis Type IVA (Morquio A syndrome)</td>
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</tr>
</tbody>
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When it started more than 20 years ago, the 340B prescription drug discount program sought to ensure that safety net hospitals could dispense brand-name drugs to low-income patients. Today, critics accuse some participating hospitals of using the program to boost profits—perhaps at the expense of health plans and pharmacy benefit managers.

What began as a well-intended program has become a textbook example of unintended consequences. Some hospitals, clinics, and health systems are buying drugs at a deep discount through a network of contract pharmacies—sometimes collecting manufacturers’ rebates on top of the discounts—then dispensing them to Medicare beneficiaries and privately insured patients and billing for them at their full price. A lack of oversight makes the situation worse; Congress has never given the agency that runs 340B the power to write clear guidelines on who exactly should get these drugs and what providers should do with the savings.

Only government-run or not-for-profit hospitals and related health care entities may participate in 340B, which was created to induce drug manufacturers to give these providers discounts on outpatient drugs prescribed to uninsured and low-income patients. Originally, 340B drugs were not intended for Medicaid patients and were exempted from federally mandated manufacturer rebates to state Medicaid agencies.

Today the potential to double-dip on discounts and rebates for 340B drugs is rampant. That was never the intention, explains Ellyn Sternfield, a health care attorney in Washington who blogs about 340B. But now Medicaid duplicate drug discounts play a big role in 340B operations and oversight, she says.

How did we get here? Think of it as a version of the shell game. The more hands that move the drugs around, the more difficult accountability becomes. Over time, more hospitals and other types of organizations participated in 340B, extending their purchasing power to owned-and-operated satellite facilities, such as outpatient clinics. By 2011, the number of covered sites had nearly doubled over 10 years to 16,500. These sites were affiliated with 3,200 hospitals and other entities, meaning that each organization had about five facilities that participate in 340B.

Then, in 2010, the Health Resources and Services Administration (HRSA), the federal agency that oversees 340B, made a significant change to 340B. It allowed participating organizations to use multiple contract pharmacies to fill 340B prescriptions. That drew more pharmacies into the program. “Once that happened, there was an explosion of very entrepreneurial, savvy individuals who figured out ways to profit from this system,” says Adam Fein, PhD, a Philadelphia-based pharmaceutical consultant.

Adding fuel to the fire, HRSA decided it would not require independent audits of the contract pharmacy arrangements. The upshot was more providers, more contract pharmacies, more drugs—and less oversight. According to a report by the Office of Inspector General, the number of 340B organizations that use contract pharmacies more than doubled between 2010 and 2014, and the number of 340B pharmacies exploded by 770%. An analysis by Fein on his DrugChannels.net blog estimated that 1 in 4 pharmacies participate in 340B.

Out of control
All of this gives the appearance of a program spinning out of control. In reality, however, a very small number of entities are taking advantage of the lack of regulation and lack of oversight in this program, according to Fein. Last year, he did a small study that found only about 300 covered entities accounted for nearly half of all pharmacy contracts, and some used networks with almost 300 pharmacies.

The evidence of 340B problems has been
mounting. The Government Accountability Office (GAO) reported in 2011 that among 340B organizations it investigateded, most of them generated “more 340B revenue from patients with private insurance and Medicare compared to other payers.” Two years later, Iowa Sen. Chuck Grassley conducted an investigation of three North Carolina health systems. At one, Duke University, only 5% of the patients who received discounted drugs were uninsured, Grassley found.

His findings, Grassley wrote in a letter to HRSA, “paint a very stark picture of how hospitals are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread.”

A study published in Health Affairs in October 2014 analyzed 340B billings for 960 hospitals and almost 4,000 affiliated clinics, and found that those that joined the program after 2004 were wealthier with higher rates of insured patients than those that joined 340B before 2004. “Our findings support the criticism that the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics,” the authors wrote.

HRSA’s own audits have uncovered evidence of contract pharmacies getting the Medicaid rebate and 340B discount on the same prescription.

Fein, the Philadelphia-based consultant, calls it “a veiled form of money laundering.” He explains the 340B money trail: “The PBM reimburses 340B and non-340B prescriptions at the same rate, regardless of the pharmacy. When using a contract pharmacy, the 340B organization gets the difference between the amount the PBM pays the pharmacy and the 340B discount price. “And the covered entities are getting some portion of those prescriptions and extracting an extra discount that the plan sponsor and PBM don’t have access to,” he says.

Problems with 340B trace back to two issues: Participating organizations broadly interpret the rules on who is entitled to the drugs, compounded by a complete lack of accountability. “If the 340B drug prices were public, other entities would be asking for those prices. The program was built with no transparency as a sort of promise to the drug manufacturers,” says Sternfield, the Washington attorney.

Fein explains why health plans and PBMs should pay attention to what’s happening with 340B: “There’s the potential for large cost shifting to pharmacy benefit managers and their plan-sponsored clients.”

Samir Mistry, PharmD, the pharmacy practice leader for Optimity Advisors, explains how 340B dysfunction affects health plans and PBMs. “If payers are paying the PBM a contracted discount rate for branded medications and then discover that these 340B pharmacies are buying drugs at 50% to 60% to 70% off of the average wholesale price, making deeper margins than the average pharmacy, they’re definitely paying too much for the medications,” he says.

“There has to be a level of fair play” when PBMs set rates with a pharmacy for branded drugs, Mistry says. “But in this case, the payers are now thinking that there are certain pharmacies that are 340B that are keeping more money than the average pharmacy should, and is that appropriate especially if the savings are not going to the right person?”

What’s the fix?
The program needs an overhaul, either by legislative or regulatory action, but Sternfield holds out little hope for the former. “There’s been a lot of lobbying in Congress—that’s one fix, an amendment that 340B pricing is only available for uninsured individuals,” she says. “But I don’t know if that genie is going back in the bottle.”

HRSA will take the rare step of inviting public comment on new “omnibus guidelines” it aims to release in mid-year in an attempt to fix the program. HRSA will define eligible individuals and hospitals and will cover topics related to contract pharmacies, recertification audits, and receipt of duplicate discounts. Those “guidelines” will be just that; they lack the teeth of regulations because Congress has never given HRSA regulatory authority.

The comment period would be an opportunity for health plans and PBMs to chime in. “The managed care industry urgently needs to focus on this topic and figure out how it can positively influence change in this program so that it benefits patients without undermining the Medicare and commercial insurance systems,” says Fein.
The FDA’s approval of the first U.S. biosimilar last month was a watershed event, resolving many questions about how the federal government agency is going to handle the approval process for biosimilars. But Sandoz’s Zarxio and other biosimilars still to come have an obstacle course ahead of them.

Zarxio’s immediate problem is a patent dispute with Amgen, the maker of the reference biologic it copies, Neupogen. The enabling legislation for biosimilars specifies an elaborate information-sharing process, nicknamed the “patent dance,” intended to prevent patent disputes.

It hasn’t worked out that way. In October 2014, Amgen filed a complaint in U.S. District Court in California alleging that Sandoz failed to follow the required dance steps and provide proper notice about its biosimilar application. That back and forth went on until two months ago, when Amgen filed a motion for an injunction to prevent Sandoz’s launch of Zarxio. A hearing for the injunction was scheduled for mid-March as this article went to press.

The legal maneuvering appears to be focused on the merits of an injunction rather than the more important issue of whether the courts will affirm the patent dance as the correct process for resolving legal disputes involving biosimilars.

“Patent disputes are a daily event in the pharmaceutical industry,” says Kurt Karst, JD, at Hyman, Phelps, & McNamara. “The issue here is whether the patent dance is the mandatory process for resolving disputes or if it is permissive.” The legal action so far is not going to be the last word, in Karst’s view, no matter what the court decides. Future biosimilars are also certain to face additional legal challenges, he says.

Profitability in doubt
Health plans and employers have lobbied for biosimilars for years, saying that high-cost biotech drugs with expired patents should face lower-cost competition, mimicking the process for generic drugs. A 2014 Rand analysis predicts that biosimilars will reduce U.S. spending on biologics $44.2 billion through 2024, about 4% of total biologics expenditures. The Rand analysts estimated that the actual savings could range from $13 billion to $66 billion, depending on how FDA regulations unfold and the number of biosimilars that come to market.

It’s increasingly difficult to estimate the economic impact of biosimilars. Much will depend on market penetration, which hinges on how many products are brought to market. A new analysis by Prime Therapeutics predicts that the only biosimilars to be profitable will be those that compete with blockbuster and near-blockbuster reference biologics. The report estimates which biosimilars would exceed their development and marketing costs. In the most likely scenario, a biosimilar will be profitable only when average annual sales of its reference biologic exceed $898 million.

Buy-and-bill affects marketing
Biosimilars are already successful in Europe, where national health systems are the payers. In fact, in Eastern Europe, some biosimilars have totally replaced brand-name biologics.

<table>
<thead>
<tr>
<th>Manufacturer (product)</th>
<th>Active ingredient</th>
<th>Reference product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandoz (Zarxio)*</td>
<td>filgrastim</td>
<td>Neupogen (Amgen)</td>
</tr>
<tr>
<td>Celltrion</td>
<td>infliximab</td>
<td>Remicade (Johnson &amp; Johnson)</td>
</tr>
<tr>
<td>Apotex</td>
<td>pegfilgrastim</td>
<td>Neulasta (Amgen)</td>
</tr>
<tr>
<td>Apotex</td>
<td>filgrastim</td>
<td>Neupogen (Amgen)</td>
</tr>
<tr>
<td>Hospira</td>
<td>epoetin alfa</td>
<td>Epogen (Amgen) and Procrit (Johnson &amp; Johnson)</td>
</tr>
</tbody>
</table>

*FDA approval announced on March 6, 2015
In the United States, the success of biosimilars will be heavily dependent upon the distribution channel. “The majority of the first biosimilars will not be managed by PBMs or sold through retail pharmacies, so their success will depend on the marketing and detailing,” says Gillian Woollett, a senior vice president at Avalere Health.

Zarxio falls into this category; in much of the market, it falls under the medical benefit, allowing providers to buy and bill for it. That means the market share it grabs from Neupogen—and its price—will depend on the negotiating leverage and clinical acceptance of hospitals, infusion centers, and physician practices. As the provider sector is so fragmented with limited negotiating leverage and variable practice patterns, the commercial success of Zarxio is uncertain.

Especially in the early going, the commercial success of biosimilars may hinge on physician attitudes. “Physicians are afraid of biosimilars, but when you ask them why, most can’t tell you,” says Robert Rifkin, MD, a practicing oncologist and medical director of biosimilars with McKesson Specialty Health and the US Oncology Network. In his opinion, physicians do not fully understand biosimilars: “Everyone wants more evidence and asks, ‘Where are the clinical trials?’” Randomized controlled trials remain the gold standard in the eyes of physicians, but the biosimilar approval pathway does not primarily rely upon that kind of clinical data.

“Clinical data are not the basis for determining biosimilarity; the criterion is analytic high similarity,” Woollett says. “A head-to-head comparison of the applicant to the reference product using state-of-the-art analysis of multiple structural and functional characteristics establishes biosimilarity and is also the basis for extrapolation.”

This head-to-head comparison is so important the FDA says there is no formal requirement for clinical studies. The need for clinical studies is determined by the FDA after the applicant presents its head-to-head comparison, notes Woollett: “If they can’t show high similarity there, then their candidate can’t be a biosimilar.”

“In theory, you can get approval for a biosimilar without ever treating a patient if you take the FDA’s guidance about the importance of analytics to the extreme,” says Rifkin.

Another factor that will play a role in the success of biosimilars is the type of approval granted by the FDA. The FDA can approve biosimilar applicants as either biosimilar or interchangeable. Biosimilars must be highly similar to the reference product, without any meaningful clinical differences.

An interchangeable biologic must meet the requirements for approval as a biosimilar but also have evidence behind it that shows that the safety and efficacy of alternating between it and the reference drug is the same or better than just taking the reference drug.

The FDA wants an additional human clinical trial as part of the requirements for approval as an interchangeable biosimilar. That study is expected to be a clinical switching study involving the reference product and the biosimilar. Although Zarxio was approved as a biosimilar, Sandoz has already completed a switching study of it. The FDA asked Sandoz to apply just for biosimilar status because biosimilars are new, and the agency wants to proceed cautiously.

Generic drugs are identical to their brand-name counterparts, and many states have laws that either require or permit pharmacists to substitute with a generic medication unless the prescriber indicates “do not substitute.”

A biologic that is approved as a biosimilar may not be substituted automatically for its reference product. An interchangeable biosimilar may be substituted, depending on state law. As of September 2014, eight states had biosimilar substitution laws.

What’s in a name? A lot
The FDA has yet to establish a policy for naming biosimilars. The active ingredient in Neupogen is filgrastim. For Zarxio, the FDA assigned “filgrastim-sndz” as a “placeholder nonproprietary name” for its active ingredient.

The naming convention for biosimilars is critical to their success. Because biosimilars are only highly similar to their reference products, the manufacturers of original biologics want to prevent biosimilar manufacturers from using the same product name. Likewise, if the same product name is assigned to the biosimilar, it will enhance the perception among prescribers and patients that the biosimilar is the same product as the original biologic. The FDA says it intends to resolve this issue soon.
Depression (cont’d): for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.

- Weight Decrease: Body weight loss of 5-10% occurred in 12/25 (96.784) of patients treated with Otezla and in 5/25 (19.382) of patients treated with placebo. Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.

- Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (eg, rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended.

- Adverse Reactions: Adverse reactions reported in ≥5% of patients were (Otezla, placebo): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4).

- Use in Specific Populations: Pregnancy and Nursing Mothers: Otezla is Pregnancy Category C; it has not been studied in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether apremilast or its metabolites are present in human milk. Caution should be exercised when Otezla is administered to a nursing woman.

- Renal Impairment: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information.

- Otezla® (apremilast) was evaluated in 2 multicenter, double-blind, placebo-controlled trials of similar design. Patients with moderate to severe plaque psoriasis (N = 1257) were randomized 2:1 to Otezla 30 mg or placebo twice daily for 16 weeks, after a 5-day titration.

- Inclusion criteria: Age ≥18 years, BSA involvement ≥10%, sPGA ≥3, PASI score ≥12, candidates for phototherapy or systemic therapy.

- Exclusion criteria: Asteur ≥5 years, PSA involvement ≥1%, VAPA ≥5

- PASI-75 response at week 16 (primary endpoint)

- Study 1: Otezla 33% vs placebo 5% (P < 0.0001)

- Similar PASI-75 response was achieved in Study 2.

- Otezla® (apremilast) is a registered trademark of Celgene Corporation. © 2015 Celgene Corporation.
IMPORTANT SAFETY INFORMATION (cont’d)

Warnings and Precautions

Depression (cont’d): for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.

- Weight Decrease: Body weight loss of 5-10% occurred in 96.784% (96/784) of patients treated with Otezla and in 19.382% (19/382) of patients treated with placebo. Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.

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Contraindications

- Otezla is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

Warnings and Precautions

- Depression: Treatment with Otezla is associated with an increase in adverse reactions of depression. During clinical trials, 1.3% (12/920) of patients treated with Otezla reported depression compared to 0.4% (2/506) on placebo; 0.1% (1/1308) of Otezla patients discontinued treatment due to depression compared with none on placebo (0/506). Depression was reported as serious in 0.1% (1/1308) of patients exposed to Otezla, compared to none in placebo-treated patients (0/106). Suicidal behavior was observed in 0.1% (1/1060) of patients on Otezla, compared to 0.2% (2/1060) on placebo. One patient treated with Otezla attempted suicide; one patient on placebo committed suicide.

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Please turn the next page for Brief Summary of Full Prescribing Information.

Ad Page 1

Ad Page 2
Interactions (7.1) and Clinical Pharmacology (12.3).

Table 3: Adverse Reactions Reported in 1% of Patients on OTEZLA and With Greater Frequency Than in Patients on Placebo: up to Day 112 (Week 16)

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Placebo (N=506) n (%)</th>
<th>OTEZLA 30 mg BID (N=920) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>6 (1)</td>
<td>29 (3)</td>
</tr>
<tr>
<td>Decrease appetite</td>
<td>5 (1)</td>
<td>26 (3)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>4 (1)</td>
<td>21 (2)</td>
</tr>
<tr>
<td>Back pain</td>
<td>4 (1)</td>
<td>20 (2)</td>
</tr>
<tr>
<td>Migraine</td>
<td>5 (1)</td>
<td>19 (2)</td>
</tr>
<tr>
<td>Frequent bowel movements</td>
<td>1 (0)</td>
<td>17 (2)</td>
</tr>
<tr>
<td>Depression</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Tooth abscesses</td>
<td>0 (0)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Foliculitis</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
<tr>
<td>Sinus headache</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
</tbody>
</table>

Two subjects treated with OTEZLA experienced serious adverse reaction of abdominal pain.

Severe worsening of psoriasis (rebound) occurred in 0.3% (4/1184) patients following discontinuation of treatment with OTEZLA (apremilast).

**DRUG INTERACTIONS**

Strong CYP 450 Inducers: Apremilast exposure is decreased when OTEZLA is co-administered with strong CYP450 inducers (such as rifampin) and may result in loss of efficacy [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:** Category C: OTEZLA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to OTEZLA during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972.

**Nursing Mothers:** It is not known whether OTEZLA or its metabolites are present in human milk. Because many drugs are present in human milk, caution should be exercised when OTEZLA is administered to a nursing woman.

**Pediatric use:** The safety and effectiveness of OTEZLA in pediatric patients less than 18 years of age have not been established.

**Geriatric use:** Of the 1257 patients who enrolled in two placebo-controlled psoriasis trials (PSOR 1 and PSOR 2), a total of 108 psoriasis patients were 65 years of age and older, including 9 patients who were 75 years of age and older. No overall differences were observed in the efficacy and safety in elderly patients ≥65 years of age and younger adult patients ≥65 years of age in the clinical trials. Renal Impairment: OTEZLA pharmacokinetics were not characterized in patients with mild (creatinine clearance of 60-89 mL per minute estimated by the Cockcroft–Gault equation) or moderate (creatinine clearance of 30-59 mL per minute estimated by the Cockcroft–Gault equation) renal impairment. The dose of OTEZLA should be reduced to 30 mg once daily in patients with severe renal impairment (creatinine clearance of less than 30 mL per minute estimated by the Cockcroft–Gault equation) [see Dosage and Administration (2.2) and Clinical Pharmacology (12.3)].

**Hepatic Impairment:** Apremilast pharmacokinetics were characterized in patients with moderate (Child Pugh B) and severe (Child Pugh C) hepatic impairment. No dose adjustment is necessary in these patients.

**OVERDOSE**

In case of overdose, patients should seek immediate medical help. Patients should be managed by symptomatic and supportive care should there be an overdose.

Manufactured for: Celgene Corporation, Summit, NJ 07901

OTEZLA® is a registered trademark of Celgene Corporation.


Based on APRPI.003 OTZ_PsO_HCP_BSv.003 09.2014
Still too many hysterectomies performed

About 1 in 3 women in the United States will have a hysterectomy by the time they’re 60, but too many do so without fully exploring alternative treatments, according to a study by researchers at the Michigan Surgical Quality Collaborative, a consortium of hospitals overseen by Blues plans. Their study, published in the *American Journal of Obstetrics & Gynecology*, tracked about 3,400 women who got the procedure as a treatment for abnormal uterine bleeding, uterine fibroids, endometriosis, or pelvic pain.

When the researchers looked at pathology reports written from Jan. 1 through Nov. 8, 2013, at 52 hospitals in Michigan, they found that the reports did not justify hysterectomy in 18% of the cases, most of which involved women under the age of 40. What’s more, 38% (1,281 out of 3,397) of the women who had hysterectomies had not considered alternative treatments prior to the procedure, the researchers found. The alternative treatments included hormonal therapy, pain management, levonorgestrel IUD, hysteroscopy, and endometrial ablation. Women younger than 40 were more likely to consider alternative treatments than those older than 40.

Lauren E. Corona, the lead author, said she and her colleagues focused on consideration of alternative treatments, instead of treatments received, in part because they wanted to know whether women were appropriately counseled about less-invasive and less-risky options to hysterectomy. The Michigan researchers suggest that a systems-based quality improvement approach to hysterectomy could help standardize treatment and ensure that appropriate alternatives have been offered to women deciding about the procedure.

The news isn’t all bad, as researchers noted the substantial decline in the number of hysterectomies performed in the United States. In 2013, Columbia University researchers reported trend data showing that the number of inpatient hysterectomies in this country declined from 681,234 in 2002 to 433,621 in 2012, a decrease of about 36% over the decade. By indication, the largest percentage decreases were hysterectomies for endometriosis (65.3%) and for benign ovarian masses (63.1%). Some of the decrease in inpatient hysterectomies might be explained by a shift toward the procedure being done on an outpatient basis.

**Considering the alternatives to hysterectomy**

<table>
<thead>
<tr>
<th>Alternative treatment considered</th>
<th>62% (2,116 women)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical management only</td>
<td>18%</td>
</tr>
<tr>
<td>Not documented</td>
<td>9%</td>
</tr>
<tr>
<td>Medical and surgical management</td>
<td>24%</td>
</tr>
<tr>
<td>No alternative treatment considered</td>
<td>38% (1,281 women)</td>
</tr>
</tbody>
</table>


**Number of hysterectomies performed by year**

When Express Scripts announced last December that it had negotiated a discount with AbbVie for Viekira Pak, the company’s hepatitis C drug, it caught the health care world’s attention. Express Scripts chose Viekira Pak’s multiple-pill-per-day therapy for its national formulary after Gilead refused to budge off its $84,000 asking price for a course of Sovaldi, its one-dose daily hepatitis C therapy.

People wondered if Express Scripts was writing its own script, putting pharmaceutical manufacturers on notice that the country’s largest pharmacy benefit manager was ready to wield its considerable influence on drug spending in a new, even more demonstrable way—particularly for specialty drugs—and in the process, anoint winners and losers in drug development.

Or had Express Scripts simply haggled an unusual one-off discount because one company was locked in a marketing battle against a rival manufacturer with an equally effective hepatitis C therapy?

Industry observers say Express Scripts was flexing the muscles that come when you have an incredible 85 million covered lives. PBMs are hardly new kids on the block, but they are exerting greater influence on the marketplace with some hard bargaining and nimble moves.

Or had Express Scripts simply haggled an unusual one-off discount because one company was locked in a marketing battle against a rival manufacturer with an equally effective hepatitis C therapy?

Industry observers say Express Scripts was flexing the muscles that come when you have an incredible 85 million covered lives. PBMs are hardly new kids on the block, but they are exerting greater influence on the marketplace with some hard bargaining and nimble moves.

And it’s not just Express Scripts. The next three largest PBMs—CVS Caremark, UnitedHealthcare's OptumRx, and Catamaran—have since announced their own special deals with pharmaceutical manufacturers. So does that mean we should be proclaiming the era of PBM power and influence?

Perhaps. But that is a rhetorical perhaps that leans heavily in the direction of it sure is.

Like any part of the health care industry that survives, PBMs have shapeshifting powers, changing and evolving with the times. The first PBMs appeared in the late 1970s and were operated by pharmacists who saw an opportunity to make money by processing claims. The industry grew quickly, and by the 1990s PBMs were thriving by controlling drug costs with tiered formularies. Then, in the early 2000s, the first of two consolidations swept through the industry. Several years ago, there was another round of consolidation.

The big PBMs, seeing economies of scale, decided the smart money was to get even bigger. They began gobbling up smaller PBMs and before long there were four major players.

Throughout these iterations, the stated goal of PBMs has remained the same—to keep a tight leash on drug spending while also making sure clinical needs are being met.

Exemplars of managed care

PBMs can, with some justification, brag that they are one of the few bona fide success stories in the management of health care costs. Millions of Americans are now taking cheaper generic drugs, in part because tiered formularies have lured people away from brand-name drugs to generics with lower copayments. Spending on retail drugs is still going up, but it has lagged behind overall spending on health care in recent years.

The value-based payment schemes sweeping through American health care are following in the footsteps of PBMs and their tiers by using cost sharing to influence patient choices. Think of those inexpensive generics as being analogous to the in-network provider with the lower copayment.

Memories have faded somewhat but the acceptance of generics came after a hard-fought battle. In an interview with Managed Care, Steve Miller, MD, chief medical officer for Express Scripts, says that the company’s 2005 move to take Lipitor off its formulary was as “newsworthy and audacious” as anything the company is doing now with the hepatitis C drugs and exclusionary formularies (see our Q&A on page 27).

As with almost anything you can think of, there’s a
web of interrelated reasons for the growing power and influence of PBMs. But two stand out. One is the flood of specialty drugs on the market. There are more than 900 and counting (the definition of specialty drug is squishy, so the count varies).

Probably the main reason PBMs have such a high profile these days is that a significant chunk of health care spending goes to cover pharmaceuticals and is paid through the pharmacy benefit that PBMs manage, says Don Liss, MD, vice president for clinical programs and policy for Independence Blue Cross in Pennsylvania: “A huge portion of health insurance premiums are dedicated to pharmacy.”

With the number of specialty drug prescriptions expected to balloon in the coming years, large insurers, unions, and private corporations are looking to PBMs to help reel in pharmacy costs. Some are integrating PBMs into their overall health care management system and having them create specialty drug precertification requirements.

PBMs are also overseeing more complicated, multi-tiered benefit plans. Unlike the old plans that featured a flat copayment, the new packages can include an elaborate set of copayments, deductibles, and coinsurance that fit together in any number of ways.

**As usual, size matters**

The other standout reason for PBM clout is their size and the market power that brings. Pharmaceutical companies, pharmacies, health plans, provider organizations—they all have to take notice.

Miller notes that Express Scripts has grown from 12 million to 85 million covered lives during the decade he has been there. As a point of comparison, Medicare has just fewer than 50 million beneficiaries. True, just 25 million of those covered lives are on the company’s national preferred formulary. Miller says half the company’s business is with managed care companies that have their own P&T committees that make their own decisions. But clearly, Express Scripts has influence. Miller clearly relishes the power-in-numbers that his company has at its disposal: “If you think about any other aspect of health care, no one has accumulated 85 million lives that they can represent.”

The more members a PBM represents, the bigger its buying power. The bigger its buying power, the larger its influence on the marketplace. “The larger its influence … well, you get the idea.”

“There are fewer choices of PBMs with which to do business, that’s for sure,” Independence’s Liss says. “But with PBMs having more market share, they are obviously trying to use that leverage in their dealings to get lower prices from manufacturers that they can then offer to their customers.” In other words, strong PBMs can be a blessing for health plans. Liss says Independence controls its formulary but has found that it has more variety and drug options now, working with Catamaran as its PBM, than it did in the past.

PBMs can use this buying power as either a stick or a carrot. For instance, a drug manufacturer unwilling to yield on a price risks having its product excluded from the PBM’s formulary (see our story on exclusionary formularies on the next page). Translation: X number of consumers won’t be using the manufacturer’s drug, and that could put a big dent in the bottom line. In our Q&A with Miller, he says that Express Scripts moved to exclude 48 drugs in 2013 to push back against coupon programs that, in his view, erode the effectiveness of formulary tiers.

For drug manufacturers, the carrot can be as sweet as the stick is harsh. Getting included on a gargantuan PBM’s formulary can open a huge market for a drug in one fell swoop. Contrast that with having to persuade hundreds, if not thousands, of individual providers.

David Lassen, PharmD, chief clinical officer at Prime Therapeutics, calibrates his comments carefully but the meaning is clear: “The formulary exclusion lists are being utilized to improve the PBM’s leverage and manage the market share of preferred products, thus producing better pricing.”

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Express Scripts has grown from 12 million to 85 million covered lives in the past decade. As a point of comparison, Medicare has just fewer than 50 million beneficiaries.

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**continued on page 26**
PBM Just Say No to Some Drugs—But Not to Others

By Thomas Reinke

As PBMs honed their tactics to manage costs and therapy, formulary design evolved from a simple arrangement of a single tier to a complex arrangement with as many as five. Now, finally, the ultimate tier has been firmly established. Exclusion—tossing drugs out of a pharmacy plan—is the logical next step.

Exclusions of brand drugs have existed since the early days of the HMO. Originally, exclusion played a relatively minor role in targeting individual drugs or crafting special benefit designs, such as an all-generics plan for cost-sensitive employers. “Exclusions also appeared early in Medicare Part D plans in classes with many me-too drugs to lower premiums and capture market share,” says Mason Tenaglia, vice president of IMS Health.

Over the past 18 months, the use of formulary exclusions has changed from being a targeted tactic to a commonly used weapon. For 2015, CVS Caremark has 95 excluded brand drugs in its standard formulary, up from 72 in 2014 and just 34 in 2012. Express Scripts has 66 excluded products in its national formulary, compared with 48 in 2014.

The excluded drugs often are nonpreferred agents with low utilization or drugs with established generic alternatives, but for the first time a couple of specialty drugs are also on the outs.

Some of the major PBMs have shifted to making exclusive formularies the default choice. “Traditionally, PBM customers had to opt into closed formularies but in 2014 Express Scripts made its national formulary with exclusions an opt-out formulary,” explains Tenaglia. Some of the PBM’s customers have briddled at being assigned to a closed formulary but Tenaglia says, overall, customers understand that choices and alternatives are available among competing drugs.

The Health Industries Research Companies, a consultant to pharmaceutical manufacturers, interviewed 20 commercial health plans and found that about a third are considering implementing an excluded drug formulary while another third said they would not. The remaining respondents were taking a wait-and-see approach. Most formularies with exclusions are found across mid- to large-employer groups and national accounts, according to David Lassen, PharmD, chief clinical officer at Prime Therapeutics.

Sorry, you’re not invited

Excluding drugs has become an integral part of contract negotiations between PBMs and drug manufacturers, and Express Scripts is an unabashed practitioner of the craft. In a Q&A in this issue of MANAGED CARE, Steve Miller, MD, the company’s chief medical officer, says exclusions were a way to push back against coupon programs (see page 27). He has also sung the praises of exclusions on the company’s website: “One of the ways we keep cost down for patients and payers is by managing the formulary. By being willing to exclude a handful of ‘me-too’ products from our formulary, we have leverage to negotiate more effectively with manufacturers and ultimately achieve lower drug prices.”

Express Scripts does not stand alone. Lassen notes that “there are a number of drug classes with viable therapeutic alternatives and an exclusion strategy can play a role in negotiations because it promotes competitive pricing within a drug class.”

Have future launches for new high-priced drugs been permanently affected by experience with the hepatitis C drugs?

Tenaglia explains that exclusions work by giving PBMs more control over the endgame in contract negotiations. “In the past five years, health plans and PBMs have had increasing power to extract rebates in exchange for preferred status, but as manufacturers have paid higher rebates they have also raised prices more aggressively.” A study by AARP shows that annual price increases for 274 common brand medications increased from 7.9% in 2008 to 12.9% in 2013.

Tenaglia says for some drugs, manufacturers have chosen to use copay cards—Miller and others call this “couponing”—rather than contract for large rebates. For example, says Tenaglia, when Novo Nordisk started selling liraglutide (Victoza), a diabetes drug, in 2010, it used copay cards rather than agree to rebates with PBMs. In open formulary plans, the drug was on the nonpreferred tier so,
in the end, it was cheaper for Novo Nordisk to pay down the copayment than contract at a higher level of rebates. “Copay cards are one of the last leverage points that manufacturers have in negotiations with PBMs,” says Tenaglia. “Some manufacturers have done a great job of maximizing their situation by using copay cards where they could and contracting where they had to.”

In other words, with open formularies when virtually all drugs are included and nonpreferred status is the worst restriction, manufacturers are able to control the endgame. But exclusion takes away that advantage and allows PBMs to shape the fate of a drug in the marketplace by deciding whether it will be covered or not.

The hep C story

The bickering and posturing about the high price of the new hepatitis C medications provides insight into the power of formulary exclusions and the role they may play with future novel medications. The ultimate test of this ultimate tier (aka exclusion) occurred several months ago.

The story is now a familiar one to those who run in managed care-slash-PBM-slash-health policy circles. Gilead’s Sovaldi came to market with an $84,000 price tag for each course of treatment. At that price, theoretically it could have generated $268 billion in revenue if all 3.2 million Americans with hepatitis C were treated, making it the most lucrative drug of all time. From the payer perspective, it was even more galling that in some countries the price was less than $1,000 per course.

Gilead was roundly criticized and pressured to lower its price but stood firm. Its argument? Look at the big picture—Sovaldi treatment cures more than 90% of patients, so it spares payers all the medical costs associated with hepatitis C.

It wasn’t until AbbVie’s comparable product, Viekira Pak, was approved in December 2014 that PBMs regained negotiating advantage. Even before Viekira Pak’s approval was announced, PBMs began price and coverage discussions with both manufacturers. The threat of Sovaldi being excluded brought Gilead to the negotiating table. The opportunity to gain market share and preferred placement was certainly enough to get AbbVie, the latecomer, talking.

The result is a mix of contracts. Express Scripts has an exclusive deal for Viekira Pak that excludes Gilead products from its national formulary, which includes 25 million of its 85 million covered lives.

CVS Caremark has an exclusive arrangement for Gilead’s Harvoni, a combination drug that includes Sovaldi and another antiviral, ledipasvir. In addition, some formularies include products from both manufacturers with price concessions from both.

In late January, Express Scripts declared victory in its campaign to obtain lower prices for HCV medications, claiming that its deals will save its clients $1 billion and, by affecting the entire market, the U.S. health care system $4 billion. The drug companies will be competing to secure market share. PBMs will be interested in controlling costs. But in his conversation with MANAGED CARE, Miller says Express Scripts and manufacturers are in discussion and that PCSK9 inhibitors are “already playing out differently.”

Tenaglia says the series of events and outcomes surrounding the hepatitis C medications may have set a precedent for presumptive action by PBMs instead of a wait-and-see approach. “The PBMs were picking the winners immediately after the launch of the hepatitis C drugs because the price and utilization were so much higher than anything they had to deal with before,” Tenaglia says. “They had no alternative but to consider restrictions or exclusion as a way to control costs.”

He says the PCSK9 inhibitors, a new class of cholesterol-lowering agents for people who haven’t responded to statins and other therapies, may set in motion moves and countermoves similar to those made with hepatitis C drugs.

Time will tell whether Miller is right. But regardless of the dynamics of the PBM–manufacturer relationship, let’s hope patients, their health, and their pocketbooks benefit.
But the very issues that are driving PBMs’ expanding influence also pose a challenge for the industry. And the answers go well beyond simply securing price concessions from pharmaceutical makers.

“We have to manage pharmacy with an eye for improved outcomes for the total cost of care,” says Lassen. “The reality is outcomes and improvement in total cost of care should drive the use of medications and drive lower total cost of care.” He adds: “PBMs simply can’t manage pharmacy in a silo by excluding drugs and lowering the price of drugs.”

Cancer may be the tougher case
That broader, nobler way of thinking works well when it comes to the new hepatitis C drugs because they are curative and presumably will save money in the long run because newly cured people won’t need as much medical care.

Agreeing to the discount may have been a pretty smart business calculation by the manufacturers rather than a display of PBM muscle.

That’s the argument Gilead has made repeatedly to justify a price that is equal to four years of tuition at some colleges or a sizable down payment on a house.

That same philosophy, however, may be precisely why the formulary decisions about equally expensive oncology drugs that offer short-term improvement but no cure will be so difficult. Lassen says that “no health care company has figured it out.” One way to address the problem, he says, would be setting standards based on quality-of-life measurements.

“We’re not simply a dictator trying to determine who should be on what medication,” Lassen continues. “If we do that, we’ve fallen short and we are not going to be relevant for addressing the true, unsustainable cost that we see coming at us.”

Miller says Express Scripts is ready to take a more aggressive approach to managing oncology drug costs, partly because there are now multiple treatments for many cancers. “We put clinical first, but when given the opportunity to pit drugs against each other, we do that.”

Maybe not such a big deal
Mark Pauly, PhD, isn’t convinced that wrangling a markdown on hepatitis C drugs constitutes a watershed moment for PBMs. In fact, the professor of health care management at the University of Pennsylvania’s Wharton School thinks that agreeing to the discount may have been a pretty smart business calculation by the manufacturers—yes, the manufacturers—rather than a display of PBM muscle. Pauly speculates (and he emphasizes that it’s only speculation) that the manufacturers of the hepatitis C drug understand that they have a one-and-done therapy.

But that’s not the case with expensive specialty drugs for rheumatoid arthritis, inflammatory bowel disease, and other chronic conditions that are managed but not cured with medications. With drugs people take for chronic conditions for the rest of their lives, there is less of a threat from the PBMs, notes Pauly. Price competition has not broken out at all, as far as he can tell.

“Buying decisions” in the future will undoubtedly include more expensive specialty drugs. So the question comes back to whether PBMs can consistently use their size and formulary tactics to negotiate price and other concessions from pharmaceutical manufacturers.

It certainly seems that things are headed in that direction with Express Scripts celebrating its discounted hepatitis C price coup.

But in Pauly’s view, it’s one thing to have price competition and PBM swagger in a new drug class when everything is fluid. It’s another to have it in an established class of drugs with very high profit margins. If price competition were to break out in the older market, then Pauly would become a believer in the new era of PBM clout—and then some: “I would think that the revolution had started.”

Robert Calandra is a freelance writer in Philadelphia with more than 20 years of experience writing about health care.
You have been called a gatekeeper, judge and jury, cost-fighting ninja, and “among the most feared” by pharma. Which label is the most accurate? I am a clinician who is passionately concerned about the cost of health care, and that’s been reflected in my career, both before Express Scripts and now. So I don’t see any of those as being quite accurate. But I find them more acceptable than some of the things I’ve been called.

What would you call yourself? A concerned clinician.

You’ve been at Express Scripts since 2005, but now you’re in the media a lot, sort of in an adversarial role. Did this come naturally to you? The first year I came to Express Scripts, we did something that was almost equally newsworthy and audacious as what we are doing now. We were the first ones to take Lipitor off the formulary. At the time, it was the biggest drug from the biggest pharmaceutical manufacturer. But when we looked at the data, it was clear that Lipitor was a great drug, but there was no clinical data that said it was any better than any of the other statins. And simvastatin was about to go generic, so we looked at that as a great opportunity to actually demonstrate that PBMs could move market share and truly drive tremendous savings for patients and plan sponsors.

That one move alone—moving Lipitor off our formulary—was a huge effort because we had 10% of our patients on that product. But it saved a billion dollars for our patients in 2006.

So the Lipitor decision set the stage for what followed, the formulary exclusions? Remember, after the Lipitor decision, we got into a disagreement with Walgreens.* At that time, Walgreens was selling 20% of our retail prescriptions. The tools that we had developed to communicate with doctors, patients, and pharmacies after the Lipitor decision allowed us to move our market share out of Walgreens into other

*Because of a contract disagreement, Walgreens was not in the Express Scripts network for eight months in 2012.
pharmacies. Having superior communication tools allowed us to almost seamlessly move those patients without blowback.

Then, you fast-forward to our 2013 formulary exclusions. We were able to exclude, at that time, those 48 drugs, and again, do it with essentially no blowback and huge savings for our plan sponsors and our patients.

**No blowback?** I won’t say zero but, you know, our clients will tell you that there has been very little noise in the HR department and very few doctors even calling for medical exceptions. Because remember, it’s not just what you have on the formularies. It’s also all the medical rules you design around it to make sure that those exceptional patients that need a certain drug can still get it.

**What went into the 2013 decision to exclude those 48 drugs?** You had a lot of coupon programs going on. Remember, coupon programs are different from patient assistance programs. Patient assistance programs help patients get the drugs they need, and we are very supportive of them. But coupons exist only when there are competing drugs in a marketplace and you’re trying to preserve your market share. The trouble with coupons is that they undermine the three-tiered benefit that plans put in place. The company doesn’t really want the 5% or 10% that the patient is contributing. They want the 90% that the plan sponsor is contributing.

**Did all 48 of those drugs have coupon programs?** Over 90% had coupons at the time.

**So the exclusions were just to push back against coupon programs?** Part of it was also to extract lower prices, because the manufacturers were now convinced—because of what we did with Walgreens and the statins—that we could actually deliver market share when we were motivated to.

So we went to the companies, and we told them, “We’re going to be pitting you all against each other. Who is going to give us the best price? If you give us the best price, we will move the market share to you. We will move it effectively. We’ll exclude the other products.”

But I told you I am a clinician at heart. We’ve always first made sure that any changes make clinical sense. We have an 18-member pharmacy and therapeutics committee that has no Express Scripts employees on it and is self-governing—if one member goes off the committee, they pick the replacement. They are completely independent.

**So you’re at 74 excluded drugs now. Do you think you’re approaching an outer limit of what can be excluded?** One of our competitors has up to 200 drugs on the list. There’s this balance between disruption and savings, and there’s no reason to go after trivial drugs that aren’t going to drive savings, just to have a long list.

**Let’s turn to the hepatitis C drugs. There are other costly specialty drugs out there. Was there something special about the hepatitis C drugs?** There are many expensive drugs that we pay for, and we do that without complaining at all because we think it’s appropriate. The difference with hep C was that this was the first time we had an extraordinarily high-priced drug for an extraordinarily large population. When you price a drug at almost $100,000 for a treatment regimen, and you have 3.2 million people that could benefit from it—there’s never been a drug that potentially could generate over $300 billion in sales. I know they weren’t all going to be treated in one year, but even if you treated them over a decade, that’s an enormous increase in drug spend for the country.

You’ve said that the pricing came as a shock, and that Gilead hadn’t discussed the cost before it was announced. **Should they have?** We’ve actually now come out with principles about how we believe we can achieve a sustainable model for pharmaceutical development in this country. One of our recommendations to the industry is to use good judgment when you bring products to the marketplace. We’ve said, “Listen, come in and talk to us prior to launch because we can give you insight as to how the payers will look at this.” You have advisory boards for doctors, you have advisory boards for patients, but most companies don’t really have payer advisory boards. And we’re willing to play that role.

You have companies taking you up on this offer? Since we’ve made that offer last summer, the number of meetings I’ve been having with the pharmaceutical manufacturers is extraordinary. Many of them are reaching out to us, and in the last few months, we’ve even had pharmaceutical companies’ boards of directors reaching out to us to speak at their board meetings.

**You see this as an outcome of the tough stand on Sovaldi?** I believe, absent what we’ve done with Sovaldi, these discussions probably would not be occurring, especially at the pace they’re occurring today.

**Let’s talk about Viekira Pak. If I had hepatitis C, why should I welcome your decision to put Viekira Pak on**
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your national formulary? It seems like it’s a lot less convenient than Harvoni: 24 weeks versus 12, several pills versus one. The vast majority of the patients actually can take Viekira Pak for 12 weeks. So you’re talking about three months, and you’re talking about taking a drug twice a day versus once a day. The cost difference even today is still over $10,000 for a treatment course. These are motivated patients who want to be cured. The vast majority are telling us, “Yes, we have followed the debate, and let’s just get on with the treatment.”

We knew some people would say patients will be less adherent. But we put in place adherence guarantees. We will refund the payer the money if the patient is not adherent. The reason we’re able to do this is that we have predictive models that indicate which patients are going to be less adherent. We’ve developed phone apps for those patients. We’re able to surround them with specialist pharmacists, social workers, and nurses. We’re even willing to make calls out to the patient every day to help them stay adherent.

Could you put a number on the amount of money you’re saving so far? We believe that for our plans alone, for Express Scripts, we’ll save about a billion dollars this year. And because of the impact it’s had on the entire market, it will save about four billion.

How much of a discount did you get from AbbVie? We’ve never disclosed our discount. Viekira Pak is for our patients on our national preferred formulary. But we also have contracts with Gilead for our 60 million members who aren’t on our national preferred formulary. And as you know, Gilead has announced that their average discount is 46%. So you can imagine the cost savings that we’re having for all of our patients across our entire book, regardless of whether they’re taking the AbbVie product or the Gilead product.

Are you saying the AbbVie discount is close to what you’re getting from Sovaldi on those other accounts, so it’s roughly 46%? Gilead has proudly said that they’re not having to discount as deeply as AbbVie, right? The discounts for both products are obviously substantial.

Are you in discussions with manufacturers of the PCSK9 inhibitors? Is this going to be Sovaldi, part 2? Or do you see PCSK9s playing out differently? It’s already playing out differently. These manufacturers—Amgen, Sanofi, Regeneron—they have been watching the hepatitis C battles. We’re already in very substantial discussions with them.

Isn’t it the same math as hepatitis C drugs—a lot of people with the condition to be treated, an expensive medication? There are 71 million people with high cholesterol in the U.S. And cardiovascular disease and stroke are the top killers. So, it’s a really important category, which potentially is going to add a lot of spend. But if you’re able to get the price to an appropriate level, and you’re able to target it to just those patients who will truly get the greatest value from it, then we think we’ll bring true value to society.

In an interview you did recently you said that you’re gearing up to take on the oncology drugs. That is a tough area to take on. Oncology is much more complicated to manage than many other therapeutic areas. Hep C—it’s somewhat bimodal. You’re either cured or not cured. In cancer, how do we judge effectiveness? Some cancer agents are really effective and prolong survival. Others just make you feel better, but you still die in the same amount of time. Some cancer agents may shrink your tumor but have no survival benefit. Are all of those good responses? And then there are all the emotions around cancer. So you’re exactly right. This is a much tougher area to take on.

You also mentioned “accumulating the keys to the puzzle” in that interview. One of the keys is medical drug management, which means that we were advising plan sponsors what should be covered under the medical benefit, and what drugs should be covered under the pharmacy benefit. There are certain drugs, however, that need to stay under the medical benefit.

The savings for America from biosimilars over the next decade could be $250 billion.

So, several years ago, we created another product called medical benefit management, where we’re doing the prior authorizations for a drug, even though they’re going to be paid for by the medical benefit.

Then, a couple years ago, we added site-of-care management, where we’re able to move drugs out of the hospitals into infusion centers, and out of infusion centers all the way into people’s homes.

One of the things we’re most proud about is our therapeutic resource centers. We have specialist pharmacists in cancer who deal with our cancer patients. And we have subdivided it where we have pediatric cancer specialists, breast cancer specialists, solid tumor cancer specialists, and leukemia/lymphoma specialists. Our cancer specialist pharmacists often have more experience than even a great oncologist. Because, for instance, if you’re at Memorial Sloan Kettering and you see 50 brain cancers this year, my pharmacist is supporting Memorial Sloan Kettering, MD Anderson, Siteman Cancer Center here in St. Louis, City of Hope in California, so they have even more experience.

We really believe that in the coming years, we’re going to start influencing both the pricing and the quality of care in oncology.
You played hardball with Sovaldi and Gilead. Do you see yourself playing hardball with oncology drugs? Well, there’s definitely opportunity there. There are more and more products that are overlapping in their indications, and as you know, one of the great things we do is we take a very data-driven approach. We put clinical concerns first. And when given the opportunity to pit drugs against each other, we do that. And, historically, oncology hasn’t had nearly the opportunity to do that. You now have a lot of treatments for kidney cancer, for prostate cancer, for different leukemias. And we believe there’s going to be great opportunity to impact pricing but also provide great care.

A little bit on biosimilars. How hopeful are you about them? I’ve been advocating for biosimilars very aggressively over the last eight years, and we just testified in front of both houses of Congress. Because the importance of biosimilars is this: For the last five years, the drug spend in the U.S. has been fairly flat because for every patient that needs to go on one of these new expensive drugs, we’ve been able to move 10 patients to generic drugs. Now that generic fill rates are over 80%, there’s no longer that opportunity to move patients to generics. So every new drug is falling directly to the bottom line, which means drug spend in the U.S. is going to go up to $500 billion over the next several years if we don’t do anything. The savings for America from biosimilars over the next decade could be $250 billion. That buys a lot of hepatitis treatment, a lot of cancer treatment, a lot of cholesterol treatment. So biosimilars can do great things for this country because they can make the same headroom that generics made in the past.

You’ve talked up mail order pharmacy. There are a couple of things you can’t use mail order for. You can’t use it for your acute prescriptions. If you have an infection today, you want to get your antibiotic today. Or if you break your leg, you need your painkiller today. But 60% of prescriptions are for chronic medications, and all of those should be coming through the mail.

Just look at the increased adherence that you get with mail and the avoidance of errors. When you go to the retailer, the chance of you having the wrong medicine in the bottle is about 1.7%. We fill prescriptions with Six Sigma perfection. We make one error per million prescriptions. So the number of prescriptions we fill prevents two million errors from reaching a patient every year. So for us, we believe that mail order is not just a great solution now, but an even better solution for the future. And it holds down costs. We’re really bullish on mail order.

PBMs have been criticized for not being more transparent. Why aren’t you more transparent, especially with respect to spread pricing? That criticism actually comes from competitors in the supply chain. It doesn’t come from our clients. Our clients actually know their pricing; they can audit their contracts; they audit our contract. So we actually provide transparency to our clients.

Aren’t you the classic middleman that people always complain about? Well, with hepatitis, we brought about four billion dollars worth of value. It gets pretty easy to demonstrate the value we bring.

It seems like PBMs, and maybe Express Scripts in particular, have picked up the mantle of managing health care costs. Why is this happening now? I think because of the continued escalation of cost, you need a PBM now more than ever. And what a best-in-class PBM like Express Scripts does really ensures great health outcomes and more affordable costs.

But why now? I think the cost of health care is so extraordinary. You’re talking about almost $3 trillion in health care spending. On the medical side, there are very few examples of effective control. I think people are paying so much attention because we’re being successful and effective.

Did something change that made you more effective? When I joined the company, we represented 12 million members. We’re at 85 million today. That gives us extraordinary sway in the marketplace. If you think about any other aspect of health care, no one else has that many lives that they can represent.

You’re persuasive that Express Scripts improves access and maybe improves people’s health. But this success of yours, maybe it comes at the expense of pharmaceutical industry innovation. I’m a basic scientist by training. I started in primary drug discovery. I care passionately about the pharmaceutical industry. I hold many patents with pharmaceutical manufacturers from my prior work.

If we hindered innovation, that would be a very bad outcome. What we do actually spurs innovation. We will reward companies that bring us innovative products, and we will reimburse them appropriately. But if you come out with a me-too product, you’re obviously going to be pitted against someone else, and you’re not going to benefit from that. We believe that our effectiveness is the reason you’re seeing so many new products come to market. That’s why there are 5,400 drugs in clinical trials today and more drugs being approved by the FDA.

So, unlike what people are saying, we actually foster innovation. And, as you know, the pharmaceutical manufacturers are making record profits these days. They’re doing just fine.
A Canary in the Coal Mine for Co-Ops?

The failure of the second largest consumer-oriented-and-operated health plan may be a bad omen for the future of other plans. Or maybe not.

By Richard Mark Kirkner

If writing laws is akin to making sausage, then the ACA may have been some of the most creative, if not messy, sausage making ever. An example is what negotiators came up with after liberal supporters abandoned their long-cherished goal of a public option: the consumer-oriented-and-operated plans, otherwise known as co-ops, now under the microscope after the collapse of the second-largest such plan.

Originally funded with $6 billion in federal seed money, these plans were to be run by not-for-profit organizations. The liquidation of CoOportunity Health, a large co-op in Iowa and Nebraska, along with an order requiring a co-op in Tennessee to close its enrollment, has caused some to question the effort.

It has become clear that starting a health plan from scratch to compete with the well-established Blues and commercial plans on the exchanges is not easy, even with federal funding in your pocket. A co-op in Vermont never got its state license even after it accepted $4 million in startup funding, most of which was returned to the government. CoOportunity, which had about 120,000 members, desperately needed a loan to stay afloat, but CMS turned down its request at the last minute. Two recently released reports, one by the insurance rating agency A.M. Best, call into question the soundness of the co-op model in meeting loss ratios during their first few months of existence.

As a Republican-dominated Congress maneuvers to restrict federal loans for co-ops, some health care observers wonder if CoOportunity is the canary in the coal mine for the 22 remaining co-ops operating in 25 states.

What are co-ops?

Co-ops are authorized in Section 1322 of the ACA, and their function is to provide a low-cost alternative to private health plans on the insurance exchanges.

The federal government turned out to be a bad business partner for co-ops because of the power shift in Congress, says health policy expert Paul Ginsburg.

The failure of the second largest consumer-oriented-and-operated health plan may be a bad omen for the future of other plans. Or maybe not.

The 10 largest CMS loans to health co-ops*

<table>
<thead>
<tr>
<th>Co-op Name</th>
<th>Loan Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freelancers Health Service Corp., New York</td>
<td>$265</td>
</tr>
<tr>
<td>Land of Lincoln Mutual Insurance Co., Illinois</td>
<td>$160</td>
</tr>
<tr>
<td>Minuteman Health, Massachusetts and New Hampshire</td>
<td>$156</td>
</tr>
<tr>
<td>Kentucky Health Cooperative, Kentucky and West Virginia</td>
<td>$146</td>
</tr>
<tr>
<td>CoOportunity Health, Iowa and Nebraska</td>
<td>$145</td>
</tr>
<tr>
<td>Maine Community Health Options, Maine</td>
<td>$132</td>
</tr>
<tr>
<td>Coordinated Health Mutual, Ohio</td>
<td>$129</td>
</tr>
<tr>
<td>Healthy CT, Connecticut</td>
<td>$127</td>
</tr>
<tr>
<td>Freelancers CO-OP of New Jersey, New Jersey</td>
<td>$109</td>
</tr>
<tr>
<td>Common Ground Healthcare Cooperative, Wisconsin</td>
<td>$108</td>
</tr>
</tbody>
</table>

*All dollar figures are in millions.

Source: CMS Center for Consumer Information and Insurance Oversight

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business model” that had already failed in the early part of the 20th century.

Despite those warnings, co-ops went into the ACA sausage to mollify centrist Democrats, appeal to Republicans (a strategy that didn't work), and provide a low-cost option for high-risk individuals so that the exchanges would be more palatable to private plans.

There's still hope that co-ops can survive, says Martin Hickey of the National Association of State Health Co-Ops. CMS indicates it will continue to fund risk corridors.

Twenty-three co-ops, including CoOportunity, received $2.4 billion in federal loans through 2014 and signed up 520,000 people. But in 2011, Congress cut co-op funding almost in half, to $3.4 billion. After CMS awarded $1.9 billion in startup and solvency loans in 2012, Congress rescinded the majority of the remaining unobligated funds. In 2014, after some co-ops received additional solvency funding and funding to expand to neighboring states, Congress moved to make the risk corridors—the mechanism through which CMS shifts money from profitable plans to struggling ones—budget neutral. “It’s almost as if the federal government turned out to be a bad business partner, not that it meant to, but because power shifted,” says Paul Ginsburg, PhD, a health policy expert at the University of Southern California.

What happened to CoOportunity?
As the co-ops were gathering themselves for a push in 2015, disaster struck CoOportunity. Peter Damiano, DDS, MPH, the director of the University of Iowa Public Policy Center, explains that when CoOportunity launched, it expected to sell about 20,000 policies on the exchanges in Iowa and Nebraska. But Wellmark Blue Cross & Blue Shield, Iowa's dominant health plan, decided to sit out the first year of Iowa's exchange, leaving only two statewide choices, CoOportunity and Coventry Health Care of Iowa, an Aetna plan. As a result, CoOportunity’s sign-ups in Iowa far exceeded expectations. (CoOportunity principals were not available for comment, as the co-op had shuttered its doors and all but took down its website, save for a notice of liquidation, by Jan. 1.)

Fateful decision
CoOportunity's fate may have been sealed when Iowa Insurance Commissioner Nick Gerhart decided in April 2014 that insurers could continue selling non-compliant plans through October 2016. Wellmark sat out the second year. CoOportunity took on the brunt of the high-risk sign-ups, so the neophyte co-op “got hammered,” says Martin Hickey, NASHCO’s chair, who was aware of talks to save CoOportunity.

Complicating CoOportunity’s risk pool was its participation in Iowa’s Medicaid expansion. “We knew again that these were going to be sicker people,” Damiano says.

In December 2014, Congress “negotiated away,” in Damiano’s words, the risk corridor payments for co-ops in the 2015 federal budget. CoOportunity estimated that change resulted in a hit of $60 million (or about half of what it predicted) in payments due through the three R’s, according to the liquidation petition (and those payments would not have been forthcoming until the second half of the year). On Dec. 16, CMS delivered what Damiano calls “the back-breaker”: the decision to turn down CoOportunity’s request for a loan.

While critics of the co-op model have questioned the credentials of some co-op managers, Damiano says that wasn’t the case with CoOportunity, which was headed by Cliff Gold, a former senior executive at Wellmark, and David Lyons, a former executive with Farm Bureau Insurance—“two very well-connected people,” according to Damiano.

Do co-ops’ balance sheets add up?
A.M. Best, the insurance rating agency, issued a briefing on co-ops in January and found that the total underwriting loss of the 23 plans was $243.6 million in the first nine months of 2014.

More than 40% of the plans had medical-loss ratios of 100 or more, and all but three plans had administrative expenses exceeding 20%. CoOportunity’s net loss of $39.8 million through September 2014 was the largest. Only one co-op, Maine Community Health Options, reported both favorable underwriting and net income at $10.9 million in the first nine months of last year.

It might have been too much to expect co-ops to be able to take on established health plans, says Peter Damiano of the University of Iowa Public Policy Center.
The Iowa health insurance market is unique in that two players, Wellmark and Coventry, dominate it, says Hickey. Competition on price and product are not what they might be if there were more players.

Hickey questions Wellmark’s strategy in sitting out the exchange. “They held back, lost potential market share for a couple of years, and now they’re going to get it back at a really high rate. If you call it a chess game, they were thinking five or six moves ahead.”

Wellmark spokesperson Traci McBee explains that Wellmark sat out the exchange because of concerns about the “customer experience. . . . Specifically, how data is transferred between the system, health insurers and the many government entities involved in determining eligibility.”

CoOportunity may have been more a victim of a unique situation in Iowa than an indicator of the soundness of the co-op model, people familiar with the situation say. An analysis of premium rates last year showed that co-ops partly achieved their goal of price competition on the exchanges. The average premiums on exchanges in states that had co-ops were around 9% lower than in states that didn’t have them. The trend appears to have held in 2015.

But Damiano, at the University of Iowa, says it might be too much to expect co-ops to take on seasoned insurers who know all the tricks of the trade: “I think it always was a bit of a stretch that you were going to be able to have these entities sort of pop out of nowhere and be able to create competition, particularly where they were most desired, and that was in states where there was a dominant insurance company.”

Roger Stark, a surgeon and analyst at the Washington Policy Center for Healthcare in Seattle, acknowledges that co-ops face challenges in keeping costs low and having adequate provider networks. “Co-ops must maintain a medical loss ratio of 95% and keep premiums as low as possible to compete with established insurance carriers,” he advises. “The proven method of controlling these challenges is by limiting the provider network, but that also makes their insurance plans look less desirable.”

Risk-corridor payments are also integral to the model. “I don’t know if any of them would even have gone into it without the risk corridor,” notes Ginsburg, “so it has really undermined the whole rationale.”

Hickey sounds a more optimistic note. CMS has sent signals that indicate a “high confidence” of paying out risk corridors in 2015, he says, and there are other sources of potential funding, such as the reinsurance fund and the tax on plans sold on the federal exchanges.

What happens if the co-ops can’t pay back their loans? The scenario is simple, says Stark: “They will close and taxpayers will be out the loans already given.” So far, the federal government is out $145 million on CoOportunity, losses that may give critics an “I-told-you-so” moment.

Richard Mark Kirkner has been writing about health care for over two decades.

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Cancer screening programs—heavily promoted and with the strong intuitive appeal of finding a disease early when it is more treatable—have turned out to have a mixed track record. The screening tests for cervical and colon cancer have had a marked impact on those cancers, reducing incidence and improving survival by finding precancerous lesions, while breast and prostate cancer screening tests are mired in controversy about whether they lead to overdiagnosis and overtreatment. Meanwhile, screening for lung cancer—which claims more lives than the next four most deadly cancers combined—has been absent from the country’s menu of preventive services. Screenings using chest X-rays and tests of sputum were abandoned in the 1970s after studies showed that they didn’t save lives. Using CT scans for lung cancer screening has seemed promising for quite some time, but concerns about cost, radiation exposure, and the possibility of too many false positives have stood in the way.

Now that is changing. Starting in January, most private insurers are required to cover low-dose CT (LDCT) scans for lung cancer of current heavy smokers (30 pack-years) or those who have quit in the past 15 years. The ACA requires private insurers to cover preventive services with a U.S. Preventive Services Task Force (USPSTF) grade A or B rating, and the task force gave LDCT screening in high-risk populations a B recommendation in December 2013. CMS was under pressure to follow suit, partly to avoid the situation in which high-risk people were entitled to coverage for screening (and without any kind of cost sharing because it is a preventive service) before becoming eligible for Medicare, but would then lose that coverage when they became Medicare beneficiaries at age 65. CMS came through with a decision in February that extends LDCT screening for lung cancer to people in both traditional Medicare and Medicare Advantage plans.

### Lung cancer screening coverage becomes more widespread

<table>
<thead>
<tr>
<th>Plan</th>
<th>Criteria for coverage</th>
<th>Cost sharing</th>
<th>Start date</th>
</tr>
</thead>
</table>
| Traditional Medicare, Part B        | Ages 55–77  
No signs or symptoms of lung cancer  
30 pack-year smoking history  
Current smoker  
Former smoker who quit in the last 15 years | No            | Feb. 5, 2015  |
| Medicare Advantage (MA)             | Same as traditional Medicare but MA plan may extend coverage to those 78 and older | Yes          | Feb. 5, 2015  |
| Plans sold on health exchanges      | U.S. Preventive Services Task Force (USPSTF) recommendation* | No            | Jan. 1, 2015  |
| Small-group and individual plans    | USPSTF recommendation                                     | No            | Jan. 1, 2015  |
| sold outside the exchanges with the exception of grandfathered plans** | USPSTF recommendation                                     | No            | Jan. 1, 2015  |
| Large group and self-insured plans with the exception of grandfathered plans | USPSTF recommendation                                     | No            | Jan. 1, 2015  |

*USPSTF recommendation: Ages 55–80, 30 pack-years, current smoker, former smoker who quit within the past 15 years.

**The ACA grandfathered plans that existed before the law was signed five years ago. Those plans are not required to meet the ACA’s preventive services requirements. About 1 in 4 people with employer-sponsored health coverage remain in such plans.

Coverage decisions, however, are only the first step toward widespread acceptance and use of lung cancer screening, and it is facing some pretty significant resistance. While the USPSTF, many physicians’ professional organizations, and groups like the American Lung Association back LDCT screening, the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), an independent group that advises CMS on clinical topics, did not, and the American Academy of Family Physicians isn’t on board either. Although findings from clinical trials are a good reason to be optimistic that LDCT screening targeting heavy smokers will, in fact, save lives, concerns remain about another cancer screening test that could lead to false positives, unnecessary biopsies, and treatment of lesions that might be indolent.

The fact that this is a screening test that targets smokers complicates matters. It may not receive the kind of broad public and political support that other cancer screening tests have gotten because of the way smokers are viewed. Lung cancer screening will be tied to smoking cessation programs in many instances, but there’s a school of thought that all the time, effort, and expense that goes into screening might be better spent on getting people to give up cigarettes (and to keep them from smoking in the first place). The American Cancer Society, which advises clinicians to “initiate a discussion” about lung cancer screening with both current and former heavy smokers, has said it is a legitimate concern that some smokers might use screening as an excuse not to quit, although studies show that lung cancer screening may have just the opposite effect and motivate people to quit when an abnormality or an early cancer is discovered.

NCI study finds mortality benefit

Lung cancer screening has languished behind other cancer screening tests for several reasons. Chest X-rays were thought to be the answer to finding lung cancer early. When studies showed no effect on lung cancer mortality, the disenchantment cast a long shadow, even though some experts argued that faulty study design, not the technology, was the reason. Low-dose CT scans that were strong enough to find lung cancer but delivered less radiation exposure than diagnostic scans were welcomed as a successor to failed chest X-rays. Early trials were promising, explains Bernardo Goulart, MD, a thoracic oncologist and investigator at the Fred Hutchinson Cancer Research Center. But the flaws—ranging from inherent biases to misguided endpoints—undercut the conclusions that would have supported screening and assuaged concerns about possible harm. Price was another factor. An LDCT scan is about 10 times as expensive as a chest X-ray.

More recently, enthusiasm for LDCT screening has been tempered by a relatively new and growing concern about the overdiagnosis and overtreatment of all cancers. Goulart says that “the new kid on the block, relative to established screening programs,” may have attracted more than its fair share of concern about false positives and overdiagnosis.

As delays in lung cancer screening mounted over the years, some frustrated patients, advocacy organ-

---

**New scoring system: Far fewer false alarms**

The American College of Radiology (ACR) has a new system for scoring lung lesions found with low-dose CT (LDCT) screening scans, and it might cut the number of false positives by two thirds.

The new system, dubbed Lung-RADS, tightens the criteria for what is considered a positive finding that requires follow-up testing. Ella Kazerooni, MD, a University of Michigan radiologist and chair of the American College of Radiology’s lung cancer screening committee, applied the Lung-RADS scoring system to data collected from the National Lung Screening Trial, a large study of LDCT lung cancer screening and the basis for many of today’s screening policies and coverage decisions.

The results, reported in the *Annals of Internal Medicine* in February, showed that 11,615 (66.6%) of the false positives in the nationwide screening trial would have been avoided had the Lung-RADS system been used. The positive predictive value of the LDCT scans also improved with the Lung-RADS scoring system (6.9% vs. 3.8% for the baseline reading).

The trade-off is that the Lung-RADS system missed 13.3% (86 out of 649) of the cancers found during the national study, but Kazerooni says many of the missed cancers are those thought to be overdiagnosed.

**LDCT screening** for lung cancer was held back by flaws in early studies, says Bernardo Goulart, MD, of the Fred Hutchinson Cancer Research Center.
the years, some frustrated patients, advocacy organizations, and clinicians have seen the stigma on smoking as being at least partly to blame.

Ella Kazerooni, MD, a professor of radiology at the University of Michigan and chair of the American College of Radiology’s committee on lung cancer screening, points instead to higher standards of evidence as an explanation: “Twenty or 30 years ago, if a new imaging application emerged, particularly if it involved the use of an already FDA-approved device, people just started using it.” These days, however, faced with budget constraints, CMS in particular requires a much higher level of evidence than before.

To definitively answer the question of whether LDCT screening might significantly reduce mortality associated with lung cancer, the National Cancer Institute invested more than $250 million in a randomized trial that enrolled more than 53,000 high-risk individuals—they had to have a smoking history of at least 30 pack-years—between the ages of 55 and 74. The National Lung Screening Trial (NLST) showed a 20% reduction in mortality in the LDCT arm compared with the control group, which was screened with chest X-rays. That works out to 3 fewer deaths for every 1,000 people screened by CT scans compared with those screened by chest X-ray. Showing a difference in mortality is the gold standard for any screening program, so these results bolstered the case for screening. The downside was the number of false positives: 39.1% of those in the LDCT group had at least one positive screening result, and the vast majority (96.4%) of those positive results were false. A lot of the harm from false positives from some screening tests lies in unnecessary biopsies and complications from those biopsies. But in the NLST a relatively small percentage (2.7%) of those with positive results that turned out not to be cancer had an invasive procedure to check out the abnormal result. The NCI released preliminary results from the NLST in 2010, and the full results were subsequently published in the New England Journal of Medicine in 2011.

Cost–benefit thumbs up
Several commercial insurers started covering LDCT screening before the preventive services task force decision in 2013. Aetna’s coverage started in September 2013. “Our policies are informed by data published in peer-reviewed literature, and we felt that evidence supported coverage for screening of high-risk individuals, based on the NLST results,” says Robert McDonough, MD, senior medical director for clinical policy research and development at the company.

A number of insurers were early supporters of community lung screening programs in regions where large industrial workforces had been exposed to substances such as asbestos. One such screening program is run by the Roswell Park Cancer Institute in Buffalo. According to Pamela Germain, MBA, vice president of strategic initiatives at the institute, three regional insurance companies began to cover the screening of the high-risk population close to a decade ago.

Aetna started covering lung cancer screening in September 2013, says Robert McDonough, MD, who oversees clinical policy research at the plan. He depends on peer-reviewed literature.

In 2012, Milliman actuaries published a cost–benefit analysis of LDCT screening in Health Affairs that might have encouraged commercial insurance coverage. They built their model on the assumption that any insurer’s screening program would be limited to current and former smokers with a 30 pack-year history. Because they wanted to figure out the costs for commercial insurers, they set the age range at 50 to 64. Figuring that half the people in that group would be screened, they calculated that the PMPM cost of a lung cancer screening program for a commercial insurer would be 76 cents with no cost sharing. That compares favorably to PMPM costs they identified for screening for breast cancer ($2.50), cervical cancer ($1.10), and colorectal cancer (95 cents), although there is an apples-to-oranges problem because the PMPM cost for those other screening tests were calculated in 2006 dollars and came after cost sharing. When the Milliman actuaries crunched the numbers for the cost for every year of life saved, the results were favorable for lung cancer screening ($18,862 per life-year saved using their baseline scenario) in comparison with Pap smears for cervical cancer ($50,162–$75,181), colonoscopy ($18,705–$28,958), and mammography ($31,309–$51,274).

The lead author of the paper in Health Affairs, Bruce Pyenson, published a similar analysis of LDCT screening of the Medicare population last year. He and his coauthors figured that about 4.9 million Medicare beneficiaries meet the criteria for lung cancer screening. Assuming that half would be screened, they calculated that the PMPM cost would be $1.02, assuming no cost sharing.

In November 2014, CMS released a coverage proposal with stringent requirements, many of which were criticized. A proposal that would have limited eligible screening centers to those that participated in the NCI trial was particularly worrisome to screening
Smoking cessation program requirements are foggy

Taking advantage of the teachable moment that lung cancer screening provides, CMS requires smoking cessation counseling of all high-risk smokers who qualify for screening. However, the criteria for acceptable counseling are vague, as are the methods of evaluation. Currently, providers simply check a box to verify that counseling has taken place, and medical records document the new non-smoking status of some patients who claim to have quit. This worries screening experts, who believe that counseling will have value only if it is implemented well and then reinforced.

“Very brief interventions that involve just warning the patient of the dangers of smoking and then handing the patient a flier aren’t going to work,” warns Anil Vachani, MD, director of lung cancer screening at the University of Pennsylvania.

ACA regulations have allowed self-insured employers and commercial insurers who offer individual coverage to charge smokers up to 50% more in premiums than nonsmokers if they make smoking cessation programs available.

Theoretically, this arrangement provides smokers with a financial incentive for quitting, but patients and insurers find the details of the requirement hazy.

Most members of Independence Blue Cross in southeastern Pennsylvania have two choices. Pregnant women and those in Medicare Advantage plans may participate in the Quit&Fit Tobacco Cessation program for free. Members in a commercial plan qualify for up to $150 in reimbursement when they participate in an approved program that focuses on behavior modification.

For private as well as public payers, the law is pretty vague about what constitutes a smoking cessation program, says Kimberly Eberbach, vice president of wellness and community health at Independence. Guidelines don’t specify whether programs should incorporate pharmacotherapy, telephone counseling or messaging, or any particular follow-up strategy. Beneficiaries seeking reimbursement for counseling do not have to prove that they’ve quit, only that they attended an approved program.

Independence would like better data to evaluate the efficacy of various programs, but “it’s a bit sticky because some members often don’t want us to know the outcomes,” says Eberbach. The company works hard to protect members’ health information and ensure confidentiality, but some members may still have concerns about how the information is being used, she says.

Smoking cessation program requirements are foggy about what constitutes a smoking cessation program, says Kimberly Eberbach, vice president of wellness and community health at Independence. Guidelines don’t specify whether programs should incorporate pharmacotherapy, telephone counseling or messaging, or any particular follow-up strategy. Beneficiaries seeking reimbursement for counseling do not have to prove that they’ve quit, only that they attended an approved program.

While experts agree that screening for cancer must go on for several years before its influence on health and health care costs can be fully determined, many are hopeful that CMS will reexamine the details of its coverage. In particular, some experts want the criteria for high-risk individuals loosened, a change that might include increasing the age range so people would be eligible for screening starting at age 50 instead of 55. They would also like to see the definition of the former smoker expanded, arguing that drawing the line at smokers who quit in the past 15 years may leave out some high-risk people.

Susan Worley is a Philadelphia freelance writer who specializes in science and medicine.
The modern world would fall apart without glue. It is critical to the manufacturing of all kinds of items we depend on in our daily lives, from shoes to shelves to the roof over our heads. High-tech adhesives hold together airplanes and keep boats afloat. And humanity has been depending on sticky stuff for a long time. The earliest evidence of the use of glue dates back 200,000 years, when birch bark pitch was used to hold stone flakes to a crude wooden spear.

Adhesive materials are also common and incredibly useful in health care. Where would we be without the humble Band-Aid? Surgeons use a variety of glues and cements to stop bleeding, bind artificial joints, and close lacerations. Now we have the first synthetic adhesive for internal soft tissue use, Cohera Medical’s TissuGlu Surgical Adhesive. Approved by the FDA in February as a medical device, TissuGlu is indicated for “the approximation of tissue layers where subcutaneous dead space exists between the tissue planes in abdominoplasty.”

**Surgeon as quilter**

Abdominoplasties—more commonly known as tummy tucks—remove excess skin and fat from the abdomen and, in most cases, involve some restoration of the muscles of the abdomen. They are done to remove hanging skin after someone has lost a great deal of weight as well as for cosmetic purposes. An abdominoplasty requires a lot of dissection, which, in turn, creates a space where fluid can pool and create seromas, pockets of serous fluid.

TissuGlu, a biocompatible polyurethane based prepolymer, creates a strong bond between tissue planes in the presence of moisture. The wound surfaces provide the moisture, so it does not need to be premixed. The adhesive is applied in drops to the tissue surface with an applicator that looks like what it is: a very precise, high-tech glue gun. The head of the applicator has a spacer guide, so the surgeon can deliver the tissue glue in grid with each drop 2.5 centimeters apart.

The adhesive takes between 30 and 45 minutes to cure, and the curing takes place while the surgeon and his team are busy with other tasks to complete the surgery. The adhesive’s bond is designed to stay strong enough to allow for complete healing and then, over time, degrade so the chemical components are eliminated from the body.

Surgical Stick-to-itiveness

TissuGlu binds tissue layers together after tummy tucks so fluid that can cause infection doesn’t accumulate and healing improves.

Thomas Morrow, MD

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Thomas Morrow, MD, is chief medical officer of Next IT. He is the immediate past president of the National Association of Managed Care Physicians and has 24 years of managed care experience at the payer or health plan level. The views expressed here are his alone. Contact him at TMorrow@ManagedCareMag.com.
TissuGlu underwent numerous biocompatibility tests for cytotoxicity, pyrogenicity, carcinogenicity, reproductive toxicity, and other harms. The adhesive was studied in two pivotal trials. The first was conducted to evaluate safety and determine whether TissuGlu plus the use of drains was superior to the use of sutures plus the use of drains. This study failed to demonstrate superiority but did demonstrate safety.

The second study was also designed to evaluate safety and adverse events but, more importantly, to evaluate whether TissueGlu, along with standard wound closure (SWC) techniques but no drain placement, is as safe and effective as SWC with drains. The endpoints included fluid management, seroma formation, subjective satisfaction, and quality of life.

Powered as a noninferiority study, 130 subjects were randomized on a 1:1 basis. The control group received SWC plus the placement of two size 12 Blake drains over the abdominal fascia, delivered through stab incisions to the pubic area that were then fixed with suture. The exclusion criteria were factors that inhibit normal healing, such as a current smoking habit, collagen vascular disease, diabetes, and concurrent use of systemic steroids or immunosuppressive agents. Almost all (98.4%) of the study volunteers were women, most (70%) were white, their median age was 42, and their median weight, 143 pounds. All had skin laxity on the abdomen.

Patient-reported outcomes, collected as descriptive with no formal hypothesis testing, demonstrated that a subset of people in the TissuGlu group were able to shower, walk up stairs, and return to work earlier than their counterparts with the drains.

The primary endpoint of the trial was postoperative treatments, including removal of drains and needle aspirations (see table). The TissuGlu group had fewer postoperative treatments than the control group because there were no drains to remove. As expected, though, the patients in the TissuGlu group experienced more seromas and had more needle aspirations. Seromas that required an operative drain placement were considered serious adverse events, and four of those occurred (two in one patient) as well as one hematoma. A subset analysis based on BMI resulted in a warning that patients with a BMI of over 28 may be at increased risk of seroma complications.

TissuGlu is fascinating. The use of this substance is an attractive alternative to quilting and drain insertion for abdominoplasty. Once surgeons become adept at using the adhesive and the applicator, the operations should take less time. Shorter operations mean less anesthesia for patients and reduced operating room time for surgical teams. By eliminating the puncture wounds required for drain placement, TissuGlu should make the recovery from tummy tucks much more comfortable. A small percentage of TissuGlu patients did end up needing drains, but the majority (73% in the pivotal trial) avoided fluid-related treatment.

**Other uses**

Although the only approved indication for TissuGlu is abdominoplasty, numerous other procedures require the placement of drains so surgeons will look for other uses.

TissuGlu is not a huge leap forward, but it demonstrates that even incremental improvements are important and that any standard medical practice is subject to disruption by Tomorrow’s Medicine!

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**Primary endpoint results of pivotal TissuGlu trial***

<table>
<thead>
<tr>
<th></th>
<th>Standard wound closing with TissuGlu and no placement of drains</th>
<th>Standard wound closing with drains</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n=66</strong></td>
<td></td>
<td>n=64</td>
</tr>
<tr>
<td>Needle aspirations</td>
<td>112</td>
<td>24</td>
</tr>
<tr>
<td>Removal of drains</td>
<td>7</td>
<td>128</td>
</tr>
<tr>
<td>Total</td>
<td>119</td>
<td>152</td>
</tr>
</tbody>
</table>

*Post-operative invasive treatments include removal of drains, needle aspirations, repositioning of drains, re-insertion of drains. Source: Cohera Medical

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A Discrete Choice Experiment to Elicit Patient Willingness to Pay for Attributes of Treatment-Induced Symptom Relief in Comorbid Insomnia

Anuja N. Roy, PhD, S. Suresh Madhavan, PhD, and Andrew Lloyd, PhD

BACKGROUND
Insomnia is an underreported (Benca 2005), underrecognized (Winkelman 2005, Rosenberg 2006), underdiagnosed, and undertreated condition, likely due to the fact that about three-fourths of cases are comorbid with other “primary” illnesses (Roth 2003, Thase 2005). Despite the individual, social, and economic burden it imposes, with annual costs estimated in the tens of billions of dollars in the United States alone (Walsh 1999, Stoller 1994), and a prevalence among adults of 6% to 30% (Roth 2007), insomnia remains inconsistently understood among health care professionals, primarily owing to the disorder’s myriad presentations and etiologies. Although pharmacological treatment options are widely available (Winkelman 2005, Rosenberg 2006), insomnia’s multifarious nature has made defining the condition difficult, and in turn has complicated evaluation of drug effectiveness. Prescription sleep aids offer varying levels of symptom relief along a number of dimensions, including improvements in sleep onset latency, sleep maintenance, and number of awakenings (Dündar 2004). Furthermore, disparities in safety profiles factor into both physicians’ and patients’ treatment decision making.

ABSTRACT
Purpose: Insomnia is a burdensome, commonly comorbid condition. How patients value various aspects of the safety and efficacy of available drugs has not been studied. The aim of the present study was to quantify patient-rated utility by studying willingness to pay (WTP) for attributes of symptom relief via a discrete choice experiment (DCE).

Methodology: Adult primary care patients (West Virginia University Hospital) with comorbid insomnia were enrolled. The attributes and levels examined were sleep onset latency (SOL; 10, 20, 30 minutes), awakenings (1, 2, 3), wake time after sleep onset (WASO; 15, 45, 60 minutes), total sleep time (TST; 6, 7, 8 hours), hangover (none, mild, moderate), FDA-approved duration of use (short term, not restricted to short term, no restrictions), and out-of-pocket cost per month ($20, $35, $50). Willingness to pay (WTP) data were analyzed using a random effects binary logistic regression model.

Results: A total of 82 patients completed the DCE (74 analyzed). SOL, WASO, TST, and cost were all found to predict treatment choice. Higher values of SOL, WASO, and cost resulted in decreased preference for a particular treatment, while higher TST predicted increased preference. Modeling revealed an estimated marginal WTP of $66.69 for an example product that improved SOL by 10 minutes, reduced WASO by 15 minutes, and improved TST by 1 hour.

Conclusion: Patient WTP for symptomatic relief in insomnia can help clinicians fine-tune interventions based on patient preferences, provide evidence for drug formulary and reimbursement decisions, and potentially guide the development of novel drugs.

As presentation varies from patient to patient, so too does the relative benefit and value patients derive from treatment. Consequently, out-of-pocket willingness to pay (WTP) may represent the best method for evaluating therapeutic utility for both patients and payers (see glossary on page 43). Although WTP for symptom relief or cure has been examined in a number of conditions, including urinary incontinence (O’Conor 1998), psoriasis or atopic eczema (Lundberg 1999), and asthma (Blumenschein 1998), WTP studies of pharmacological interventions of insomnia remain scant in the literature. To remedy this gap in understanding, a discrete choice experiment (DCE) was conducted to estimate patients’ WTP for various attributes of pharmacologically mediated symptom relief in insomnia. Determining the price that patients place on improvement of various symptoms and on complete symptom relief would enable an understanding of how patients value the impacts of insomnia...
drugs in improving disease symptoms. Attributes for which patients are likely to pay greater amounts of money would be the ones that patients value more. These highly valued attributes could provide critical evidence for drug formulary and reimbursement decisions, as well as potentially guiding novel drug development. As such, an assessment of differential WTP for various insomnia treatment attributes and complete symptom relief would constitute a valuable addition to the literature.

**METHODS**

**Inclusion criteria/recruitment**

Patients visiting the Clark K. Sleeth Family Medicine Center (West Virginia University, Morgantown) during the 6 months prior to the study were recruited via the clinic’s database. Adults (≥18 years of age) with an ICD-9 diagnosis code pertaining to any of five predefined classes of chronic conditions (cardiovascular, diabetes, gastrointestinal, musculoskeletal, and obstructive airways disease) were eligible to participate. Patients diagnosed with psychiatric conditions (eg, depression) or with other sleep disorders (eg, obstructive sleep apnea) were excluded.

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**Corresponding author:**

Anuja N. Roy

40 Robin Hood Lane

Chatham, NJ 07928

Telephone: (201) 400-1671

Email: anuja.roy@novartis.com

A survey packet, comprising a demographic and general health questionnaire and a screening questionnaire for insomnia (the Insomnia Severity Index [ISI]—a validated 7-item instrument [Bastien 2001]), was initially mailed to all selected participants. A cut-off score of >15 on the ISI was used to identify patients suffering from insomnia (Bastien 2001). Results of this survey have been described elsewhere (Roy 2014). Respondents identified as having insomnia via the ISI were subsequently mailed the DCE survey.

**Glossary**

**Approved Duration of Use**

The period of time over which a drug may be safely used, as specified by the FDA. The FDA approves some sleep aids for short-term use (3–4 weeks), and some are approved with no short-term restrictions, so they may be used for a few months or years. Other sleep aids are approved with no restrictions on duration of use whatsoever, meaning they can be used indefinitely. Sleep aids approved with lesser restrictions presumably would be considered safer and thus favored by patients.

**Awakenings**

The number of disruptions in a sleep period. Sleep aids that reduce the number of awakenings in a given sleep period presumably would be favored by patients.

**Discrete Choice Experiment (DCE)**

A means of elucidating preferences across a given set of attributes. In a DCE, subjects select their preferred alternative from a number of hypothetical alternatives, where each option is described by a unique combination of attribute levels.

**Hangover**

Residual sedation attributed to a pharmacological sleep aid. Sleep aids with less of a hangover presumably would be favored by patients.

**Sleep Onset Latency (SOL)**

The delay between the attempt to sleep and actual sleep onset. Sleep aids that reduce SOL presumably would be favored by patients.

**Total Sleep Time (TST)**

The cumulative amount of time spent asleep in a sleep period. Sleep aids that increase the total amount of time spent asleep presumably would be favored by patients.

**Wake Time After Sleep Onset (WASO)**

The cumulative amount of time spent awake in a sleep period. Sleep aids that reduce the amount of time awake following an awakening presumably would be favored by patients.

**Willingness to Pay (WTP)**

A measure of the utility or value, in monetary terms, assigned to a particular therapeutic attribute or set of attributes.

**Rationale behind study design**

WTP can be estimated using a DCE, an attribute-based stated preference valuation technique used to quantify preferences (ie, utilities) for commodities. By including a “price” attribute in a DCE, a monetary measure of benefit (ie, WTP) may be estimated (Kleinman 2002). In a DCE, subjects choose their pre-
Willingness to Pay for Insomnia Treatments

KEY POINTS

- Sleep onset latency (time it takes to fall asleep), wake time after sleep onset (cumulative amount of time spent awake during a sleep period), total sleep time, and cost are useful in predicting sleep aid preferences.
- People are willing to pay $2.22 per month for every minute of reduction in sleep onset latency.
- People are willing to pay $1.44 per month for each minute less they are awake during the sleep period.
- An increase in total sleep time from 6 to 7 hours is highly valued, but people are indifferent to adding sleep time over 7 hours.
- Willingness to pay changes with financial circumstances, so these findings might not apply to people in different circumstances.
- The study did not include cognitive debriefing of the respondents that would help identify issues related to respondent understanding of the discrete choice experiment (DCE) scenarios.
- People in this study were recruited at an outpatient clinic of a hospital, and their insomnia was associated with other health conditions. These findings may not generalize to other populations.

ferred alternative from a number of hypothetical choices. Each choice is described by a unique combination of attribute levels. For example, in a hypothetical DCE examining three levels of both dosing (once, twice, or thrice daily) and method of administration (oral, intravenous, or topical), a potential choice-set presented to subjects might be an oral medication administered once daily versus a topical medication administered thrice daily. Using a DCE, it is possible to identify the relative importance of the individual attributes, and quantify how individuals weigh the tradeoffs between them. Including cost as an attribute can yield marginal WTP estimates for the various attributes as well as total WTP for combinations of attribute levels (Ryan 2001). Although WTP may be directly estimated by other means, DCEs may provide richer information than such methods by accounting for how constituent attributes affect utility (Louviere 2000).

Design of the discrete choice experiment

The attributes and levels examined in the DCE were determined via a review of the literature and expert input (interviews with three sleep specialists and a focus group discussion with eight general practitioners). Specifically, experts were queried regarding hypnotics in the context of patients seeking treatment for insomnia comorbid with other somatic conditions.

Based on the results of these investigations, the following attributes and levels were chosen as representative of the important determinants in choosing a prescription sleep aid: sleep onset latency (SOL; 10, 20, 30 minutes), awakenings (1, 2, 3), wake time after sleep onset (WASO; 15, 45, 60 minutes), total sleep time (TST; 6, 7, 8 hours), hangover (none, mild, moderate), FDA-approved duration of use (short term, not restricted to short term, no restrictions), and out-of-pocket cost per month ($20, $35, $50). Out-of-pocket costs were estimated based on input from a pharmacy manager regarding typical monthly payments made by patients for prescription sleep aids.

Because it wasn’t feasible to present all unique choice-sets to respondents, a set of 18 unique, two-choice scenarios (Table 1, page 46) was chosen based on an experimental design using the Addelman-Kempthorne orthogonal array, the simplest specification with the correct number of attributes and levels (Addelman 1961). Choice-sets were generated based on input from clinicians and an expert in DCE methodology. Scenarios were designed to exhaustively examine attributes of potential interest to patients and to be easy to understand. Figure 1 on page 45 is an example of one of the choice scenarios presented to the study subjects.

Administration of the discrete choice experiment

Participants were mailed paper-and-pencil format DCE questionnaires and an instruction booklet. Patients were instructed to imagine a situation in which they wanted to get a prescription for a sleep aid either for the first time or because their current sleep aid was not helping, and to select one treatment they preferred from each set of treatment choices offered. A scenario superior on all attributes was posed as a consistency check. Data from respondents failing the consistency check (i.e., those not choosing the clearly superior scenario) were discarded. Respondents were offered a gift card of $15 as a gesture of appreciation for completing the questionnaires.

Ethics and blinding

All research activities were approved by the Institutional Review Board (IRB) of West Virginia University prior to study commencement. Privacy safeguards in compliance with the IRB and the Health Insurance Portability and Accountability Act were instituted for the study, and all patient-level data (related to diagnoses, age, and insurance status) were obtained from patient records extracted by participating clinic staff.
Relative utility varied among the attribute levels examined (Table 3). A positive trend with increasing level was observed in FDA-approved duration and cost, initially indicating a progressive increase in estimated utility among respondents for increasing values of those attributes (log odds ratios are linearly related to the unknown utilities for each attribute level [Louviere 2000]). The opposite trend, however, was observed in WASO, which proceeded from a positive marginal mean of 0.3 for the 15-minute level to −0.3 at 45 minutes. Similarly, SOL, awakenings, and TST all showed initial increases followed by a decreasing or flattening trend, while hangover exhibited the opposite (ie, an initial decrease followed by an increase across attribute levels).

Statistically significant Wald statistics (P ≤ 0.05) for the parameter estimates for SOL, WASO, TST, and cost were observed.

The marginal means (ie, utilities) of the log odds for the various attributes were calculated based on the odds of a respondent choosing a particular attribute profile and are summarized in Table 3. The WTP model based on binary logistic regression analyses of these data is presented in Table 4. Estimates of WTP for changes in each of the attributes are provided in Table 5.

### RESULTS

Altogether, 82 patients completed the DCE. Eight respondents failed the consistency check and were discarded, for a total of 74 submitted to analysis. Over 60% of the respondents were women; the average age was 52 years. Demographic and socioeconomic data are presented in Table 2.

### Statistical analyses

WTP data were analyzed by a random effects binary logistic regression model, which was implemented using SPSS (version 14.0). First, odds and the logarithm of the odds of choosing each particular scenario within a profile were calculated. Subsequently, the marginal means (or utilities) of each particular attribute were calculated. Finally, a logit model was employed to estimate binary response probabilities among scenario pairs.

### TABLE 2

<table>
<thead>
<tr>
<th>Demographic characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), years</td>
<td>51.7 (±25.1)</td>
</tr>
<tr>
<td>Sex, female</td>
<td>62.2%</td>
</tr>
<tr>
<td>Race, white</td>
<td>94.6%</td>
</tr>
<tr>
<td>Married currently</td>
<td>55.4%</td>
</tr>
<tr>
<td>Educational status</td>
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</tr>
<tr>
<td>High school or less</td>
<td>47.3%</td>
</tr>
<tr>
<td>Some college</td>
<td>18.9%</td>
</tr>
<tr>
<td>College graduate</td>
<td>32.4%</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
</tr>
<tr>
<td>Employed full time</td>
<td>41.9%</td>
</tr>
<tr>
<td>Employed part time</td>
<td>8.1%</td>
</tr>
<tr>
<td>Not employed</td>
<td>48.6%</td>
</tr>
<tr>
<td>Annual household income</td>
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</tr>
<tr>
<td>&lt;$25,000</td>
<td>40.5%</td>
</tr>
<tr>
<td>$25,001−$50,000</td>
<td>29.7%</td>
</tr>
<tr>
<td>$50,001−$100,000</td>
<td>13.5%</td>
</tr>
<tr>
<td>&gt;$100,000</td>
<td>12.2%</td>
</tr>
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</table>
TABLE 1
Orthogonal array of attribute level choice-sets

<table>
<thead>
<tr>
<th>Question</th>
<th>Sleep onset latency (minutes)</th>
<th>No. of awakenings</th>
<th>Wake time after sleep onset (minutes)</th>
<th>Total sleep time (hours)</th>
<th>Hangover</th>
<th>Duration of use approved</th>
<th>Cost</th>
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<tbody>
<tr>
<td>1</td>
<td>10</td>
<td>1</td>
<td>15</td>
<td>6</td>
<td>None</td>
<td>3–4 weeks</td>
<td>$20</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>2</td>
<td>45</td>
<td>7</td>
<td>Mild</td>
<td>6 months</td>
<td>$20</td>
</tr>
<tr>
<td>3</td>
<td>30</td>
<td>3</td>
<td>60</td>
<td>8</td>
<td>Moderate</td>
<td>Indefinite</td>
<td>$20</td>
</tr>
<tr>
<td>4</td>
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<td>45</td>
<td>8</td>
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<tr>
<td>5</td>
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<td>60</td>
<td>6</td>
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<td>3–4 weeks</td>
<td>$20</td>
</tr>
<tr>
<td>6</td>
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<tr>
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<td>$35</td>
</tr>
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<td>60</td>
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<td>3–4 weeks</td>
<td>$35</td>
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<tr>
<td>10</td>
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<td>6 months</td>
<td>$35</td>
</tr>
<tr>
<td>11</td>
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<td>15</td>
<td>7</td>
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<td>$35</td>
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<tr>
<td>12</td>
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<td>3–4 weeks</td>
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<td>15</td>
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<td>Moderate</td>
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<tr>
<td>16</td>
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<tr>
<td>17</td>
<td>20</td>
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<tr>
<td>18</td>
<td>30</td>
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<td>15</td>
<td>6</td>
<td>Mild</td>
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<td>$50</td>
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<tr>
<td>Sleep onset latency (minutes)</td>
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<td>Total sleep time (hours)</td>
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<td>Duration of use approved</td>
<td>Cost</td>
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<td>7</td>
<td>Moderate</td>
<td>3–4 weeks</td>
<td>$20</td>
<td></td>
</tr>
</tbody>
</table>
data is that the participants placed no value on the avoidance of hangover or restrictions on use in this sample of patients in which the DCE was conducted. Based on these estimates, the marginal WTP for an example product that improved SOL by 10 minutes, reduced WASO by 15 minutes, and improved TST by 1 hour would be: $(2.22 \times 10) + (1.44 \times 15) + (22.89 \times 1) = $66.69 per month.

**DISCUSSION**

The objective of the study was to determine patients’ preferences for various types of treatment-induced symptom relief by assessing WTP, which has not been studied previously. Based on the results, the attributes of SOL, WASO, and TST were useful in predicting choice of hypnotic, while awakenings were not. Specifically, higher levels of SOL or WASO (ie, the amount of time trying to fall asleep or the time awake following a sleep interruption) were associated with a lower preference, while a greater TST (ie, the overall amount of sleep) was associated with increased preference.

Attributes demonstrating statistical significance may be considered to be especially useful in explaining the DCE model. Individually, findings reveal some nuance among patient preference (or lack thereof) for particular attributes. The awakenings attribute, for example, did not reach statistical significance; however, WASO, which did, incorporates the concept of both number of awakenings and the duration of such awakenings, and therefore the concept of awakenings was validated and remained accounted for in the model. With respect to SOL, the

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**TABLE 3**

<table>
<thead>
<tr>
<th>Marginal means (utilities) of levels*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep onset latency (10, 20, 30 minutes)</td>
</tr>
<tr>
<td>Awakenings (1, 2, 3)</td>
</tr>
<tr>
<td>Wake time after sleep onset (15, 45, 60 minutes)</td>
</tr>
<tr>
<td>Total sleep time (6, 7, 8 hours)</td>
</tr>
<tr>
<td>Hangover (none, mild, moderate)</td>
</tr>
<tr>
<td>FDA-approved duration of use (short term, not restricted to short term, no restrictions)</td>
</tr>
<tr>
<td>Costs, out-of-pocket per month ($20, $35, $50)</td>
</tr>
</tbody>
</table>

*Marginal means represent the utilities attached to the different levels of the attributes.

**TABLE 4**

<table>
<thead>
<tr>
<th>Variables and their parameters estimates in the equation (results from the basic logistic regression analyses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attributes</td>
</tr>
<tr>
<td>Sleep onset latency</td>
</tr>
<tr>
<td>Awakenings</td>
</tr>
<tr>
<td>Wake time after sleep onset</td>
</tr>
<tr>
<td>Total sleep time</td>
</tr>
<tr>
<td>Hangover, none</td>
</tr>
<tr>
<td>Hangover, mild</td>
</tr>
<tr>
<td>Hangover, moderate</td>
</tr>
<tr>
<td>FDA, short term</td>
</tr>
<tr>
<td>FDA, not restricted to short term</td>
</tr>
<tr>
<td>FDA, no restrictions</td>
</tr>
<tr>
<td>Costs, out-of-pocket per month</td>
</tr>
<tr>
<td>Constant</td>
</tr>
</tbody>
</table>

B=logistic coefficient, df=degrees of freedom, Exp(B)=change in odds ratio, SE=standard error, Wald=Wald statistic.
negative sign on this attribute indicated that respondents preferred a reduction in SOL. Similarly, the negative coefficients on WASO suggest that respondents preferred a decrease in the attribute and would be willing to pay for it. Also, as anticipated, marginal utilities decreased with increasing WASO (ie, patients preferred a decrease in WASO) and increased with lengthening TST. Although the increase in sleep time by 1 hour was valued very highly, as shown by the increase in utilities moving from 6 to 7 hours, patients seemed to be relatively indifferent to an increase in total sleep time over 7 hours.

FDA-approved duration of use performed inconsistently, and while the coefficient for one level of this attribute was positive, indicating that longer approved duration of use may be of value to patients, the attribute did not reach statistical significance. Hangover similarly performed inconsistently, as sign varied counter to expectations. These results were possibly the consequence of the study participants misinterpreting the attributes and levels as they were responding to questions in a mailed survey. Therefore, we chose to interpret this data in the simplest and most appropriate way and treat it as though the participants did not place any value on the two attributes.

Despite the minor deviations noted, overall the model appears consistent with a priori expectations that, in choosing an insomnia treatment, patients have different preferences for the various aspects of symptom relief examined.

**Limitations**
Discrepancies have been observed between what patients claim they will pay and what they actually pay (Blumenschein 2001). Although the results of the present study indicate a WTP for symptom relief in insomnia, true WTP may differ in real-world scenarios, especially in the face of other financial commitments. This may be particularly true among the population sample described in the present study, of which 48.6% were unemployed and a further 8.1% employed only part-time—figures likely related to the relatively high proportion of subjects (47.3%) completing only high school or less. Generally, WTP is most influenced by ability to pay and the severity of the disease condition. As such, similar studies employing samples more representative of the nation as a whole, or with varying proportions of more well off or severely afflicted individuals, may differ considerably in their findings.

As previously noted, respondents were a small convenience sample of patients from the outpatient clinics of a university hospital, which, in addition to the considerations noted above, may limit its generalizability and statistical power. In particular, owing to the predominately Caucasian makeup of the sample (94.6%), it is unclear whether WTP might differ across a more racially diverse population.

It is also worth noting that, in the absence of an understanding of what constitutes an ideal response burden for the survey population, the number of questions asked may not have been optimal and thus had an unpredictable effect on response rates. Nevertheless, these findings are instructive with respect to the relative importance patients ascribe to the various attributes of symptom relief.

**Importance**
Knowledge of WTP for symptomatic relief in insomnia can help clinicians understand the preferences of patients and fine-tune an intervention based on characteristics of the prescribed treatment. Data with respect to patient WTP may help assess whether important benefits from treatment are in line with patients’ preferences and how much patients value those benefits.

Such knowledge can also help guide decision makers in the cost-effective provisioning of health care. As estimates of direct and indirect costs of untreated insomnia have pegged 6-month expenditures as $1,253 greater for patients with insomnia (Ozminkowski 2007), the incentives to effectively treat the condition are strong. Payers and hospital policy makers can use WTP information as a relevant outcome measure to create a monetary rank-order based on stated user value, and thereby make decisions concerning formulary inclusions and pharmacy benefits as new
products are introduced into clinical practice. Manufacturers can also use information on patient preferences and WTP for various product-related attributes to guide product development and marketing. Such informed decisions are especially critical in an age of increasing accountability for health care dollars spent and patient-centered health care. Ms.

REFERENCES

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A shift toward value-based reimbursement, which only a couple of years ago seemed very slow in the making, may unseat the entrenched fee-for-service (FFS) payment model in five years, according to experts.

Health care usually moves glacially, but that’s not what’s happening here.

Managed Care reported in 2013 (http://tinyurl.com/FFS-article) about FFS medicine’s inertia. The use of CPT codes have enmeshed FFS payment into the delivery of American health care. Many health plans lack the information systems needed to sustain whatever might replace FFS payment. A move away from FFS payment will mean that contracts with thousands of provider groups will have to be rewritten.

In its first scorecard on payment reform, released in March 2013, the Catalyst for Payment Reform (CPR), a not-for-profit organization that advises large employers and insurers about quality improvement, reported that just 11% of payment to providers is not under a FFS model. Well, guess what? CPR’s second report card last year found that 40% of commercial health plan payments were made through payment methods designed to improve quality and reduce waste. CPR cautions, however, that more study is needed to determine whether value-based reimbursement actually leads to better and more cost-effective care.

That’s quite a jump—but not a complete surprise, considering the clues. Top executives at UnitedHealthcare, Anthem Blue Cross, and Aetna have all been quoted in recent months about the concerted value-based efforts their companies are making. CMS is throwing its weight behind the trend by mandating that 30% of Medicare outlays by 2016, and half by 2018, be routed through alternative payment models such as ACOs and bundled payments.

McKesson Health Solutions has no doubts about which way the wind is blowing. After surveying top-level managers at 114 payers and 350 hospitals, the consulting company said that “there can be no question as to health care’s embrace of value-based models” and reported that the payment landscape is changing so fast that value-based payment will overtake FFS by 2020. In fact, according to McKesson’s findings, the future has already arrived, with 90% of payers and 81% of providers using some mix of value-based reimbursement and FFS.

One note of caution: Value-based payment is in vogue, and the term is deployed loosely. In some hands, it’s being used to describe almost any kind of payment that has a quality or performance metric attached.