The JAMA Forum

A New Focus on Prescription Drug Spending

Gail Wilensky, PhD

A chorus of concern over the cost of prescription drugs for both patients and the health system has been growing louder. Spending on prescription drugs surged 13% last year to a record $374 billion, according to a report from IMS Institute for Healthcare Informatics (http://bit.ly/1DzzWMw). That’s the largest increase in the pace of prescription drug spending since 2000-2001, when drug spending rose by 16%, and significantly faster than the 6.8% spending growth projected by the Centers for Medicare & Medicaid Services (CMS) (http://go.cms.gov/1G35bAD).

Much of the attention has been focused on 2 new drugs introduced by Gilead Sciences in 2013 (Solvadi; the highest-selling drug in 2014 at $7.9 billion, according to the IMS report) and 2014 (Harvoni) for treating hepatitis C virus (HCV) infection, as well as other new biologic or specialty drugs for cancer, diabetes, and multiple sclerosis. The recommendation by a US Food and Drug Administration (FDA) panel in June 2015 to approve 2 injectable cholesterol-lowering drugs is certain to keep the questions that are raised by the chorus of concern over the cost of these new drug types front and center.

But the reasons for the prescription drug-spending increases are more complicated than simply the introduction of the 2 new HCV medications. The number of

Mental Health in the Aftermath of Assault

Mental health services are an important part of recovery for students who have experienced sexual assault. Amy Hoch, PsyD, chair of the campus safety and violence coalition and a psychologist at Rowan University, mentioned that techniques like cognitive processing, prolonged exposure, and trauma-focused cognitive behavioral therapy can help individuals heal from traumatic events.

The confidentiality of medical health records, particularly in the context of mental health care, is a critical concern. It is not always clear to students when and whether such personal information will be protected under medical privacy laws. A recent incident at the University of Oregon drew attention to this issue when a student’s mental health records from the campus clinic were released to the university’s attorney when she sued the school for mishandling her sexual assault case (http://n.pr/1UcTzFR).

Such incidences can shake students’ confidence in campus mental health services, raising doubts as to whether their privacy will be protected (http://n.pr/1UcTzFR). Yale University provides one possible model for dealing with gaps in understanding confidentiality of reported information related to the assault, including medical records: a detailed online resource outlining what level of confidentiality campus and local authorities provide (http://smr.yale.edu/).

If You Don’t Talk About It, It Won’t Go Away

If nothing else, the recent media and legislative attention surrounding campus sexual assault means progress on one front: people may be more willing to talk about it.

According to recent statistics, only 20% of cases of rape or sexual assault get reported to police (http://1.usa.gov/1f1lQ5). Furthermore, campuses themselves may be underreporting cases of sexual assault. The Clery Act requires all campus crimes to be reported in a daily log and an annual security report. A 2015 study found that when universities were audited for Clery Act violations, the rate of sexual assault reporting jumped by 44%, but it dropped back to baseline after completion of the audit (Yung CR. Psychol Public Policy Law. 2015;21[1]:1-9).

Underreporting can make it challenging for campuses to recognize and assess with accuracy their sexual assault prevention and intervention needs and may also stymie open discussion and dialogue on the issue.

“Nobody wants to talk about rape. Nobody wants to talk about sexual assault. And they sure as [heck] don’t want to talk about it in their communities,” said Goryl.

What’s more, the success of a prevention program can also result in more reported cases of sexual violence as a result of increased awareness and education, noted Van Orman. This may serve as a deterrent for some campuses that, as mentioned in the 2015 Yung study, have an interest in maintaining their reputations and avoiding fines and potential loss of student aid that can come from running afoul of Title IX regulations (http://bit.ly/1HyABUG). At the time this story went to press, there were 118 schools being investigated by the US Department of Education’s Office for Civil Rights for sexual assault-related Title IX violations (http://1.usa.gov/1H3CaJ0).

Despite the complexities and challenges in addressing campus sexual assault, campus health care services play an important role in efforts to develop appropriate prevention and intervention programs for college students.

“Lots of places are really working hard to do the right thing,” said Koenick. “Some places could use a little help. Or a lot of help.”

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people with HCV infection receiving treatment in 2014 grew by a factor of 10, but because these drugs and other HCV therapies can actually cure the disease, this type of increase is not expected to continue, as previously untreated patients are identified and treated. On the other hand, spending on diabetes, which surged 30% in 2014, is unlikely to slow, given the continuing problem of obesity in the United States (http://bit.ly/IDzzWMw). Expiring patents have slowed drug spending for the last few years, but a relatively modest number of drugs lost patent protection in 2014, contributing to the spike in drug spending.

**Specialty Drugs in the Spotlight**

It’s not surprising that the medicines that have garnered the most attention are the extremely expensive specialty drugs that typically target serious and complex diseases. The experience with Gilead’s new HCV drugs is especially interesting because they have been vulnerable to competitive pressure when alternative novel treatments become available, despite their patent protection. After trying to negotiate with Gilead for almost a year, Express Scripts, the largest pharmacy benefit manager, chose to cover AbbVie’s competitive HCV product, Viekira Pak, approved in late 2014, and cover the Gilead products only under certain exceptions. Viekira Pak had a list price similar to the Gilead products but AbbVie agreed to a significantly lower price, in line with the types of discounts pharmacy benefit managers and large insurers have negotiated for other drugs.

The public has been historically more sensitive to changes in drug prices—especially outpatient prescription coverage—compared with the cost of other components of health care, because insurance coverage has traditionally been more extensive for hospital use and physician services. A poll by the Henry J. Kaiser Family Foundation released on June 16 indicates that most people believe the costs of prescription drugs are “unreasonable,” with 77% citing the drug company profits and 64% citing the high cost of medical research as major factors contributing to the costs (http://bit.ly/IFZSFWF). Half of those polled said they were currently taking a prescription drug; more than three-quarters of people in this group said it was easy to pay for their prescription medicines. Even so, the Kaiser Family Foundation report noted, majorities of the public said that addressing high drug costs should be a top priority for Congress and the president.

Discussions about potential policy options need to recognize that there are dilemmas inherent in drug pricing that make this area even more challenging than elsewhere in health care. The country’s track record in getting pricing “right” in other areas of health care, such as the 2-decade battle over the formula used to determine payment for physician services for Medicare beneficiaries, has demonstrated just how difficult this can be (http://bit.ly/1cXQOXF).

The basic dilemma is that to encourage investment in innovations like prescription drugs and new biologics, the government needs to provide intellectual property protection for these products through patents. While the appropriate length of patents can be debated, they effectively provide monopoly power to the patent holders. The more unique the product, the more effective the monopoly power, although pricing products beyond certain points will lower the profits to the patent holder. Whether the specialty drug company profits are “excessive” or even unusually high is not easy to ascertain and would require calculating returns on invested capital for industries with a similar risk profile—numbers not readily available.

What is clear is that the presence of a monopoly will lead to higher prices than would be expected in a more competitive market. Further complicating appropriate pricing for drugs is the long time lag between when investments are made and when a product could potentially make it to the marketplace. This means that changing the investment patterns won’t be felt until many years later.

But despite the monopoly power associated with patents, Express Scripts’ success in negotiating a lower price for AbbVie’s HCV product compared with the prices for Gilead’s new HCV drugs indicates the power that alternative therapies can have. It also suggests that expedited and efficacious reviews by the FDA for new and potentially competing biologics is one strategy to keep pressure on pricing.

**Role of Third Party Payers**

The role of third party payers in health care also complicates getting the pricing “right.” Because most insured people are not paying the full cost of a drug (or paying nothing out of pocket at all, in many cases), the usual indication of value that consumers find in other markets is absent.

Now, however, discussions of trying to provide information about approximate value of new oncology drugs to patients, even explicitly discussing the concept of value in oncology, are receiving increased attention. For example, the American Society for Clinical Oncology (ASCO) recently published a conceptual value framework to help physicians and patients better assess the value of new cancer treatment options based on clinical benefit, adverse effects, and cost (http://bit.ly/1GxpFMJ). All of this was unimaginable just a few years ago.

It remains to be seen whether clinicians and patients will be comfortable using concepts of value when choosing among oncologic drugs or when weighing other therapeutic products. But the fact that these issues are even being discussed indicates a new willingness to consider concepts of value when considering competing therapies—and represents an important first step in improving the value of health care provided to even the sickest patients.

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