

UPDATE: BARGAINS NO MORE

The drama of prescription drug pricing continues.

BY JAMES INCOLLINGO, MA, CONTRIBUTING EDITOR



The prescription drug market continues to be marked by staggering increases in the prices of certain generics, a category of drugs once nearly synonymous with “bargain.” The traditional setup of reliably inexpensive generics and their pricier branded counterparts seems just a memory. Now entering its third year, the problem has attracted the attention of lawmakers at the state and federal level. Hearings have been held, and legislation is afoot.

OUTCOMES OF THE HEARING

After a crescendo of complaints from constituents, in November of last year, Senator Bernie Sanders (I-VT), chairman of the Subcommittee on Primary Health and Aging, and Representative Elijah Cummings (D-MD), ranking member of the House Committee on Oversight and Government Reform, held hearings in Washington, DC. Their goal was to explore the extent of the problem, investigate its causes, and determine if new legal intervention could mitigate the situation. “It is unacceptable that Americans pay, by far, the highest prices in the world for prescription drugs,” said Mr. Sanders in a statement to the press. “Generic drugs were meant to help make medications affordable for the millions of Americans who rely on prescriptions to manage their health needs. We’ve got to get to the bottom of these enormous price increases.”¹

At the hearing, Mr. Cummings declared, “Some companies are exploiting monopolies and disruptions in supply to implement massive price increases in order to reap unconscionable profits.”² The hearing followed a round of letters sent last October to 14 generic drug makers requesting explanations for recent dramatic increases in the prices of 10 prescription drugs. The CEOs of Marathon, Lannett, and Teva Pharmaceutical Industries were also invited to testify at the November 20 hearing, but all declined to appear. Lannett attracted attention last year from the Connecticut’s Attorney General and the Justice Department’s antitrust division as well, which subpoenaed documents pertaining to the company’s generic drug sales.

At the hearing, Rep. Cummings and Sen. Sanders announced their Medicaid Generic Drug Price Fairness Act, a bill that would mandate that generic drug manufacturers provide rebates to Medicare and Medicaid from price increases in excess of the inflation rate. This requirement is

already in place for the makers of branded drugs. Witnesses at the hearing suggested encouraging fast-track applications at the FDA to clear out the backlog and increase competition among the makers of generics.

RESPONSES AT THE STATE LEVEL

Officials and legislators at the state level are beginning to act as well. Vermont’s Attorney General Bill Sorrell is leading a coalition of attorneys general from other states who will analyze the issue of generic drug prices. In particular, they will look for evidence of collusion among sellers, as reported by Vermont Public Radio in January 2015. “Each of us [is] trying to get state-specific information on some very significant price spikes,” said Mr. Sorrell, “and sharing that information and seeing where it takes us.” Although pharmaceutical CEOs balked at testifying at the Cummings-Sanders hearing last November, Sorrell has pledged to use his power as attorney general to compel the executives to explain their actions on the record.³

In addition, some states are beginning to pressure drug makers directly for price reductions. For example, to counter a 50% to 100% increase in the price of naloxone, an antidote to heroin overdose used by police and other emergency health care providers, maker Amphastar Pharmaceuticals agreed in February to a rebate request from New York State. Ohio is looking to be next in line.⁴

WHAT IS HAPPENING, AND WHY?

It remains to be seen whether governmental intervention will lead to substantial improvements for patients, doctors, or pharmacists. Even if any corrupt or illegal activity surrounding drug pricing is stamped out, broader market forces—over which officials have much less control—will still be at play. The demand for drugs continues to outstrip supply, owing to the limited number of manufacturers, the rising number of prescription users entering the market, laws mandating the use of generic drugs for health care entitlements, and insurance and pharmacy companies’ policies favoring generics for profitability.

According to an ophthalmologic drug industry insider who spoke off the record, public and private insurance plans’ driving consumers toward generics is “creating a bigger divide between people and their access to medications. I think it’s going to continue without some kind of fix, because the plans are still mandating and contracting for

better rates, and branded makers typically have to rebate anywhere from 20%, 30%, up to 50% of the product. It's a pretty crazy market, as you can imagine." Muddying the waters is the growing involvement of third parties such as pharmacy benefits managers, who seek their own profits in an increasingly complex commercial environment. With such huge sums of money at stake—the global generics sector was valued at \$269.8 billion in 2012—the incentives are powerful for all parties involved.⁵

RISING COSTS

According to the TruVeris National Drug Index, drug prices in general increased by 10.9% in 2014, with branded pharmaceuticals rising 14.8% and generics up 4.9%.⁶ These are palpable price rises in aggregate, but the real sticker shock lies with the prices of specific generic drugs. Truecostofhealthcare.org, a physician-run blog covering health care costs, compared the quarterly National Average Drug Acquisition Cost prices—the average price that all retail pharmacies pay for each medication—of 1,240 generic listings of more than 400 separate medications from October 2012 to January 2015. The group discovered a byzantine, chaotic record of price changes. "Nearly half of the generic listings (607 in total) went up in price—many way up. Among these, 314 of the listings went up at least 50% in price, 240 of the listings (20%) at least doubled in price, 87 went up at least five times in price, and 42 of them went up 10 or more times."⁷ By now, doctors with patients using these medicines are thoroughly acquainted with the extremity of the situation.

Payers, whether insurance companies or consumers, are scrambling to find ways to blunt the bite. Pharmacists fear finding themselves underwater—that is, paying a now sky-high wholesale price for a drug that has an old dirt-cheap reimbursement price that may not be renegotiated for many months. Dealing with more demands on their time from both insurers and patients, physicians and their billing clerks also bear costs of this crisis in the form of uncompensated labor and aggravation.

THE UPPER HAND

The pharmaceutical pricing system is murky. Almost no one outside a given company can know what it costs to actually make a specific drug. The price paid for a particular agent varies among buyers, and it may have risen by the time a specific buyer goes to the pharmacy for a refill.

When pressed for an explanation, the industry points to regulation and market forces as the main drivers, and it describes generics as a cost-saving boon to global health care. Analysts largely agree that consolidation and certain oversight and enforcement actions (eg, closing down sub-par manufacturing facilities) have reduced competition, while the Affordable Care Act has driven up demand. Interested



"The trend continues for price increases across branded and generic medications but especially generics. [We are also seeing more] roadblocks for patients who need medications."

—John Hovanesian, MD

observers are less moved by assertions that the industry is scrupulously ethical, operates heroically under a nearly crushing regulatory burden and competitive environment, and does not set prices (retailers handle that). In a statement to the press regarding the Cummings-Sanders inquiry letter, a Mylan spokeswoman declared, "The pricing of any specific product or products simply cannot be discussed or evaluated in a vacuum."⁸

The Generic Pharmaceutical Association, an industry trade group, responded to the proposed Cummings-Sanders bill with a statement from its president and CEO, Ralph G. Neas: "This legislation once again misses the forest for the trees. In actuality, generic drugs continue to be a resounding success in lowering health care costs and benefiting patients. Indeed, generics saved \$239 billion in 2013 ... and more than \$1.46 trillion over the recent decade. ... The proposed bill reflects a basic misunderstanding of the pharmaceutical marketplace and attempts to impose brand pharmaceutical provisions on generic drugs. This effort is misguided and will threaten patient access to affordable medicines." Mr. Neas stated that fostering competition, not new regulations or enhanced enforcement, is the best way to lower the price of generic medicines.⁹

Jaded observers will factor a desire for profit as well as supply, demand, and competition into drug pricing. Among others, Sen. Sanders has observed that "there is greed at work in the pharmaceutical industry," but industry spokespeople say otherwise.¹⁰

WHAT, ME PAY?

To stanch the outflow of cash dispensed for expensive drugs, generic or otherwise, insurance companies have an incentive to reduce their policyholders' use of high-priced drugs.

"The trend continues for price increases across branded and generic medications but especially generics," reported Orange County, California, ophthalmologist John Hovanesian. "The other trend that we're seeing is more and more roadblocks for patients who need medications. Payers

who want to reduce their costs are putting in place obstacles that require a doctor to spend an undue amount of time to gain approval to prescribe certain drugs. They require a form to be filled out by the doctor explaining why I've considered and chosen this drug over an alternative that might be lower cost or generic." In some cases, a telephone conversation with a company representative is necessary.

"In other words," said Dr. Hovanesian, "the insurance company is saying, 'We cover this drug but only after you jump through these hoops to get us to cover it.' The awkward conflict arises when a doctor who just wants to practice medicine has to invest his staff's time or his own time into ensuring each patient gets the prescribed medication. So if the doctor is seeing many patients—30, 40, 50 patients a day or more in some cases—it becomes impossible to keep up with the workload that's induced. A doctor and his staff can spend as much time doing these prior authorizations as he does seeing patients."

COPING WITH RISING COSTS

In a survey appearing in their 2015 "Outlook Report," *Managed Healthcare Executive* magazine asked insurance payers and pharmacy benefits managers how they were coping with the rising costs of specialty drugs: "The most common response among those surveyed has been to require some form of prior authorization to label (48.5%) or to studies used to gain FDA approval, before agreeing to provide coverage (17.9%)." Although doing so allows them to monitor a doctor's treatment plan and control off-label drug use, ostensibly improving outcomes and increasing efficiency, prior authorizations are clearly burdensome for physicians and thus make it less likely that they will prescribe restricted drugs.¹¹

Doctors cannot bargain collectively except through their societies, but they are not powerless to respond as individuals. According to Dr. Hovanesian, one way doctors could address the issue is to charge patients for processing prior authorization. "When I take my pediatrician a camp physical form to be filled out for my son, she charges \$25 to fill out each one," he said. "Why? Because it's time-consuming, excess paperwork that's not part of the standard care of the patient that they can bill for. I think it's an understandable request to bill the patient for that. Similarly, we could take care of patients' prior authorizations, and each one would cost a certain amount to cover staff time, and the fact that there's no code to bill an insurance company for that. That's one solution. Substituting with generics is another, and that's probably the most common one. A doctor will simply switch a patient to another drug that doesn't require prior authorization." Prior authorizations are an unobvious way to make some drugs more difficult to get so they won't be prescribed as often. It is also a drag on physicians' professional freedom that did not used to exist.



"In South Florida, prior authorizations are a constant and in place for a long time. It feels like almost every patient has issues."

—William Trattler, MD

"A third choice," said Dr. Hovanesian, "is that, with electronic medical records, a lot of systems allow doctors to upload an insurer's formulary, including a list of what requires prior authorization so that, at the point of prescribing, they can see that information. But this requires a doctor to keep on top of this for every payer they contract with and every drug that's under that payer, they have to keep that list up to date. There's a whole layer of complexity here for prescribing that arises out of these rising prices."

THE UNAVOIDABLE

Dr. Hovanesian believes that both direct and back-channel efforts to deflect costs will continue. "This is the next wave and a natural byproduct of the rising prices," he remarked. "Market forces generally equalize everything, but right now, we're going through a very tough time."

Across the country on the East Coast, the problem is less new but no less vexing. According to Miami surgeon William Trattler, "In South Florida, prior authorizations are a constant and in place for a long time." He stated that delivering high-quality care has unquestionably become harder at his practice owing to rising drug prices and the pressures they create in the system. "It feels like almost every patient has issues," he commented. "There are Medicaid patients that don't qualify for some drugs and are frustrated, and we have insurance patients who don't know if they have a copay or not or if their deductibles have gone way up. The pharmacists are trying to switch patients out from one drug to another depending on the insurance plan, so I never quite know what product my patients are on."

Fellow Miami ophthalmologist Carlos Buznego is also caught in the back-and-forth. "We continue to have issues with patients' being unable to fill the prescriptions they've been prescribed, and unfortunately, this causes a whole lot of [problems] on various different levels," he said. "A patient who gets a prescription for a branded medicine may not have coverage, so they never actually fill the prescription and just go ahead and get their surgery. Oftentimes, we'll have untoward events in their recovery period as a result."



“A patient who gets a prescription for a branded medicine may not have coverage, so they never actually fill the prescription and just go ahead and get their surgery.”

—Carlos Buznego, MD

Dr. Buznego continued, “There are times when a patient will call in before surgery to get switched over to the generic medication, which can cause several different issues. One is potency with generics and formulation problems, for example, with a poorly made suspension medication; each drop may have variable amounts of medication actually delivered.”

He added, “Then finally, even when a patient gets prescribed a generic medication, if the cost is too high, they don’t go ahead and get it. Even if a patient is on a generic, the patient is calling in complaining about the cost, and that creates a whole chain reaction through the office, where my technicians who are involved with pharmacy call-backs are also involved in taking care of my patients on a day-to-day basis. So, we’re seeing an increasing number of patients and trying to do it in an efficient fashion, but every call-back from a pharmacy is taking staff away from patient care or resulting in a delayed response to the pharmacy for the patient because they have too big a workload.”

For doctors and their staff, too many phone calls and haggling over drug prices is a hassle, to say the least, but poor compliance can produce poor clinical and surgical outcomes. That is what really worries the typical physician. Recent studies confirm the assumption that higher drug prices lower patients’ compliance with prescribed medical therapy.¹²

THE FUTURE

Still in flux are the international trade negotiations known as the Trans-Pacific Partnership (TPP) talks, underway since 2002. Last year’s TPP document release by Wikileaks raised suspicions that big pharma may be strong-arming the talks in their favor at the expense of drug consumers.

In a review of publicly available information as well as the leaked documents, the Centre for Health Equity Training Research and Evaluation at the University of New South Wales, Australia, cited concerns that “the US is seeking to prevent countries from refusing to grant patents for minor variations to existing products even when there

is no evidence of additional benefit. This provision would encourage evergreening of patents—a strategy patent holders use to extend their monopolies by gaining additional patents, thus preventing competition from cheaper generic versions for longer periods.” The Centre report cited other potential pocketbook threats, as well, and whether they are real or imagined will be revealed at the TPP Honolulu meeting this spring, when agreement proposals are expected to be finalized.¹³

CONCLUSION

Some physicians and observers take heart from cost-saving dropless surgery and biosimilar medicines or a hoped-for smartphone app that could consolidate patients’ insurance formulary and reimbursement information with pharmacy prices, coupon options, and availability. Dr. Trattler remarked, “I wouldn’t be surprised if doctors figured out a way through computer technology to be the adjudicator, to be able to figure out even last-minute how to get the medications they want their patients to be on from the beginning.” Short of that, it is certainly possible that market forces will fix everything. ■

1. Sanders B. Congress investigating why generic drug prices are skyrocketing. October 2, 2014. <http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing>. Accessed March 30, 2015.
2. Senate hearing on generic drugs. Bernie Sanders website. November 20, 2014 media. <http://www.sanders.senate.gov/newsroom/recent-business/senate-hearing-on-generic-drug-prices>. Accessed March 30, 2015.
3. Kinzel B. Sorrell advances national investigation into generic drug price hikes. Vermont Public Radio website. January 2, 2015. <http://digital.vpr.net/post/sorrell-advances-national-investigation-generic-drug-price-hikes>. Accessed March 30, 2015.
4. Silverman E. Lawmakers pressure amfstar over price hikes for its heroin antidote. *The Wall Street Journal*. March 3, 2015. <http://blogs.wsj.com/pharmalot/2015/03/03/lawmakers-pressure-amfstar-over-price-hikes-for-its-heroin-antidote>. Accessed March 30, 2015.
5. Global markets for generic drugs. BCC Research website. January 2014. <http://www.bccresearch.com/market-research/pharmaceuticals/generic-drugs-markets-phm009g.html>. Accessed March 30, 2015.
6. Americans faced double digit increases in prescription drug prices in 2014. Truveris blog. January 26, 2015. <http://truverisblog.tumblr.com/post/109228668907/americans-faced-double-digit-increases-in>. Accessed March 30, 2015.
7. Belk D. Generic medication prices. The True Cost of Healthcare blog. January 2015. http://www.truecostofhealthcare.org/generic_medication_prices. Accessed March 30, 2015.
8. Hyland M. Generic drug prices spiking. Fox43 News website. February 9, 2015. <http://fox43.com/2015/02/09/generic-drug-prices-spiking>. Accessed March 30, 2015.
9. Statement by Ralph G. Neas, President and CEO, GPhA, regarding proposed legislation on generic drugs. Generic Pharmaceutical Organization website. November 20, 2014. <http://www.gphaonline.org/gpha-media/press/statement-by-ralph-g-neas-president-and-ceo-gpha-regarding-proposed-legislation-on-generic-drugs>. Accessed March 30, 2015.
10. Sanders B. Senate Hearing on Generic Drugs. November 20, 2014 media release. <http://www.sanders.senate.gov/newsroom/recent-business/senate-hearing-on-generic-drug-prices>. Accessed February–March 2015.
11. Bendix J. Pharma pricing strategies: prior authorizations, specialty pharmacies seen as solutions. Managed Healthcare Executive. Modern Medicine Network. October 10, 2014. <http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/pharma-pricing-strategies-prior-authorizations-specialty-pharmac-0?page=full>. Accessed March 30, 2015.
12. Townsend A. High prescription drug prices cause people to skip doses, make other cost-saving measures, study shows. Cleveland.com. January 29, 2015. http://www.cleveland.com/healthfit/index.ssf/2015/01/high_prescription_drug_prices.html. Accessed March 30, 2015.
13. Hirono K, Haigh F, Gleeson D, et al. Negotiating healthy trade in Australia. Health impact assessment of the proposed trans-pacific partnership agreement. Centre for Health Equity Training Research and Evaluation, University of New South Wales. February 2015. http://hiacconnect.edu.au/wp-content/uploads/2015/03/TPP_HIA.pdf. Accessed March 30, 2015.

James Incollingo, MA

- writer, editor, and founder of Texterity, a communication consulting firm
- jim@texterityllc.com; www.linkedin.com/in/jamesincollingo