FROM THE EDITOR'S DESK

Are There Any Solutions to the High Cost and Shortages of Drugs?

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THE PROBLEM

We have a serious problem with high drug prices in the United States, but at last, major changes are in the wind.

Prescription drugs are a massive market; Americans spent $329.2 billion on prescription drugs in 2013. In the December 2016 issue of JLGH, Matthew Eberts, PharmD, director of pharmacy services for Penn Medicine Lancaster General Health, discussed some of the causes of high prices (as well as the challenge of drug shortages).[1] A Harvard study in *JAMA* also reviewed the causes, which have seemed intractable.[2]

Drug prices in the United States are much higher than in other developed countries. U.S. patent protection (i.e. marketing exclusivity) for new drugs lasts 20 years. Though this benefit is lessened by the seven to eight years it can take to gain FDA approval, manufacturers often extend their monopolies by tweaking nontherapeutic parts of drugs, such as pill coatings, and making "pay for delay" payments to generics manufacturers not to market generic alternatives.

In other developed countries, national health programs negotiate drug prices, and usually don't cover drugs they deem overpriced, but Big Pharma lobbyists prevailed on the Republican-majority Congress in 2003 to bar the new Medicare drug program from negotiating prices. They argued that profits fund the development of new drugs, even though drug companies spend only 8%-20% of their revenue on research and development.

In 2015, the latest year for which data are publicly available, 89 of the top 100 pharmaceutical companies spent more on marketing and sales (M&S) than on R&D. (Forty-three spent five times as much, and 27 spent 10 times as much.[3]) Overall, the top 100 pharmaceutical companies spent only 8.32% of their revenues on R&D that year. The biggest spender, Johnson & Johnson, spent a staggering $17.5 billion; AbbVie spent $357 million to market a single drug – Humira for Crohn's disease.

Doctors are indirectly part of the problem; marketing to doctors works so well that in 2013, 68% of all drug marketing expenses targeted physicians, while 21% was spent on direct-to-consumer advertising.

Because Medicare can't negotiate, drug prices are determined mainly by what the market will bear.[2] As Ebert's article[1] noted, the pharmaceutical industry's claim that it costs $1.32 billion to bring a new drug to market[4] was debunked in a 2011 study which found that cost may be overstated as much as tenfold,[5] since the scientific research that leads to new drugs is commonly funded by NIH grants or venture capital.[2]

Though private insurers could check high drug prices by negotiating with drug manufacturers, they rarely do so. Instead, they work with pharmacy benefit managers (PBMs) to negotiate rebates and discounts, or "kickbacks," which lower the insurers' costs, but don't lower the published prices of drugs for retail consumers. Though insurers claim that kickbacks enable them to lower premiums, the recent trend of insurers merging with PBMs will further tighten their control of prices. (Approval was recently granted for Aetna's merger with CVS, which owns the PBM Caremark, and approval is expected for Cigna's merger with Express Scripts.)

PROPOSED SOLUTIONS

Fixing America's drug price problems won't be easy.[2] Congressional gridlock and the power of the pharmaceutical lobby make it unlikely that Medicare will be authorized to negotiate prices. Still, as I noted in my previous column,[6] the results of the midterm election, and the upcoming presidential election, have focused attention on health care. Several U.S. senators have recently introduced strong legislation, a hospital consortium has proposed a radical initiative, and the Trump administration is also weighing in.

I. Democratic senators Richard Blumenthal, Kamala Harris, Jeff Merkley, and Amy Klobuchar have introduced the Curbing Unreasonable Rises and Excessively (CURE) High Drug Prices Act.[7] It would require pharmaceutical companies to submit justification to HHS for price increases above certain limits. If deemed "unreasonable," HHS could require

the company to roll back prices, reimburse consumers and payers, including Medicare and Medicaid, and pay a civil penalty.

Separately, Blumenthal supported legislation to allow federal programs to negotiate lower drug prices, Merkley put forward the Low Drug Prices Act, and Sen. Bernie Sanders introduced the Prescription Drug Price Relief Act.

II. Sen. Elizabeth Warren introduced the Affordable Drug Manufacturing Act, a far more ambitious proposal that would establish an Office of Drug Manufacturing within HHS to manufacture select generic drugs and sell them at a "fair" price that guarantees affordability. (An identical bill was introduced in the House.) [8]

These legislative proposals reveal the intensity of interest in health care in an election season. (All the aforementioned politicians have expressed interest in running for president, or have announced their candidacy.) Still, none of these Democrat's initiatives will reach the Republican-controlled Senate floor for a vote.

III. A consortium of hospitals in the western United States plans to fight drug shortages and high prices by taking the radical step of launching its own nonprofit, generic drug company.[9] Led by Intermountain Healthcare, a system of 22 hospitals based in Salt Lake City, the company will be called Civica Rx. Though independent, the board will include "governing members" that include Intermountain, the Mayo Clinic, and for-profit HCA Healthcare, among others.

The company says it will first market 14 common generic drugs (as yet unnamed) that have been in short supply, and whose prices have risen in recent years. It will begin applying to the FDA this year, and will likely start out by contracting with existing manufacturers to make the medications under its label. Eventually though, it could buy manufacturing facilities of its own.

Action by hospitals is long overdue. A recent report for the American Hospital Association and related organizations pointed out that "continued rising drug prices, as well as shortages for many critical medications, are disrupting patient care and forcing hospitals to delay infrastructure and staffing investments and identify alternative therapies, straining hospitals' budgets and operations." [10]

Average total drug spending per hospital admission increased by 18.5 percent between fiscal years 2015 and 2017, including increases in some drug classes of more than 80 percent and exceeding the Medicare payment update by fivefold.

The report noted multiple problems, including: abusive price increases for old generic drugs when a company manages to monopolize production; persistent shortages of standard, essential drugs and IV fluids as companies consolidate and there are fewer producers; particularly egregious increases in the price of insulin, leading many diabetics to ration their insulin with serious, even fatal consequences; and continuing failure of Congress to pass meaningful legislation.

IV. As we go to press, the Trump administration is proposing that under Medicare and Medicaid, manufacturers may not legally give rebates to PBMs, only directly to consumers.[11] Critics contend this will disrupt the drug marketplace, and without rebates, insurers may raise premiums. Stay tuned.

CONCLUSION

Considering all these proposals, there is reason to hope the logjam on drug pricing and availability may be loosening up. For a long time, high drug prices seemed unassailable, but at last it seems that change is in the air. It has been a long time coming.

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