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News

## Public outcry over US generic drug price hikes

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Summary Full Text Tables and Figures

Steep, sudden price hikes of several generic medicines in the USA have sparked public outcry, even prompting two democratic candidates for the 2016 US presidential nomination to denounce pharmaceutical price-gouging.

Among the affected medicines was cycloserine, used as a second-line treatment for multidrug-resistant (MDR) and extensively-drug-resistant (XDR) tuberculosis, rights to which were acquired in August, 2015, by Rodelis Therapeutics. Rodelis raised the price for 30-tablet blister packs of cycloserine from US\$500 to nearly \$11 000, but in the face of nationwide outcry over the move, returned rights to the drug to the non-profit Purdue Research Foundation's Chao Center (West Lafayette, IN, USA), which then reduced the cost to \$1050 per pack.

"The degree of the price hike was unconscionable", says Society of Critical Care Medicine President Craig Coopersmith (Emory University School of Medicine, Atlanta, GA, USA).

Had the price hike remained in place, the cost of a 2-year course of cycloserine would have exceeded \$788 000 per patient—preventing some patients from accessing it, according to Charity Dean, president of the California Tuberculosis Controllers Association (Santa Barbara, CA, USA).

The cycloserine price hike was shocking, says Charles Daley (National Jewish Health, Denver, CO, USA). "The cost would be borne largely by public health departments. New drugs including new MDR tuberculosis drugs like bedaquiline and delamanid are very expensive but these are new drugs that have better activity than cycloserine and are tolerated better, so their prices do not seem as surprising", he said. "The initial [subsequently rescinded] cycloserine price increase would have made it more expensive than the new drugs." There are only about 100 cases of MDR and XDR

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tuberculosis in the USA each year, notes Daley. According to the US Centers for Disease Control, 72% of patients with MDR tuberculosis in the USA receive cycloserine.

The price for pyrimethamine, a standard of care treatment for toxoplasmosis (a parasitic infection that can cause cysts in brain, retinal, and lung tissue), also jumped overnight in August, from \$13.50 to \$750 per pill, following Turing Pharmaceuticals' acquisition of rights to the drug.

"Drug prices have risen at astronomical rates, growing 12·6% in the last year, and they now account for 19% of spending in the US Medicare programme", says Erik Rasmussen (American Hospital Association, Washington, DC, USA). "As drug costs eat up more of the health care pie, hospitals are left with fewer resources to treat patients."

Although dramatic, these price spikes are just the latest of such moves by generic drug makers, experts say.

"It is a continuation of a trend we've seen emerging in recent years", says Steve Morgan, Professor of Health Policy (University of British Columbia, Vancouver, BC, Canada).

Even seemingly affordable price spikes, like the jump in price for norepinephrine from \$1.61 to \$13 per vial, take a toll, says Coopersmith. "Consider the amount of norepinephrine used in a health system, and these numbers easily represent millions of dollars in additional drug costs for an institution—for the same drugs we've been using for decades."

There is a fundamental difference between new, on-patent drugs and generics, Coopersmith and others say: branded drug prices are partly an effort to recoup research and development costs, whereas manufacturers of generics bear no such costs. But when a generic drug's sole manufacturer enjoys a "natural monopoly", the temptation to set higher prices can be great, and is frequently only countered by the possibility that pushing prices too high will attract new competition, Morgan says.

In the past, high drug prices were seen primarily among branded, on-patent drugs, notes Sara Parker-Lue (Rutgers Business School, Newark, NJ, USA). They did it "because they could", she says — "patent protection gave them a licensed monopoly, so there was no concern that raising prices too high would attract competitors. Now we're seeing this among drugs where patent protection is long gone, however, where free competition is meant to help keep prices down."

When a small patient population is affected by such price spikes, the risk that competitors will emerge to produce a generic is relatively low, says Parker-Lue.

"We may need to consider new decision-making criteria about drug pricing", Morgan says. "Should there be some government intervention or intellectual property intervention to control prices?" He notes that, at the global scale, compulsory licensing of drug patents is allowed when the price of drugs is high enough to represent a threat to public health.

However, Michael Rie (University of Kentucky Medical Center, Lexington, KY, USA), a member of Physicians Against Drug Shortages (PADS), blames large hospital group purchasing organisations (GPOs) and their member hospitals for the generic drug shortages and the resulting price spikes. He and other PADS members say GPOs control purchasing for about 5000 US hospitals, and liken them to cabals that engage in anti-competitive contracting and pricing practices. In 2014, the US Government Accountability Office identified GPOs as one of the potential underlying causes of drug shortages.

"For generic injectables almost all drugs in short supply have only one or two worldwide vendors", notes Bob Campbell (PADS, Lebanon, PA, USA). "The result for consumers in this kind of marketplace is high prices, low supply, and [few] incentives for quality."



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