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Should States Use Bonds to Pay for Breakthrough Drugs?

That's what a new report proposes as states limit potentially life-saving but expensive new drugs. But some say that would be surrendering to drug makers.

When the maker of a breakthrough hepatitis C drug Sovaldi set the price at \$1,000-a-pill but promised a cure that could lower costs in the long term, states scrambled last year to limit treatment to patients with the most severe cases, anticipating billions in near-term costs. A new report argues a good solution might be to use an approach that state governments already prefer with infrastructure and some social programs — taking out bonds.

The idea comes from the California-based RAND Corporation, a research organization that specifically drew on the case of Sovaldi, which earned \$10 billion in sales last year for its maker, Gilead Sciences. The company boasted that its clinical trials proved the drug effectively cures the slow-moving liver disease in more than 90 percent of patients at a cost of about \$84,000 for a 12-week treatment, far better than a liver transplant, which costs about \$600,000.

But critics in Congress, state governments and elsewhere alleged price-gouging, noting Gilead charges other markets at a fraction of the U.S. In addition, critics say, the drug's effectiveness outside of controlled clinical settings is unclear, and hepatitis C moves so slowly that restricting Sovaldi until cheaper alternatives enter the market is the most sensible option. Express Scripts, the pharmacy benefit management company, estimated covering all of the 750,000 hepatitis C patients in state programs would cost governments more than \$55 billion.

RAND is suggesting a way to make the drug more affordable, though some critics question its strategy. With more specialty drugs and breakthrough vaccinations expected to hit the market in the coming years, insurers — including state Medicaid agencies — should consider a strategy that promotes long-term investment, argued Soeren Mattke, an author of the report.

Mattke recommended that insurers issue debt instruments like bonds or mortgages directly with manufacturers. If the insurer issued a bond, it could pay interest to the manufacturer until the maturity date followed by a larger balance payment. Or they could offer fixed monthly payments, or credit lines with payments at pre-established points.

What those agreements should also include, RAND argued, are performance agreements that set payments according to proven outcomes. Scotland already has such an arrangement over Olysio, another hepatitis C treatment, according to RAND. To reduce the administrative cost of tracking patients, RAND recommended letting an impartial outside group study a sample group that represents the population.

Mattke said he had Medicaid agencies in mind specifically when he developed the idea, along with middle-income nations like Brazil and less cash-rich countries — southern Europe, for instance — that face short-term budgetary constraints. "I think Medicaid is actually the only situation where it would work in the U.S.," he said. Rather than limiting treatment to, say, 10 percent of patients, agencies should think long-term, he added. "It's a bad financial decision, because those 90 percent

will continue to accrue medical costs while they're waiting for Sovaldi."

But the key problem with RAND's proposal is that it concedes the policy fight over the steep cost of drugs like Sovaldi, countered Matt Salo, executive director of the National Association of Medicaid Directors. The paper's approach "completely throws the white flag of surrender on drug prices," he said by email. "It says, 'We're okay with the price of Sovaldi being \$84,000 or even \$200,000, because if we can spread the actual costs out over 20 years or so, nobody will actually notice or feel the pain.'"

But additionally, Salo argued, reports from the Institute for Clinical and Economic Review call into question cost-effectiveness over the long windows envisioned under a debt agreement. If RAND's idea extends into areas like Alzheimer's, which pharmaceutical companies argue costs society trillions of dollars, manufacturers could continue charging staggering sums under questionable assumptions, he said.

Jeff Myers, who heads the trade group for private Medicaid plans, didn't dismiss the idea of debtfinancing outright, but he argued that pharmaceutical companies will have to bear substantially more risk before insurers should agree to bond deals, and introductory costs do need to go down. That means accounting for actual outcomes outside of clinical settings and potentially finding ways to help patients adhere to their medications, he said.

"With hepatitis C, Gilead says [it's a] 90 percent [cure rate], but it turns out in the real world it's a lot less," he said. "That percentage has a true cost in the health system, yet Gilead bears no risk when it doesn't actually work as well as they say it does."

Chris Koller, a former insurance commissioner who runs the Milbank Memorial Fund, said he thinks the RAND idea does take cost-effectiveness into consideration. But he does question whether manufacturers that are already raking in profits would be interested in revenue streams that grant them less control, and unlike other countries, the U.S. system of public and private payers for different populations and different age groups poses logistical challenges and questions about who actually receives the financial reward of breakthrough medications.

Still, he said, he's seen arrangements in which different payers pool their money for things like vaccines in Rhode Island, where he served as a health insurance commissioner. "This is, by its design, meant to trigger discussion," he said. "We shouldn't shoot it down just because it's hard to implement."

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Chris Kardish | Staff Writer

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