Who gets hepatitis C drugs? Who pays?

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The recent op-ed by North Memorial Healthcare CEO Kevin Crosston and Medica V.P. Robert Longendyke responded to a first-in-the-nation class action lawsuit seeking the new FDA "breakthrough" cure for life-threatening hepatitis C infections by 1,500 Minnesota Department of Corrections prisoners, first reported by Chris Snowbeck of the Star Tribune.

New Yorkers with hepatitis C and allies protest outside of the World Health Organization's NYC office on May 8, 2013, on the eve of World Hepatitis Day. WHO has called hepatitis C a "viral time bomb" yet has done little to address the epidemic. An estimated 150 million people have chronic hepatitis C infection worldwide, and about 350,000 people die from hepatitis C-related liver disease each year.

They wrote that the prisoners' suit – filed by the International Humanitarian Law Institution that I founded and direct – had started a statewide "conversation" about "ethics, costs and access" because the drugs are a 95 percent effective cure but cost $90,000 for the 12-week course of daily oral medication. In conclusion, they wrote, "(T)he best patient and consumer is … informed and able to be his or her own best advocate."

The fact that respected health care executives acknowledge that this prisoners' lawsuit has encouraged this statewide health policy "conversation" is very gratifying. But a meaningful "conversation" about either the lawsuit OR treating the hepatitis C epidemic is not possible without providing facts the authors left out:

"Who gets treated for hepatitis C?" is a medical decision for infectious disease specialists, not a question of "ethics, costs or access" for well-meaning executives.

"Who pays?" depends on measuring the real social costs of failing to treat a national epidemic and cannot be measured by the limited considerations of private entities and public agencies in a single state, or even several states.

First, a "Minnesota conversation" is valuable, but the HCV epidemic infects some 4 million Americans, most of whom don't know they are infected. The Centers for Disease Control say more die from the Hep C virus (HCV) than from HIV/AIDS every year. Like polio, the nation's bloodstream has to be cleared of HCV for Minnesotan's to be clear of the infection. The HCV epidemic does not respect borders.

Second, the Minnesota lawsuit was filed after the FDA approved the "breakthrough drugs" and professional associations the American Association of Liver Disease, the Infectious Disease Society of America and the International Antiviral Society-USA issued HCV "standard of care" protocols for all physicians:www.HCVguidelines.org.

The Minnesota suit has been followed by similar suits in Massachusetts and Pennsylvania, with other states to follow. As of June 2015:

- All HCV-infected patients should be treated immediately with the most recent FDA breakthrough drugs, known as Harvoni and Viekera Pak;
- All prior treatments – using Interferon – are NOT medically recommended;
- ONLY healthcare providers lacking financial resources may triage treatment of patients with more serious symptoms first – such as cancer, fibrosis or cirrhosis.

Prisons and jails must provide the current medical "standard of care" for serious illness irrespective of cost, according to the Supreme Court. Some government providers may triage services. But private healthcare providers must also provide the current "HCV standard of care" because their doctors cannot provide less, so the authors' employers are bound by it, too.

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Third, $90,000 is the retail price the "patient/consumer" pays, not healthcare providers. The authors don't mention UnitedHealth, private pharmacy wholesalers, the Veterans Administration and other healthcare providers have already

reduced their wholesale costs nearly 50 percent by negotiating with AbbeVie and Gilead Sciences. the two U.S. manufacturers.

Forbes reports generic versions of the same drugs sell for $900 overseas, and cost of production is about $1.00 per dose. The cost would be much less than $90,000 if retailers passed wholesale prices along to "patient/consumers."

World renowned political prisoner Mumia Abu Jamal is suffering intensely with hepatitis C, the photos showing him before and since his diagnosis became known. Pennsylvania prisons are refusing him and others with the disease the life-saving but expensive drugs that have a 95 percent cure rate. His lawyers have sued the state for medical neglect and support the class action suit for access to the drugs by all infected Pennsylvania prisoners.

Fourth, the monopoly pricing is likely to come down. In addition to the two manufacturers now in the U.S. market and generic suppliers overseas, two additional manufacturers are in FDA trials. Gilead Sciences has been sued for monopoly pricing. Both the California and U.S. Senate have held hearings into unreasonable HCV "breakthrough" drug pricing. Presidential candidate Sanders has called for a repeal of the patent, in part, because the Veteran's Administration cannot afford to treat all of the HCV-infected veterans, which could prevent 5,000 infections and 500 liver transplants a year.

Fifth, treating HCV is cost-effective overall, even at retail pricing. As the authors point out, the costs of not treating the national HCV epidemic are staggering, with a liver transplant upwards of $500,000. But they fail to mention that two recent studies published by Stanford and the Journal of Hepatology report that even treating at the retail price would be cost-effective by preventing the HCV epidemic from spreading and by saving Medicare, Medicaid and secondary costs to the society.

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Sixth, "managing costs" requires re-examining how those costs are allocated in the first instance or whether there are social costs and benefits that don't appear in a single company's income statement and balance sheet? The American people have already made the long-term public investment to create the educational, scientific and technological infrastructure that made the HCV breakthrough drugs possible and have long been bearing the cost of a "silent" epidemic that could be cured using the model of low-cost mass treatment pioneered by eliminating other formerly fatal infectious diseases, like polio, measles and the flu.

This is not the first time science has promised to transform the health of the nation by taming potentially fatal disease as it did with the Salk and Sabin polio vaccines, insulin, penicillin or the flu vaccine. Of course, in those days such pharmacological miracles were considered part of the social wealth of the nation and "consumers" were not forced to pay $1,000 a dose because one or two manufacturers were not permitted to control the market for life-saving medications needed by the whole population.

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Of course, that was then and this is now, when market-oriented thinking so dominates healthcare policy "conversations" that the actual medical standard of care, required to cure all HCV-infected patients, is not even on the agenda. The authors are correct when they write that "responses" to the HCV epidemic are ideological, and their own op-ed is a good example.

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