

NEWS ADVISORY

IHLI Civil Rights Suit: MnDOC Blocks "FDA Breakthru" *Cure* --
Hep-C Policy Exposes Inmates-Public to Fatal "Silent Epidemic"

- 2014 Stanford Study: "95% Effective HCV Cure--*Lowest Total Cost*" •

May 27, 2015

FOR IMMEDIATE RELEASE

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- 2012 MnDOC Policy *Admits*: 1500 Infected - 7 a Year Get HCV-Meds¹
- No Regular HCV Testing • No HCV Screening or Meds at Discharge

ST. PAUL -- IHLI Litigation Director Peter Nickitas (651.238.3445 cell) filed the first federal civil rights class action in the nation (*Lignons, et al v. Mn. Dept. of Corrections, et al*).² that would bring a state prison system in line with the Federal Bureau of Prisons, which adopted the 12-week "FDA-breakthrough HCV *cure*" in June 2014.³

Blood-borne HCV irreversibly destroys the circulatory system, digestive system and liver, leading to cancer, cirrhosis, and liver failure. The potentially fatal infection worsens every day MnDOC withholds the 95% effective anti-HCV "breakthrough" drugs.

Plaintiffs Ronaldo Lignons and Barry Michaelson were HCV-infected years ago by unsanitary MnDOC living conditions. Much of Peter Ryan's liver was removed just before he entered prison 6-months ago. But, he can't get the 12-week HCV cure either, even though he is in the infirmary and uses a wheelchair awaiting his release in October 2015.

2012 MnDOC policy documents *admit* only 7 HCV-infected inmates a year, out of 1500 HCV-infected (20% with potentially fatal infections), receive anti-HCV drugs.⁴ More may be infected, MnDOC only *estimates* the percentage of HCV infected inmates, it doesn't keep track.

The "FDA breakthrough" drugs *Olysio, Sovaldi, Harvoni* and *Viekera-Pak* are now the "standard of care," confirmed by infectious disease associations AASLD/IDSA (www.hcvguidelines.org) and all federal agencies.

The CDC, VA, NHS and FBOP have adopted the "breakthrough" medications, as has Medicare, Medicaid and even the Minnesota DHS. Minnesota-based UnitedHealth and most major private insurers have provided the "breakthrough" drugs since mid-2014.

"Silent HCV Epidemic" Now Curable

Most of the 4-5 million HCV-positive Americans are *not* prisoners, and up to 75% don't know they are infected. The CDC recommends screening for *everyone* born between 1945-1965.

About 80% of HIV/AIDS survivors are unknowingly HCV co-infected and HCV takes more lives than HIV/AIDS every year. But unlike HIV/AIDS, *HCV can be cured, now*.⁵

95% of the 2.2 million prisoners in the U.S. will to return the families and friends. The 12-week HCV "breakthrough *cure*" may be the fastest way to remove HCV from the blood-pool of the *entire* nation, by "filtering" the HCV-positive blood pool from jails and prisons.

Before the "FDA-breakthrough," the only alternative was 48-weeks of toxic, "chemo-like" side-effects from daily *Interferon* injections with cure-rates no better than 50%. MnDOC forms still inmates HCV treatment is "life-threatening"⁶ and 50% effective. But, this has not been true since the "FDA-breakthrough" drugs were available in 2013/2014. (www.hcvguidelines.org).

12-Week HCV "Standard-of-Care" Most Cost-Effective

An Oct. 2014 Stanford Med School study concluded the 12-week "breakthrough" drugs were cost-effective, compared with \$30,000 ineffective 48-week daily *Interferon* injections and long-term costs of \$250,000-plus liver transplants, chronic cirrhosis and HIV/AIDS co-infections.⁷

Gilead Sciences, the largest supplier known for monopoly pricing, has discounted products nearly 50% to federal agencies and begun overseas "giveaway" programs to increase foreign markets. Private insurers have announced discounts from Gilead and other suppliers. In April 2015, the FDA announced *additional* "breakthrough" drugs to further increase price competition.

Pricing will inevitably yield to competition, but "price" *never* has been a lawful reason for prisons to deny life-saving drugs to prisons, particularly when those drugs are the undisputed current standard-of-medical-care with a 95% *cure rate*. Prisoners' lives are entirely in the hands of the government that imprisoned them, and is responsible for their life and health.

"HCV-Free" Prisons Protect Everyone's Health

The Supreme Court has long-held state prisons that refuse or delay treatment of known serious illness inflict "cruel and unusual punishment" that is not part of their criminal sentence. When a prisoner needs a liver-transplant, MnDOC defendants can't lawfully deny the transplant because of cost or non-medical reasons.⁸ Medication that *prevents* liver transplants should be similar.

The lawsuit requests the same 12-week HCV *cure* that is the standard-of-care in the HCV medical treatment community, generally. If the requested relief is granted, Minnesota prisons would be the *first* largely "HCV-free" state system in the nation, with the cost-savings predicted by the Stanford study.

All Minnesotans benefit when MnDOC prisons are no longer a *source* of HCV-infected friends and loved-ones who may unknowingly carry HCV back home to infect others. If MnDOC does not provide the 95% effective HCV-cure in prison, MnDOC will be responsible for *knowingly* spreading the HCV "silent epidemic" to the *rest* of Minnesota and shifting the costs of the "silent HCV epidemic" to other agencies, and to all of us.

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¹ *Chronic Hepatitis C Management and Procedures*, MnDOC Health Services Unit 5/9/2012

² 0:15-CV-202210

³ Federal Bureau of Prisons, *Interim Guidelines for the Management of Chronic HCV Infection*, May 2014.

http://www.bop.gov/resources/health_care_mngmnt./sp

⁴ *Chronic Hepatitis C Management and Procedures*, MnDOC Health Services Unit 5/9/2012

⁵ CDC Public Health Grand Rounds, *25th Anniversary of the Discovery of the Hepatitis-C Virus*, June 17, 2014

⁶ *Chronic Hepatitis C Management and Procedures*, Health Services Unit 5/9/2012

⁷ Jeremy Goldhaber-Fiebert, *Annals of Internal Medicine*, Oct. 21, 2014,

⁸ *Farmer v. Brennan*, 511 U.S. 825 (1994), *Erickson v. Pardus* 551 U.S. 89 (2007)