

Hepatitis C in Prisons: Treatment Update for Advocates

October 2, 2017

Hepatitis Education Project
Treatment Action Group
National Viral Hepatitis Roundtable

Learning Objectives:

- HCV epidemiology & treatment access in prisons
- Overview of NASEM recommendations to eliminate HCV in the US – Mandy Altman, HEP
 - treatment in prisons is key
 - financing proposal
- Update on the latest DAA approvals – Annette Gaudino, TAG
 - How are Mavyret and Vosevi different from currently available drugs?
 - Pricing
- Legal challenges to secure treatment in prisons – Elizabeth Paukstis, NVHR
- Putting information into action: what can you do?

HCV Elimination in the US: Brief Overview of HCV in Prisons & NASEM Recommendations

Mandy Altman, MPA
Correctional Health Program Manager

[Hepatitis Education Project](#)

October 2, 2017



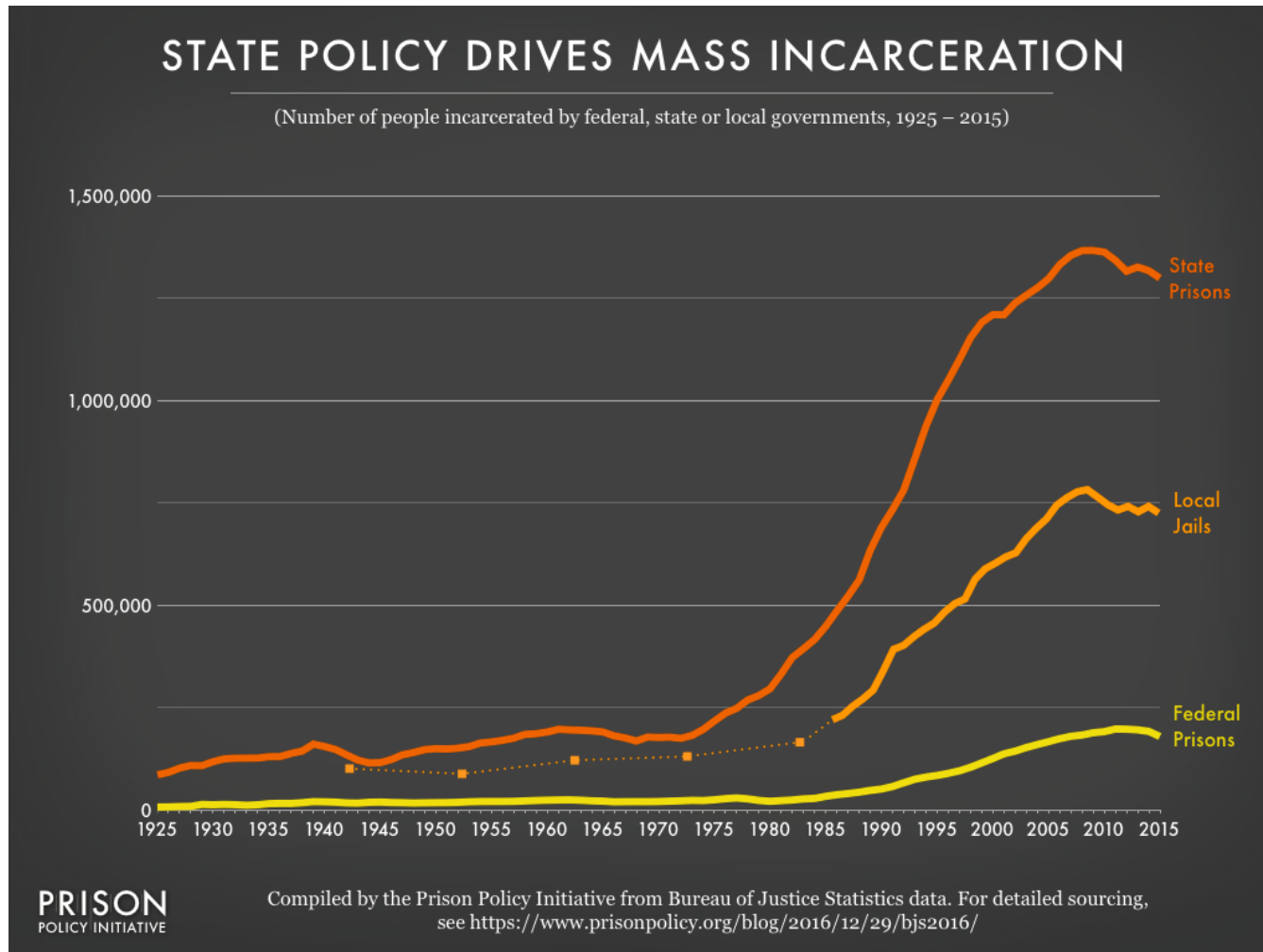
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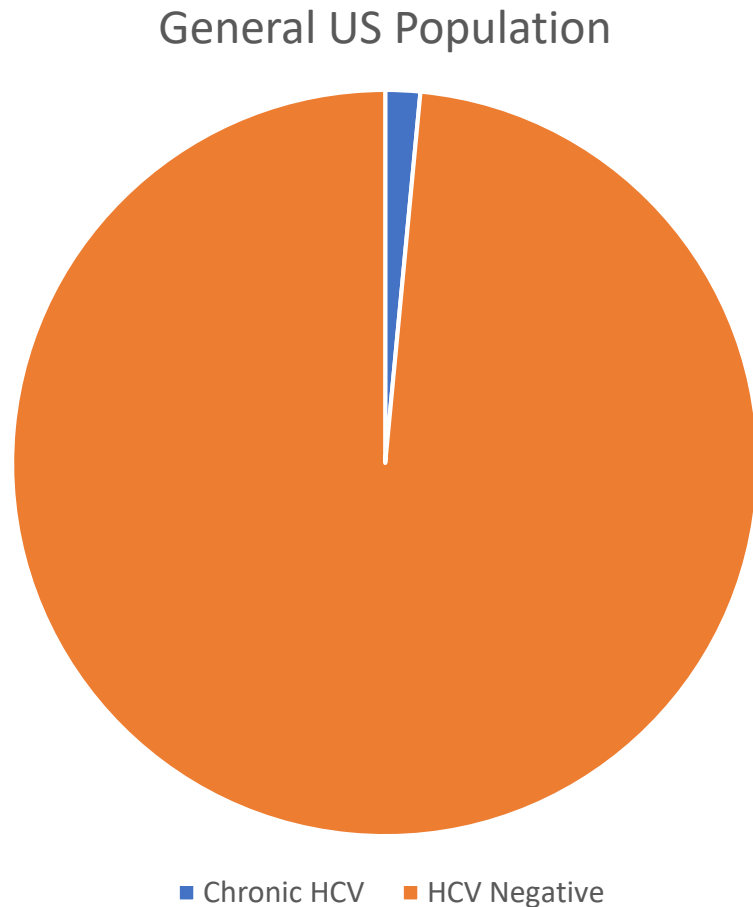
US Prisons Statistics



- US has highest incarceration rate in the world
- More than 2.3 mil people in US facilities
- 693 per 100,000 Americans
- Nearly 500,000 locked up on drug offense; true number higher
- 641,000 prisoners released annually

Source: <https://www.prisonpolicy.org/reports/pie2017.html>

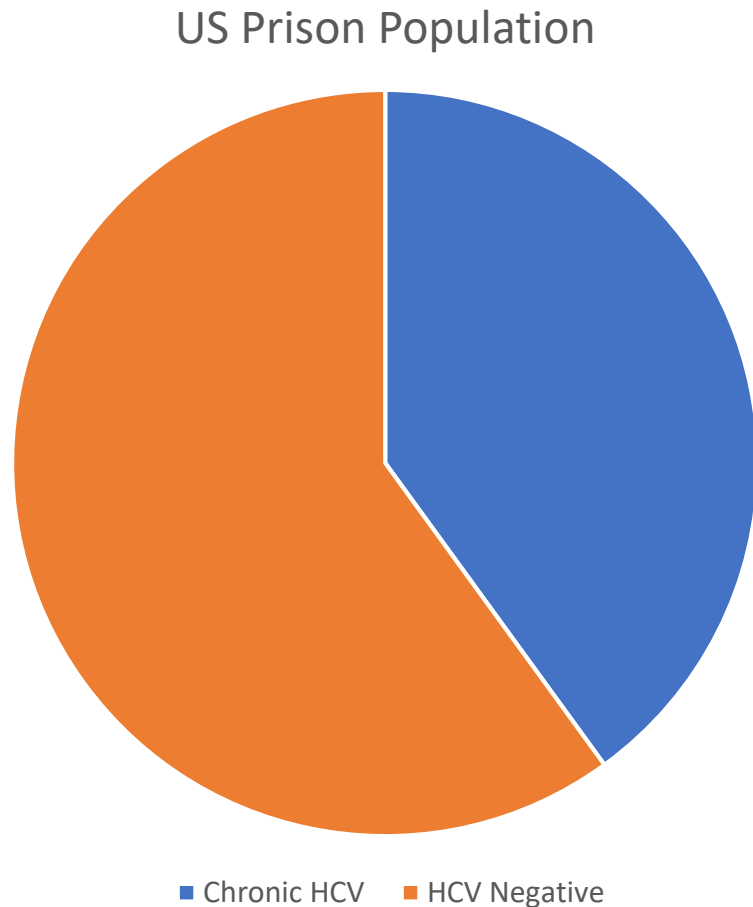
Prevalence of Hepatitis C in the United States



- HCV prevalence in the United States is estimated to be between 2.7-3.9% (3.5-5.5 million)
- 75% of those with chronic HCV are baby boomers (born 1945-1965)
- 20,000 deaths per year

Source: <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>

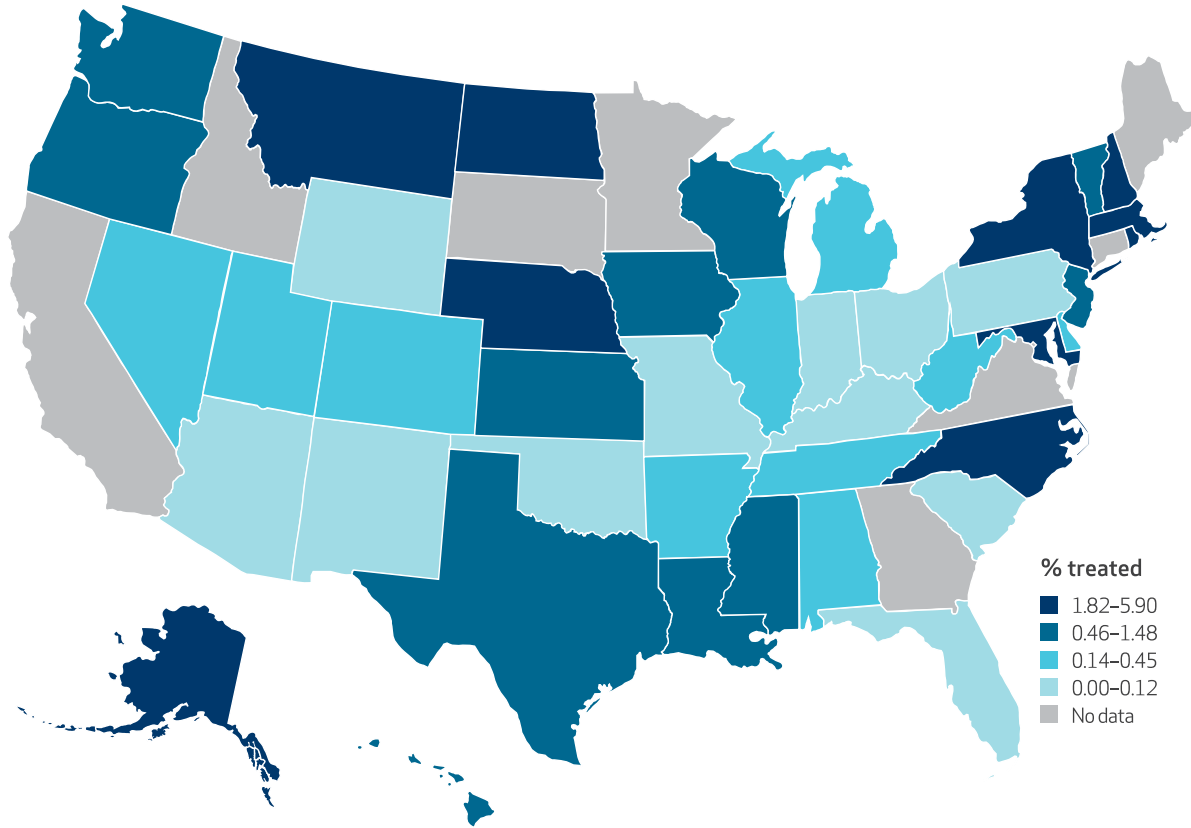
Prevalence of Hepatitis C in US Prisons



- HCV prevalence in US prisons is estimated to be between 12-35%
 - 1% in NC vs 40% in NM
 - Testing varies
- Correctional population represents 1/3 of US HCV population
- 20-55% of prisoners report IDU
- 90% of prisoners will be released

Source: <http://content.healthaffairs.org/content/35/10/1893.abstract>

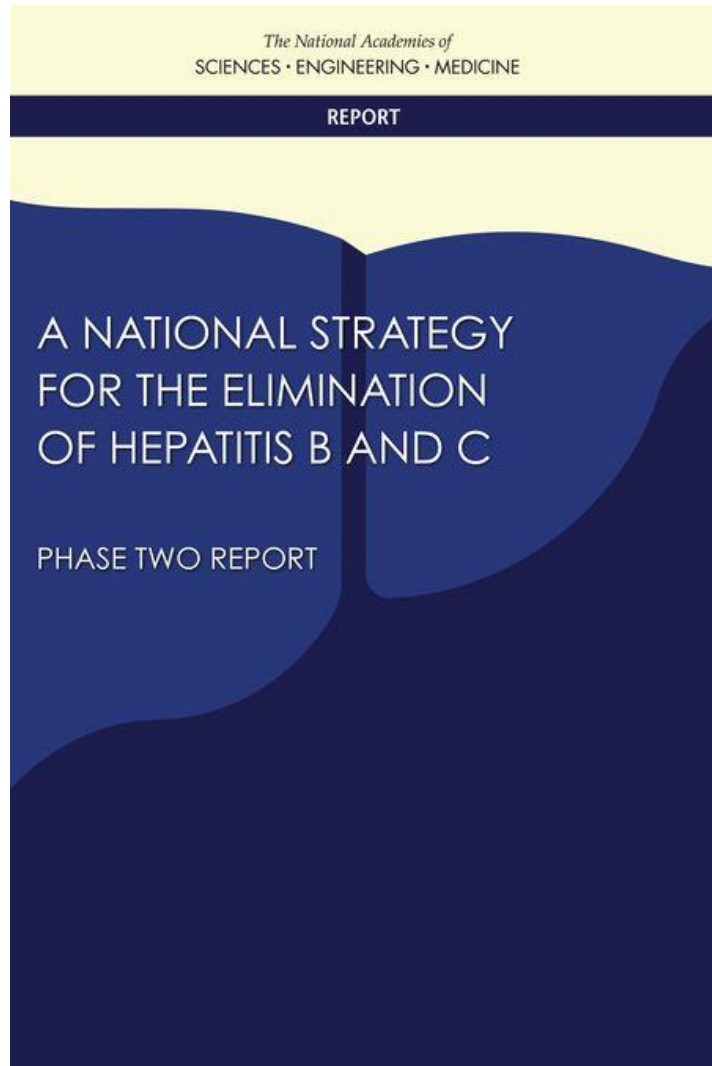
Treatment of HCV in Prisoners



- Recent study indicates that less than 1% of HCV chronic prisoners are being treated
- Average of 6% of DOC drug budget
- State prison systems bear disproportionate burden of cost of HCV treatment

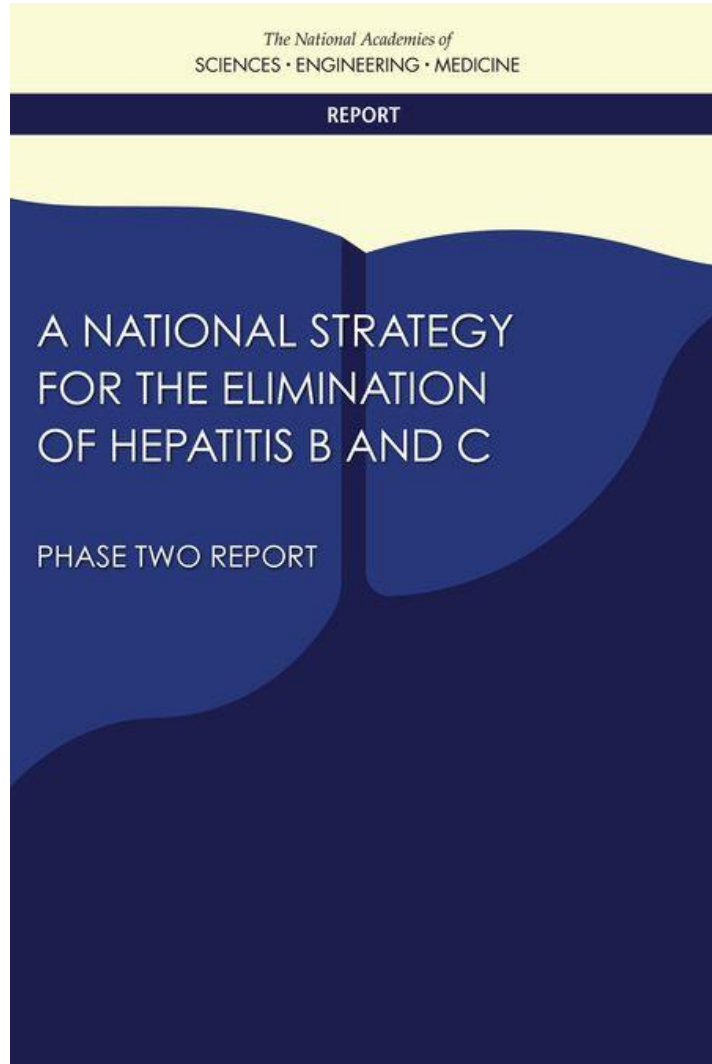
Source: <http://content.healthaffairs.org/content/35/10/1893.abstract>

NASEM Report – March, 2017



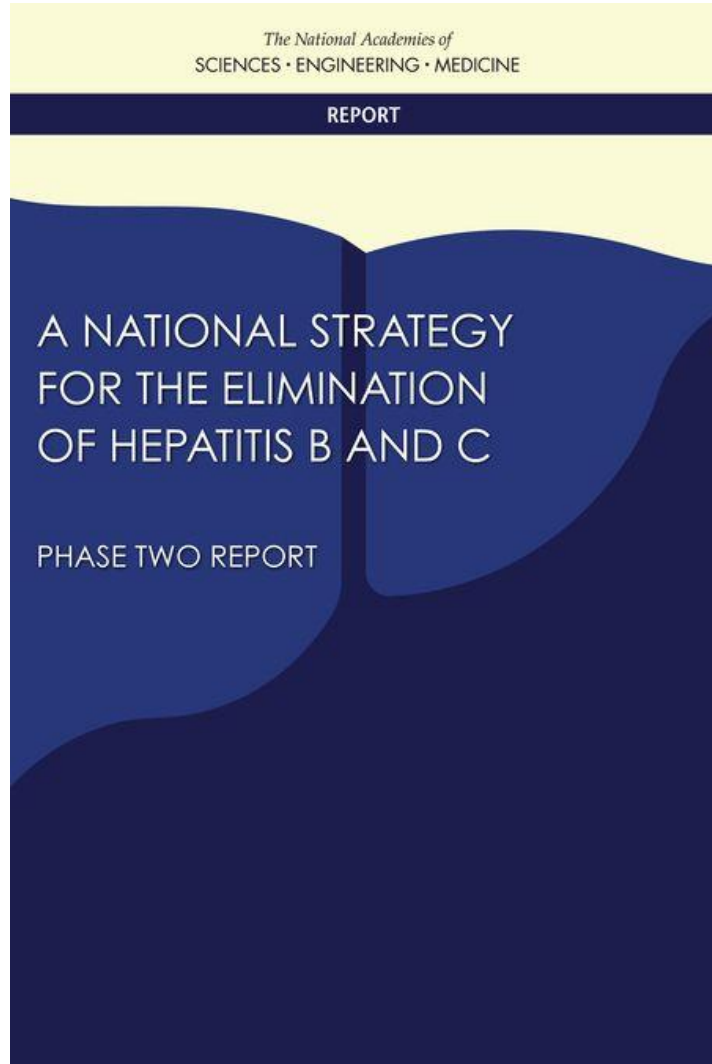
- 2016 Sustainable Development goal to combat viral hep by 2030
 - [US National Viral Hepatitis Action Plan](#)
- National Academies were commissioned as a result of the National Viral Hepatitis Plan
 - NASEM founded in 1863 to advise policymakers
- [Phase 1](#): Eliminating the Public Health Problem of Hepatitis B and C in the United States – “Could Be”
- [Phase 2](#): A National Strategy for the Elimination of Hepatitis B and C – “Here’s How”

NASEM Recommendations



- Collecting Information
 - Gov't help with data collection
- Essential Interventions
 - HBV immunization
 - Unrestricted HCV treatment
- Service Delivery
 - Rural and underserved
 - Tx from PCPs/Pharmacists
 - Prisons should screen, vaccinate, and treat
- Financing Elimination
 - DAAs patented until 2029
 - Gov't should implement voluntary license for prisoners and Medicaid beneficiaries

NASEM Financing Recommendation



- Multiple effective DAAs
- Patent distant future
- Cost effective
 - \$2 billion for licensing
 - \$140 million cost for states
 - Treat 700,000 patients
 - Status quo of \$2 billion year treating only 240,000 patients

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Treatment Action Group

- Treatment Action Group (TAG) is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus.
- Think tank and policy shop spun off from ACT UP/NY Treatment and Data committee in 1992

Update on the latest DAA approvals

Is a new competitive landscape emerging?

New DAA Approvals in 2017

- Vosevi, Gilead Sciences, FDA approved July 18, 2017 for adults with genotypes 1-6 without cirrhosis or with mild cirrhosis
 - Also patients who have been previously treated with sofosbuvir or an NS5A inhibitor
- Mavyret, AbbVie, FDA approved August 3, 2017 for adults with genotypes 1-6 without cirrhosis or with mild cirrhosis
 - Includes patients with moderate to severe kidney disease and on dialysis
 - Also genotype 1 infected patients who have been previously treated with an NS5A inhibitor or an NS3/4A protease inhibitor but not both

Vosevi: sof/vel/voxilaprevir (Gilead)

- **GT1-6**
- +/- compensated cirrhosis
- 1 pill, once daily
- 12 wks
- **No RBV**
- Not recommended for decompensated cirrhosis
- Not studied in HIV coinfectd (only HIV+ healthy volunteers)
- Not for patients with CKD or ESRD
- **Salvage** for treatment experienced patients

Mayvret: glecaprevir/pibrentasvir (AbbVie)

- **GT1-6**
- +/- compensated cirrhosis
- **3 pills**, once daily **with food**
- treatment naïve patients: **8 wks (78%)**, 12 wks with compensated cirrhosis
- treatment experienced: 8/12/16 wks based on cirrhosis, prior drug or GT1
- **No RBV**
- safe and effective with **CKD**, including **dialysis**
- not for HIV coinfectd patients on atazanavir, rifampin or protease inhibitors

DAA price comparison

Brand Name	Company	Wholesale Acquisition Price
Harvoni (sof/led)	Gilead	\$94,500 12 weeks \$63,000 8 weeks
Epclusa (sof/vel)	Gilead	\$74,760 12 weeks
Vosevi (sof/vel/vox)	Gilead	\$74,760 12 weeks
Mayvret (G/P)	AbbVie	\$26,400 8 weeks \$39,600 12 weeks \$52,800 16 weeks
Zepatier (elb/grz)	Merck	\$54,600 12 weeks

Mandated payer discounts

- Big 4 Federal Purchasers receive mandated Federal Ceiling Price:
 - Department of Defense – active military
 - Public Health Service – Native Americans
 - Coast Guard
 - Department of Veterans Affairs (VA) - able to negotiate additional discounts
 - ~40%
- Medicaid drug rebates:
 - 17-23.1%
- 340B Program created under Veterans Health Care Act:
 - 35% discount to safety net hospitals and community pharmacies
 - Price inflation penalties

Other purchasing options

- Direct negotiations with originator companies
 - Not shown to lower prices (per Yale study)
 - Limited capacity in prison settings
- Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP)
 - Open to all correctional institutions
 - Increases purchasing power

Website: **www.mmcap.org**

Email: **mn.multistate@state.mn.us**



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Hepatitis C Treatment in Prisons: Legal Standards and Challenges

Elizabeth Paukstis, M.A., J.D.

Public Policy Director

National Viral Hepatitis Roundtable

October 2, 2017

HCV and incarceration in the United States

- 2.3 million = number of people incarcerated in *federal and state prisons, local jails, juvenile and immigration facilities, and other confinement facilities*
- 1.5 million = number of people in federal and state prisons
 - 1.3 million = number of people in state prisons (87 percent)
 - 196,455 = number of people in federal prisons (13 percent)

About 17 percent of people in *state* prisons have HCV

- This number is **likely higher** because most state prisons do not perform routine, opt-out testing

Sources: Bureau of Justice Statistics, National Prisoner Statistics, 2004-2015. Updated Dec. 2016; Beckman A, et al. New Hepatitis C Drugs Are Very Costly And Unavailable To Many State Prisoners. *Health Aff* October 2016 vol. 35:1893-1901.

The legal right to medical care in prisons and jails

Estelle v. Gamble (1976)

- State prisoner brought civil rights action under 42 U.S.C. § 1983 against the Texas Dept of Corrections, alleging inadequate treatment of back injury violated the Eighth Amendment (8A)
- *Held*: Prison officials' "deliberate indifference" to the serious medical needs of prisoners constituted cruel and unusual punishment in violation of the 8A
- Such deliberate indifference "constitutes the 'unnecessary and wanton infliction of pain,'" as identified in *Gregg v. Georgia* (1976), "proscribed by the Eighth Amendment."

Why do incarcerated people have this right, and unincarcerated people do not?

- "An inmate must rely on prison authorities to treat his medical needs; if the authorities fail to do so, those needs will not be met. In the worst cases, such a failure may actually produce physical 'torture or a lingering death,' *In re Kemmler, supra*, the evils of most immediate concern to the drafters of the Amendment."
- Substandard medical care could lead to pain and suffering that serve no "penological purpose."

How does a person or entity show “deliberate indifference?”

- Prison doctors could display deliberate indifference in their responses (or lack of responses) to the prisoner’s medical needs, and prison guards could do so by “intentionally denying or delaying access to medical care.” (*Estelle*, 104-05)
- Mere negligence “in diagnosing or treating a medical condition” constitutes medical malpractice, not a constitutional violation
- To state a claim, the prisoner had to allege the occurrence of certain “acts or omissions” that were “sufficiently harmful” to show deliberate indifference to “serious medical needs.” (*Estelle*, 106)
- “It is only such indifference that can offend ‘evolving standards of decency’ in violation of the Eighth Amendment.” (*Estelle*, 106, quoting *Trop v. Dulles* (1958))

The constitutional protection against future harm

Helling v. McKinney (1993)

- Nevada state prisoner alleged that prison officials had subjected him to cruel and unusual punishment by forcing him to live in a cell with an inmate who smoked five packs of cigarettes per day.
- Defendants countered that they could not be deliberately indifferent to future harm, only to current serious medical need.
- *Held*: Prison officials' deliberate indifference to circumstances that were "sure or very likely to cause" illness or suffering could amount to 8A violation
- Prison officials cannot be "deliberately indifferent to the exposure of inmates to a serious, communicable disease on the ground that the complaining inmate shows no serious current symptoms."
- Prison officials cannot ignore conditions that "pose an unreasonable risk of serious damage to [an inmate's] future health."

The right of prisoners to protection from future harm extends to those with asymptomatic or earlier-stage HCV who have been denied the most appropriate care.

The heavy burden of proof

Farmer v. Brennan (1994)

- Two-prong test, with both objective and subjective components, for showing deliberate indifference
- *First*: plaintiff must show that the prison official's violation was "sufficiently serious" and posed a "substantial risk of serious harm" to the prisoner.
- *Second*: plaintiff must show that prison official knew of and disregarded an "excessive risk" to the prisoner's health or safety.
- To display deliberate indifference, the official must 1) be "aware of facts," from which he can infer that there is a "substantial risk of serious harm," 2) draw that inference, and 3) fail to take reasonable steps to reduce the risk.

The *Farmer* standard makes it more difficult for a prisoner to show deliberate indifference

- Courts may vary in their interpretations of "substantial" and "reasonable."

The *Farmer* standard: a disincentive for prisons to test inmates

- If prisoners are not screened, then how can a prison official know of and disregard an "excessive risk" to the prisoner's health?
- If prisons screen inmates, they have an obligation to treat – otherwise they could face a legal claim based on deliberate indifference.

Incarcerated individuals launch lawsuits

Notable from 2015:

Paszko v. O'Brien: class action alleging that Massachusetts Dept of Corrections violates 8A by delaying and denying treatment and testing

- Treatment protocol is based on disease severity, length of stay, disciplinary reports
- Testing is often not performed to evaluate disease severity
- Plaintiff Emilian Paszko died on March 14, 2016

Chimenti v. Pennsylvania Department of Corrections: class action alleging that PA Dept of Corrections violates 8A by denying any kind of HCV treatment, not just DAAs

- Plaintiff Salvatore Chimenti has advanced cirrhosis
- Plaintiff Daniel Leyva was told by a prison doctor that the newest treatments “cost too much”
- An estimated 20 percent of Pennsylvania’s prison population has HCV

More recent:

Rigglesman v. Clarke (2017): class action alleging that Virginia Dept of Corrections violates 8A by delaying and denying treatment

- Plaintiff Terry Rigglesman learned of HCV diagnosis while incarcerated in 2009
- Denied access to medical file in 2014 (told to pay 10 cents/page for hundreds of pages)
- Multiple requests for treatment denied through 2017; medical reason given was “Not meeting criteria.”

Mumia's case: the game changer

Abu-Jamal v. Kerestes: brought civil rights action under 42 U.S.C. § 1983 alleging that the Pennsylvania DOC violated 8A by denying treatment

- Aug 2015: First amended complaint filed; motion for preliminary injunction
- Aug 2016: Judge denied motion for preliminary injunction because the plaintiff named the wrong defendants, BUT found that the PA DOC's treatment protocol "may well" violate 8A
 - "[W]ere the proper defendants named, the Court believes there is a sufficient basis in the record to find that DOC's current protocol may well constitute deliberate indifference..."
- Sept 2016: Second amended complaint filed
- Oct 2016: Motion for preliminary injunction filed
- Jan 2017: Judge grants motion for preliminary injunction to compel DOC to treat plaintiff
 - The DOC's protocol "presents a conscious disregard of a known risk that inmates with fibrosis, like Plaintiff, will suffer from hepatitis C-related complications..."
 - "While the Court is sensitive to the realities of budgetary constraints and the difficult decisions prison officials must make, the economics of providing this medication cannot outweigh the Eighth Amendment's constitutional guarantee of adequate medical care."
- March 2017: Third Circuit Court of Appeals denies DOC's request for stay of the order
- April – July 2017: Plaintiff undergoes treatment for HCV
- Sept 2017: Most recent tests show plaintiff's HCV is undetectable

Some states with ongoing HCV prison litigation

Alabama

Braggs v. Dunn

Colorado

Aragon v. Raemisch

Florida

Hoffer v. Jones

Massachusetts

Paszko v. O'Brien

Minnesota

Ligons v. Minnesota Dept of Corrections

Missouri

Postawko v. Missouri Dept of Corrections

Pennsylvania

Chimenti v. Pennsylvania Dept of Corrections

Tennessee

Graham v. Parker

Virginia

Reid v. Clarke

Riggleman v. Clarke

NVHR

National Viral Hepatitis Roundtable

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Join NVHR: www.nvhr.org/join



Include prisons in state based efforts:

- Louisiana considering U.S. Code Section 1498 under Title 28 to compensate patent holders and access generic medications



Louisiana Proposes Tapping A Federal Law To Slash Hepatitis C Drug Prices

By Sarah Jane Tribble | May 4, 2017

- New York State HCV Elimination Summit bringing together stakeholders

timesunion

N.Y. officials on board to end hepatitis C

Destroying virus is possible, but high drug cost is major challenge

By Claire Hughes Updated 12:14 am, Wednesday, February 8, 2017

Join the National Hepatitis in Corrections Network

Annual Meeting, March 2018

Go to www.hcvinprison.org for more information

