

# **Policy in Corrections: HCV Cost and Care**

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# I. Context

## Changing HCV treatment landscape:

Combination therapy ->

Triple Therapy ->

Sofosbuvir & Simeprevir ->

Harvoni (no Interferon) ->

**??????????**

# I. Context (cont.)

## Call for broader HCV treatment in prisons

- NEJM: *Responding to Hepatitis C through the Criminal Justice System* (Rich, et al.) (5/15/14)
- Hepatology: *(Hepatitis C virus treatment for prevention among people who inject drugs: Modeling treatment scale-up in the age of direct-acting antivirals)* (Martin, et al.) (11/13)

# I. Context (cont.)

**Plus ça change, plus c'est la même chose...**

- NBCNews.com: *Prison's Deadliest Inmate, Hepatitis C, Escaping* (3/14/07)
- Clinical Infectious Diseases: *Clinical Outcomes of Hepatitis C Treatment in a Prison Setting: Feasibility and Effectiveness for Challenging Treatment Populations* (Smith & Maru, et al.) (10/1/08)

# I. Context (cont.)

**For the prisoner patient, it's also more of the same:**

- First we need to \_\_\_\_\_
- We're awaiting approval for \_\_\_\_\_
- You should wait for the new medications
- You should wait until we treat your \_\_\_\_\_
- You should wait until you get out
- You aren't sick enough
- You're too sick
- Didn't you get a d-report for \_\_\_\_\_
- And there's one other (unstated) problem...





# I. Context (cont.)

- Josiah Rich *et al.* ask (in NEJM): we should treat HCV widely in prison, but aren't we *required to treat widely*?
- Litigation – inevitable?
- Depends on the legal requirements governing prison medical care.



## II. Legal Requirements

### Why obligated to treat prisoners?

U.S. Constitution, Amend. VIII  
(cruel and unusual punishment)

&

United States Supreme Court  
(*Estelle v. Gamble*, 429 U.S. 1066 (1976))

## II. Legal Requirements (cont.)

### *Estelle v. Gamble:*

- “evolving standards of decency”
- Failure to treat, even in less serious cases, “may result in pain and suffering which no one suggests would serve any penological purpose.”
- “Deliberate indifference to serious medical needs”
- *Not* accidents or inadvertence

## II. Legal Requirements (cont.)

### *Brown v. Plata*, 131 S.Ct. 1910 (2011)

- Release order to solve overcrowding, which caused systemic inadequacies in medical and mental health care
- “A prison that deprives prisoners of basic sustenance, including adequate medical care, is incompatible with the concept of human dignity and has no place in civilized society.”

## II. Legal Requirements (cont.)

### What is “adequate” care?

- *U.S. v. DeCologero*, 821 F.2d 39 (1<sup>st</sup> Cir. 1987)
- Motion for reduction of sentence
- “[T]hough it is plain that an inmate deserves *adequate* medical care, he cannot insist that his institutional host provide him with the most sophisticated care that money can buy.”
- Adequate care = “services at a level reasonably commensurate with modern medical science and of a quality acceptable within prudent professional standards.”

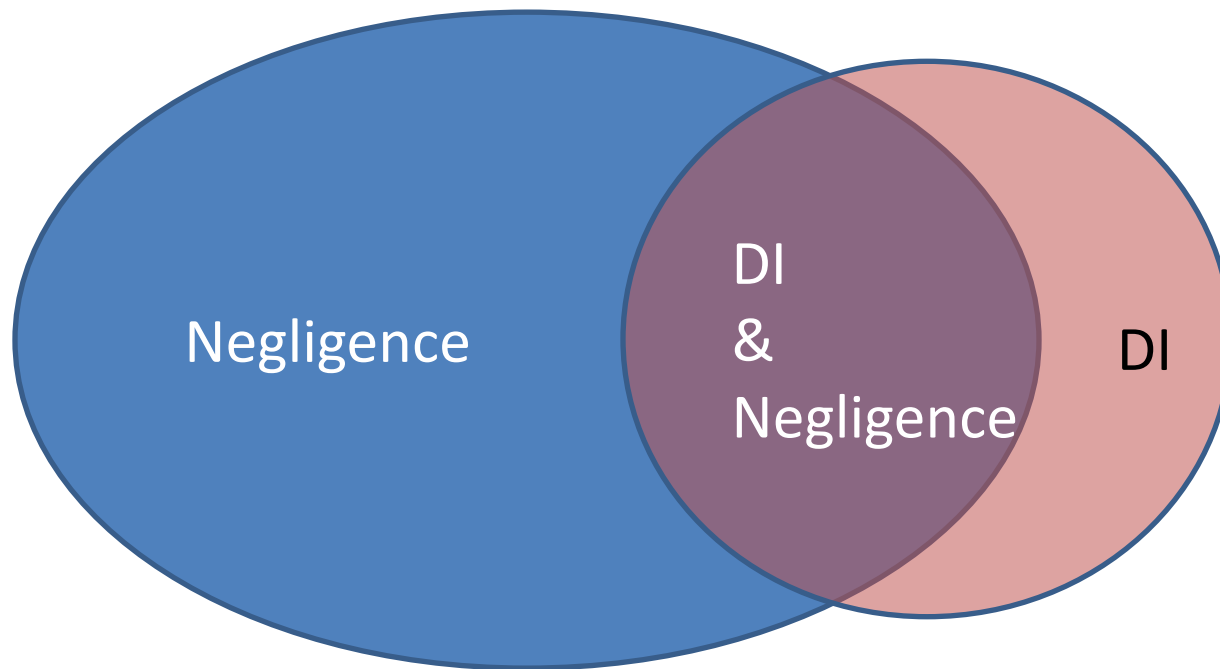
## II. Legal Requirements (cont.)

**What conduct is prohibited?**

***Farmer v. Brennan*, 511 U.S. 825 (1994)**

- “Deliberate indifference” = more blameworthy than negligence, less than intent to harm or knowledge that harm will result
- Knowing disregard of a substantial risk of serious harm, and failure to take reasonable measures to prevent it

## II. Legal Requirements (cont.)



## II. Legal Requirements (cont.)

### Making the case for broader HCV treatment of prisoners – challenges:

- Proof of need (screening)
- Courts set the floor
  - “reasonably commensurate with modern medical science”
  - Prisoners not entitled to choice of treatment
  - Somewhere below the standard of care?
- Proof of Harm / Risk of Harm

## II. Legal Requirements (cont.)

- Difficult to persuade a court that broader treatment of HCV in prison is required
- Potential for litigation is a prison (and provider) concern, but outcomes generally don't favor patients
- One example of a case where litigation changed the course of treatment...



# III. Providers Trump Protocol

## HCV Protocol: Not the Final Word

***Johnson v. Wright*, 412 F.3d 398 (2d Cir. 2005)**

- ***Background:***
  - HCV+ prisoner treated with Interferon
  - Responded initially, then VL rose
  - Physicians recommend adding Ribavirin
  - Denied per protocol: substance abuse w/in 2 yrs
  - Physicians were aware but recommended anyway

# III. Providers Trump Protocol (cont.)

## *Johnson v. Wright* (cont.)

- ***Holding***: prison officials may exhibit deliberate indifference where they “reflexively applied DOCS policy in the face of the unanimous, express, and repeated – but contrary – recommendations of the plaintiff’s treating physicians, including prison physicians...”

# III. Providers Trump Protocol (cont.)

## *Johnson v. Wright* (cont.)

- Protocol: “No evidence of active substance abuse...during the past 2 years.”
- Question is not whether protocol is generally justifiable, but whether following the protocol in this patient’s case amounted to deliberate indifference
- That question is for jury

# III. Providers Trump Protocol (cont.)

## *Johnson v. Wright (cont.)*

- Jury could find knowing disregard of a substantial risk of harm:
  - Physicians knew of positive marijuana test but recommended Ribavirin anyway
  - No evidence that defendants investigated whether medically appropriate to ignore physician recommendations
  - Substance abuse exclusion stems from concern over toxicity and compliance
  - No toxicity concern
  - Conflicting evidence on whether compliance concerns justify denial
  - Especially where patient was compliant with Interferon despite one positive marijuana result

# III. Providers Trump Protocol (cont.)

## *Johnson v. Wright* (cont.)

- ***Takeaways:***
  - Beware the blanket protocol
  - Treatment exclusions can be pushed too far
  - Treating providers matter!

# IV. What's to Come?

- **Could litigation increase HCV treatment capacity for prisons?**
  - Pro: existence of uniform community protocol  
<http://www.hcvguidelines.org/> (AASLD, IDSA)
  - *See* DHHS clinical guidelines for HIV
    - Many aspects of treatment beyond reasonable dispute
    - Departures must be justified
  - *See Kosilek v. Spencer*, 740 F.3d 733 (1<sup>st</sup> Cir. 2014)  
(referring to WPATH Standards of Care for gender dysphoria)

# IV. What's to Come? (cont.)

- Pro: treatment as prevention
- Con: *see above*, Sec. II., Legal Requirements
  - How many need?
    - Screening / diagnosis
    - Monitoring / evaluation
  - Is care inadequate?
    - “reasonably commensurate with modern medical science”
    - Do reasonable experts disagree?

# IV. What's to Come? (cont.)

- Proof of harm / risk of harm
  - The Goldilocks patient
  - Would statistical probability of harm be enough?



# IV. What's to Come? (cont.)

- **A Massive Federal Investment?**
  - Josiah Rich, *et al.*, in NEJM: need investment similar to Ryan White Care Act, with HDAP-type programs
  - Though HDAP does not cover state prisons
  - Could prisons find their way to 340b pricing?
  - Who are the advocacy organizations?
    - Poster child?

# IV. What's to Come? (cont.)

- **Will the Affordable Care Act help?**
  - Virtually all prisoners qualifying for insurance
  - Enrollment in Medicaid for new prisoners, with suspension of benefits
  - Off-site hospitalization (>24 hours) billable to Medicaid?
    - Determination of need (guard against overuse)
    - Transportation and monitoring (correctional staff)

# IV. What's to Come? (cont.)

- **Will competition bring down prices?**
  - HCV: will there be a competitor for Harvoni?
    - Is one enough?
    - Will older meds come down in price?
  - HIV: arrival of generics
    - Will they come? (Magic number = 3?)
    - What if they are less effective?

## **IV. What's to Come? (cont.)**

- **Will we see an end to the HCV treatment exclusion for imminent release date?**
  - Concern was interruption in treatment
  - Now, shorter duration of treatment
  - And continuity of care (Medicaid)

# V. Quick - Issues in HIV

- **HIV-based segregation comes to an end**
  - *Henderson v. Thomas* (Alabama)
  - South Carolina (DOJ settlement)
- **Blanket DOT policy is generally permissible**
  - *Nunes, et al. v. UMCH, et al.* (Massachusetts)
  - Insufficient showing of harm or discrimination