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Litigation for Eradication: Expanding Prisoners’ Access to Hepatitis C Treatment

1. A Public health context for Hep C litigation
2. A little law
3. A few steps back: History of HCV litigation
4. Current litigation
5. Looking forward

I. A Public Health Context for HCV Litigation

Litigation as a tool to fight an epidemic...

Surveillance
Litigation
Intervention
Regulation
Education

Public Health Toolbox

“There’s a tsunami of death and disease that’s already starting to crash down on us, and will continue to in the decades ahead.”

…Dr. Josiah Rich
II. A Little Law

The Eighth Amendment to the United States Constitution

Estelle v. Gamble

The Key Facts

- Texas prisoner suffered a workplace injury
- Over the next several weeks, he is seen by prison health care staff
- Citing several alleged failures to provide him with proper medical care, the prisoner files a lawsuit claiming that prison staff violated his constitutional rights
- Case goes to the United States Supreme Court

Estelle v. Gamble

These elementary principles establish the government’s obligation to provide medical care for those whom it is punishing by incarceration.
Estelle v. Gamble

This conclusion does not mean, however, that every claim by a prisoner that he has not received adequate medical treatment states a violation of the Eighth Amendment.

429 U.S. 106 (1976)

Estelle v. Gamble

In order to state a cognizable claim, a prisoner must allege acts or omissions sufficiently harmful to evidence deliberate indifference to serious medical needs.

429 U.S. 106 (1976)

Farmer v. Brennan

So... to violate the Constitution, there must be “deliberate indifference to serious medical needs”

Farmer v. Brennan

Prison officials can be held liable for a constitutional violation if they:

Have knowledge of a substantial risk of serious harm and fail to take reasonable steps to abate that risk.

Farmer v. Brennan

Farmer v. Brennan

Helling v. McKinney

Helling v. McKinney
**Helling v. McKinney**

We would think that a prison inmate also could successfully complain about demonstrably unsafe drinking water without waiting for an attack of dysentery. Nor can we hold that prison officials may 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.

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**III. A Few Steps Back: A Brief History of HCV Litigation**

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**The Pegylated Interferon/Ribavirin Days**

- 24/48 week treatment regimens
- Multiple serious side effects, risks, contraindications
- Middling SVRs
- Expensive
- Picky as to genotype
- No AASLD/IDSA universal treatment recommendation
South Carolina

circa 2012

C. Relative contraindications to treatment for Hepatitis C are medical or psychiatric conditions that could be addressed, and once stabilized, the inmate could be eligible for Hepatitis C treatment.

6. Uncontrolled diabetic inmate with Rv A2.7.5.

V. Other Issues.

K. Inmates who are non-compliant with any phase or element of treatment for Hepatitis C will be immediately discharged from Hepatitis C treatment and will not be eligible for re-treatment. The specific issue of noncompliance and the decision made to discharge the inmate from treatment should be noted in the OTR. (Send copies of MABs with the patient to GE clinic for the gastroenterologist to review.)

L. Inmates unable to continue with the treatment for any reason (medical or psychiatric) will be discharged and will not be eligible for re-treatment in the future.

G. Any inmate who is convicted of any drug/alcohol charge or who is found to be housing drugs, buying, or selling medication, or who tests positive on a urine drug test will be discharged from Hepatitis C treatment and will not be eligible for re-treatment in the future.

III. Initial Screening for Eligibility for Hepatitis C Treatment

A. The following criteria must be met before proceeding with any further testing:

1. The inmate must have a minimum of two years remaining in his/her sentence.

3. The inmate must have NO drug/alcohol or medication longing convictions against him at any time during his incarceration. (This includes tobacco related and tattoo-related charges?) If charges are pending, file for the disbarment of the disciplinary charge before proceeding with this protocol.

**Cowan v. Allen**

“It is clear that the decision to administer drug therapy for Hepatitis C is an extremely complicated one which involves consideration of numerous individual factors that differ from patient to patient and one which is well outside the expertise of this court to second guess or mandate....

Even under normal circumstances, the mere disagreement between an inmate and medical professionals regarding the suitability or advisability of treatment is not, alone, sufficient to present a constitutional claim.

This seems especially true in the light of the complicated nature of Hepatitis C therapy and the multitude of factors that go into the determination to provide or withhold Interferon treatment.”

**Class Actions from the Peg-Riba Days**

**Settled**
- Anstett v. Oregon (Protocol review)
- Hilton v. Wright (SAT)

**Failed**
- Runkle v. Pa. DOC* (Sentence tail)

**Interlude:**

The Changed Landscape
The Changed Landscape: DAAs

- Much shorter courses of treatment
- More options for more genotypes
- Fewer contraindications
- Fewer side effects
- AASLD/IDSA “treat everyone” recommendation
- “Normalization” of HCV
- DAAs make cost of Peg-Riba look like pocket change

Orr v. Elyea

“When this case began nearly 8 years ago, whether treatment should be started and what that treatment should be was dependent upon many factors, making it difficult to find the commonality necessary for a class action. Also, the treatment had serious side effects, which further individualized treatment decisions.

Now, as the court has learned... new treatments are available to successfully treat most cases of Hepatitis C in 12 weeks with minimal serious side effects....

The court is not defining a class for injunctive relief in this order. The court is only indicating its willingness to do so.”

IV. Current Litigation

[no relevant clipart found]
**Massachusetts**

*Fowler v. Turco*

No: 1:15CV12298 (D. Mass.)

Interesting Facts:

1. Plaintiff Emilian Paszkodied died of complications from HCV on 12/14/15. He had been identified at one point as an appropriate candidate for Harvoni but did not receive treatment. (Class Cert. Motion at 8).

2. In 2014 and 2015, approximately 35 patients were treated. In 2016, approximately 65 patients were treated.

Injunctive Relief Sought:

- A treatment protocol that includes screening for HCV;
- Timely evaluation and staging of HCV+ prisoners;
- Timely treatment with the most effective medications;
- Treatment of side effects to ensure treatment is successful;
- No unjustified exclusions and denials of treatment.

(First Amended Complaint at 17).

**Fowler v. Turco (Massachusetts)**

Case Type: Class action for injunctive and declaratory relief

Filed: June 10, 2015

Claims: Cruel and Unusual Punishment

Status: Joint Stipulation of Class Certification, discovery ongoing.

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**Missouri**

*Postawko v. Missouri DOC*

No: 16-CV-4219-NWL-P [W.D. Mo.]

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**Fowler v. Turco (Missouri)**

Injunctive Relief Sought:

- A treatment protocol that includes screening for HCV;
- Timely evaluation and staging of HCV+ prisoners;
- Timely treatment with the most effective medications;
- Treatment of side effects to ensure treatment is successful;
- No unjustified exclusions and denials of treatment.

(First Amended Complaint at 17).
**Postawko v. Missouri DOC**

**Case Type:** Class action for injunctive and declaratory relief with damages sought for named plaintiffs, jury trial demanded for appropriate claims

**Filed:** July 14, 2016

**Claims:** Deliberate indifference, violation of Americans with Disabilities Act

**Class Definition Sought:** Prisoners who have been or will be diagnosed with HCV but who are not treated with DAAs.

**Status:** Third Amended Complaint filed 12/15/16

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**Some Allegations from the Third Amended Complaint:**

“The severity of a person’s fibrosis or cirrhosis should never be used to determine whether a person should be treated...” (Third Amended Complaint at 15).

“Defendants... have a policy or custom of using an APRI score... to determine whether a person should be treated... and relying exclusively on APRI score to determine [fibrosis] stage... [is] in contravention of the prevailing standard of care...” (Third Amended Complaint at 18).

“MDOC subjects members of the Class to discrimination by withholding medically appropriate treatment that will likely cure their disability, although MDOC does not withhold life-saving treatments from individuals with different disabilities.” (Third Amended Complaint at 27).

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**Injunctive Relief Sought:**

- An HCV treatment policy that meets the prevailing standard of care, including identifying persons with HCV;
- Treatment with appropriate DAAs;
- Appropriate and accurate assessments of fibrosis or cirrhosis, counseling on drug-drug interactions, and ongoing medical care for complications and symptoms of HCV. (Third Amended Complaint at 25-26).

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**Ligons v. Minnesota DOC**

**Case Type:** Class action for injunctive and declaratory relief with damages sought for named plaintiffs, jury trial demanded for appropriate claims

**Filed:** May 1, 2015

**Claims:** Cruel and Unusual Punishment, Americans with Disabilities Act and § 504 of the Rehabilitation Act

**Class Definition Sought:** Four class/subclass definitions

**Status:** Expert reports disclosed, briefing schedule set for class certification and summary judgment motions

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**Second Amended Complaint: Interesting allegations**

“All Plaintiffs are daily exposed to HCV infection, or reinfection while incarcerated, due to... Defendants who have not adopted the safer more effective treatment protocols for HCV treatment...” (Second Amended Complaint at 12).

Doctors and other HCV treatment providers are professionally obligated to prescribe DAAs to any patient presenting HCV positive... This is the case for all MDs... including Defendant MN DOC and its contractors. (Second Amended Complaint at 13).

Complaint challenges the state’s chemical dependency treatment requirement.
**Ligons v. Minnesota DOC**  
Injunctive Relief Sought:
- No using 48-week Interferon-based treatments
- Removal of chemical dependency treatment requirement
- No withholding treatment absent evidence of fibrosis, scarring, cirrhosis, or cancer
- Treatment of HCV+ inmates with 12+ weeks of sentence remaining
- Universal HCV testing
- Individual relief for named plaintiffs

**Tennessee**  
*Graham v. Parker*  
No. 3:16-cv-01954 (M.D. Tenn.)

**Graham v. Parker (Tenn.)**  
- **Case Type:** Class action for injunctive and declaratory relief  
- **Filed:** July 25, 2016  
- **Claims:** Cruel and Unusual Punishment (8th Amendment)  
- **Class Definition Sought:** All persons currently incarcerated...who have at least twelve weeks remaining on their sentences who are HCV+ or who are determined to be HCV+ after testing by DOC.  
- **Status:** Class certification briefed.

**Pennsylvania**

*Chimenti v. Pennsylvania DOC*  
No. 2:15-cv-03333 (E.D. Pa.)

- **Injunctive Relief Sought:**  
  - ...A plan to eliminate the substantial risk of harm that Plaintiffs and members of the Plaintiff Class suffer due to Defendants' inadequate diagnosis, assessment, and treatment of HCV infection. Defendants' plan shall comport with the community standard of care and the advice of medical experts."

**Some Good News:**  
F3s and F4s are now being treated.
**Chimenti v. Pennsylvania DOC**

- **Case Type:** Class action for injunctive and declaratory relief with a damages claim for Plaintiff Chimenti
- **Filed:** June 12, 2015
- **Claims:** Cruel and Unusual Punishment, violation of PA Constitution, medical malpractice
- **Class Definition Sought:** HCV+ prisoners with 12+ weeks remaining on their sentences with a life expectancy of over one year.
- **Status:** Class certification briefed, discovery ongoing.

**Injunctive Relief Sought:**
- An HCV policy that meets community standards of care;
- Treatment with DAAs based on individual medical testing;
- Ongoing monitoring and care per the standard of care, including but not limited to evaluation by a hepatologist and assessment for need for partial or full liver transplant.

**Some Good News:**
F3s and F4s are now being treated.

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**Abu-Jamal v. Kerestes**

- **Case Type:** Individual action for injunctive relief
- **Filed:** May 18, 2015
- **Claims:** Deliberate indifference
- **Injunctive Relief Sought:** That Mr. Abu-Jamal be treated with DAAs
- **Status:** Terminated.

*The Interim Protocol* (circa late 2015)

Prioritization for treatment based on:
- Decompensated cirrhosis, CTP score 7-9
- Risk of developing decomp. cirrhosis
- Risk of dying from liver or HCV-related disease
- Infxn of transplanted liver, or in prep for liver xplant

“Patients at highest priority for anti-viral treatment should be those with advanced cirrhosis, selected patients with HCC awaiting transplant, transplant recipients, and patients with serious extra-hepatic manifestations such as cryoglobulinemia”
A three-day evidentiary hearing was held, and...

“Court’s Conclusions of Law

“The protocol as currently adopted and implemented presents deliberate indifference to the known risks which follow from untreated chronic hepatitis C.”

But...

Abu-Jamal had named the wrong defendants.

“The New Protocol” (effective 11/7/2016)

Purports to follow April 2016 BOP treatment criteria for prioritization purposes.
Abu-Jamal v. Wetzel

Court’s Findings of Fact

• Defendants’ expert testified that the HCV standard of care should be the same in prisons as in the community.

• Defendants’ expert testified that there is a “fiscal component” to who receives treatment.

• DOC’s new protocol, like the old one, is a “prioritization protocol.”

• Plaintiff was likely F2 or F2.5 with possible extra-hepatic symptoms.

Abu-Jamal v. Wetzel

Court’s Conclusions of Law

• DAAs are the standard of care for HCV tx.

• The HCV protocol “presents a conscious disregard of a known risk” that prisoners with fibrosis will suffer from HCV-related complications, continued liver scarring progressing to cirrhosis, portal hypertension, hepatic encephalopathy, etc.

Abu-Jamal v. Wetzel

Court’s Conclusions of Law

• Defendants “deliberately denied administering DAA drugs to Plaintiff despite knowing that administering such drugs was the standard of care. In choosing a course of monitoring over treatment, they consciously disregarded the known risks of Plaintiff’s serious medical needs…”

Abu-Jamal v. Wetzel

Victory?

5. Defendants shall provide Plaintiff with DAA medication no later than 7 days after the Supervising Physician’s determination that there are no contraindications for the administration of DAA medications to Plaintiff.

Robert D. Makin
United States District Judge
Abu-Jamal v. Wetzel

**Department Defendants’ Notice of Appeal**

Notice is hereby given that Defendants Wetzel, Noel, Silva, BHCS Assistant Medical Director, and BHCS Infection Control Coordinator (“Department Defendants”), hereby appeal to the United States Court of Appeals for the Third Circuit from the order and preliminary injunction entered in this action on January

**Motion for Contempt and Alternative Relief and for an Order to Show Cause**

Plaintiff hereby moves for an order to hold the defendants Wetzel, Silva, Noel, BHCS Assistant Medical Director, BHCS Infection Control Coordinator, Correct Care Solutions representative and Correct Care Solutions in civil contempt.

Bumps and Potholes on the Road Ahead

- Class certification
- PLRA restrictions on prospective relief
- Bad pro se decisions
- Moving targets
- Testing
- The judicial “WOW!!” factor
- Adverse rulings on 8th Amendment and cost
- Community standard vs. prison standard of care

Partners in a Public Health Mission

We have a chance to subdue a public health crisis. We’re all in this together.

- Prisoners
- Lawyers
- Correctional Physicians
- Correctional Administrators
- Plaintiffs
- Defendants
- Nurses
- Experts
- Detainees
- Courts
- Advocates
- Agencies
- Educators
- HCV Specialists
- Medical Directors
- Public Health Practitioners
- Researchers
- Congress
- Professional Organizations
- Reentry Coordinators
- Community Activists
- State Legislators
- Governors
- Presidents

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