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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS

JEFFREY D. ORR, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	08-2232
	)	
WILLARD O. ELYEA M.D., *et al.*,	)	
	)	
Defendants.	)	

ORDER ON PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTIVE RELIEF

I.

This is a case brought under the provisions of 42 U.S.C. § 1983. In this potential class action by numerous inmates of the Illinois Department of Corrections (IDOC) claiming deliberate indifference to their serious medical conditions, the plaintiffs have moved the court for immediate injunctive relief (d/e 397). They seek a court order directing the Illinois Department of Corrections to follow the guidelines promulgated by the American Association for the Study of Liver Disease (AASLD). Plaintiffs ask for treatment with the direct-acting antiviral drugs for all IDOC inmates with at least six months left to serve on their sentence. (Pls.' Brief, p. 9-10, d/e 424.) The AASLD guidelines call for treatment of all patients with Hepatitis C, while the IDOC guidelines generally do not start treatment until an inmate reaches fibrosis level 3.[1] [2]

The disagreement of the parties centers on two aspects of treatment of the disease. First, when should treatment begin, and second, how long must the patient be available for completion of the treatment and follow up examination. The Plaintiffs contend that treatment should begin immediately regardless of fibrosis level. The defendants insist that treatment beginning at fibrosis level 3 is

appropriate and that the patient must remain in the IDOC for completion of the treatment and follow up examination.

The question presently before the court is: what are the appropriate medical protocols for the diagnosis and treatment of Hepatitis C? The court concludes that the present record is sufficient for the court to find what the appropriate medical protocols are for the diagnosis and treatment of Hepatitis C, but the record is insufficient for the court to grant mandatory relief to any particular plaintiff or group of plaintiffs. As will be further explained in this order, mandatory relief requires more specific identification of the individuals or groups of individuals. *See* 18 U.S.C. § 3626(a)(2)("Preliminary injunctive relief must be narrowly drawn, extend no further than necessary to correct the harm the court finds requires preliminary relief, and be the least intrusive means necessary to correct that harm"); Fed. R. Civ. P. 65(d)(order directing injunction must be specific).

II.

Nine physicians have testified in this case:

1. *Steve Meeks, M.D.* is the current, relatively recent medical director of the IDOC. He is board certified in emergency medicine and embraces the current protocols for treatment of Hepatitis C. Dr. Meeks oversees the provision of medical services for IDOC, but the actual provision of those services are performed by Wexford Health Sources, Inc. (Wexford). (Meeks Trans., p. 7, d/e 428.) He inherited the IDOC's Hepatitis C treatment policy. Based on his understanding of that policy, the policy appears medically appropriate and does not place an inmate's health at a substantial risk. He stated that he relies on Dr. Young and Dr. Patel to determine the treatment protocol. Id. at 31.

2. *Michael Dempsey, M.D.* He is the Chief of Psychiatry for the IDOC. Before that he was the acting IDOC Director for about five months. He testified to the division of responsibilities between

IDOC and Wexford. IDOC employs two physicians. IDOC also employs a health care administrator at each prison and some of the nurses and pharmacy technicians. Wexford provides the physician at the prison, who is overseen by a regional medical director, also employed by Wexford. Then there is a corporate medical director in Pitttsburgh. The IDOC has a contractual arrangement with other parties besides Wexford. For example, there is a contractual arrangement between IDOC and the University of Illinois in Chicago (UIC) regarding dialysis services.

Dr. Dempsey testified that the 2015 fiscal year budget for the provision of medical services for IDOC inmates was $170 million dollars. Fiscal year 2017 is near $200 million dollars. (Dempsey Trans., p. 53, d/e 428.) The IDOC requests appropriations from the Illinois General Assembly to pay for UIC services. (Summary of Responsibilities, Ex. 7.) Roughly, Dr. Dempsey estimated that about 80 inmates with Hepatitis C were treated in 2016. He did not dispute the estimate of Plaintiff's counsel that 4,000 inmates in 2016 had Hepatitis C. (Dempsey Trans., p. 78, d/e 428.)

Dr. Dempsey is of the opinion that some inmates should not receive Hepatitis C treatment because they do not have the support system in place when they are released to avoid the behaviors that exposed them to Hepatitis C in the first place. (Meeks Trans., p. 68, d/e 428.) A person can be reinfected with Hepatitis C after being cured through treatment.

3. *Scott Cotler, M.D.* He is a physician, board certified in internal medicine, gastroenterology, and transplant hepatology. He is now the Director of the Division of Hepatology at Loyola in Chicago, but before that he worked for the University of Illinois to help establish the Telemed program with IDOC. (Cotler Trans., p. 75-76, d/e 376.) If the screening criteria are met under the Hepatitis C guidelines, inmates are referred to consultations with UIC physicians. Id. at 77. Dr. Cotler says it is appropriate to wait to begin treatment on a Hepatitis C patient until the patient reaches a fibrosis level of 3 because the disease is a slowly progressing

disease. Id. at 80-82; Cotler Trans. 2, p. 97, d/e 428. He testified that, "[i]n a resource limited system, [the IDOC treatment protocol] is good common sense, it's good medicine, and it protects the patients from developing the outcome that we are trying to avoid, so I think that it is completely appropriate under the circumstances". (Cotler Trans. 2, p. 98, d/e 428.) In his opinion, close monitoring of inmates at stages 0-2 will identify those who have extrahepatic conditions that might warrant earlier treatment. Id. p. 100. He believes that the "end result tends to be the same" whether treatment is given at the early stages or later stages. Id. p. 101. He also expects that more people will be treated as the cost of the treatment decreases. Id. p. 109, 111.

4 & 5. *Jeremy Young, M.D. and Mahesh Patel, M.D.* Both are physicians at UIC. Dr. Patel is board certified in infectious diseases, pediatrics, and internal medicine. Dr. Young is board certified in internal medicine and infectious diseases. Through the Telemed program between UIC and IDOC, they help manage the medical care for IDOC inmates with HIV and Hepatitis C. (Patel Trans., p. 100; Young Trans., p. 139, d/e 376.) Under this program, a physician or medical provider working at an IDOC prison (most likely a physician employed by Wexford) may refer an inmate for a video consultation with Drs. Patel or Young for consideration of initiating Hepatitis C treatment. Id. at 101-02. The UIC doctors have nothing to do with selecting which inmates are referred to UIC to be considered for Hepatitis C treatment, though they do help create the standards used by the medical providers at the prison to determine who should be referred. Most inmates the UIC clinic sees are stage 3 or 4, with some stage 2 if certain additional factors are present, such as the inmate also has HIV. (Patel Trans. 2, p. 70, d/e 427.) The UIC doctors prescribe the Hepatitis C medicines, which are delivered overnight to the prison and administered by the prison nurse. (Young Trans. 2, p. 75, d/e 427.) The UIC doctors then manage the patient and order labs. The Wexford physicians on site review the notes but are not directly involved in managing the patient during treatment. (Young Trans. 2, p. 86, d/e 427.)

Drs. Patel and Young have participated in modifying the IDOC medical protocols for treating Hepatitis C as treatments have advanced. Dr. Patel does not believe any medical harm occurs without treatment between stage 1 and stage 2, and also believes that there is probably not significant harm without treatment from stage 2 to stage 3. (Patel Trans., p. 117-18, d/e 376.) Similarly, Dr. Young is not aware of any peer reviewed study showing a significant health benefit by starting treatment at stage 1 or 2 versus stage 3 in the normal patient. (Young Trans., p. 157-158, d/e 376.) Dr. Patel testified that eighty percent of patients with Hepatitis C have no complications. (Patel Trans. 2, p. 82, d/e 427.) Dr. Patel acknowledged that cost is a factor in determining who gets treatment and that, from a medical standpoint, there is no reason not to treat regardless of fibrosis level. Id. at 124, 130. Neither Dr. Young or Dr. Patel have anything to do with how much money is allocated to treating inmates with Hepatitis C or "how far down the list" treatment goes. (Young & Patel Trans. 2, p. 75, d/e 427.)

Dr. Young described the guidelines as prioritizing who receives treatment because the cost necessitates that prioritization, rather then excluding anyone from treatment. (Young Trans. 2, p. 73-74, d/e 427.)

6. *Lara Strick, M.D.* Dr. Strick is board certified in infectious disease and works for the Washington State Department of Corrections as an infectious disease consultant. (Strick Trans., p. 164, d/e 376.) She is of the opinion that the IDOC's Hepatitis C treatment guidelines are in line with guidelines from other state prisons and the federal bureau of prisons. She is also of the opinion that there is no serious risk of harm to health by waiting until stage 3 to treat. Id. at 173-74.

7. *David Thomas, M.D., M.P.H.* Dr. Thomas is one of the two court recruited experts in the field of liver diseases. He the Director of the Division of Infectious Diseases at Johns Hopkins Medicine. He is a specialist in the treatment of liver disease and is board certified in infectious diseases and internal medicine. He was a

member of the AASLD panel that drafted that association's medical protocols for the treatment of Hepatitis C in the past but is not currently on that board and does not speak on behalf of the association.

Dr. Thomas testified in his deposition that the current AASLD guidelines set forth a consensus of the standard of care for patients with Hepatitis C. He is, quite naturally, a staunch supporter of the AASLD medical protocols for the treatment of Hepatitis C.

The AASLD guidelines recommend treatment for all patients with Hepatitis C except for patients with short life expectancies that cannot be prolonged with intervention. (Thomas Dep. 6, p. 16, d/e 382.) The new therapies allow for a 90 percent cure rate (total eradication) with minimal side effects. Id. at 7. Curing the disease reduces the risk of liver cancer and liver failure by 80-90 percent as well as reducing the risk of developing conditions associated with the disease such as non-Hodgkin's lymphomas, renal disease, and diabetes. Id. at 8. Delaying treatment can lead to liver disease, cirrhosis, liver cancer or those other conditions that might not be reversible by treatment. Id. at 10-11. Dr. Thomas stated, "[E]ven at stage 3 there's a clear risk, increased risk, of liver cancer. So if you wait till stage 4, then, you miss all – even in stage 2 you can miss about 20 percent of the people you think are stage 2 are actually stage 3". Id. at 34. Patients treated at stage 3 or 4 should be monitored indefinitely every 6 months for liver cancer. Id. at 40. Patients treated at stages 1-2 do not necessarily need follow-up monitoring if the treatment is successful. Id. at 41; Thomas Trans. 2, p. 7, d/e 101.

If Dr. Thomas has a patient at stage 3 and insurance denies coverage, Dr. Thomas still prescribes the medicines and informs the insurance company in writing that the company is outside the standard of care. Id. at 35. If that does not work, Dr. Thomas will try to get the medications for free through an expanded access program. Id. at 35.

Prioritization was initially included in the AASLD guidelines when the new drugs were available, but that section has now been removed. Id. at 21. Dr. Thomas was able to treat everyone in his practice within a few weeks of the new drugs' availability. Id. at 20. The guidelines still acknowledge, though, that in some settings prioritization may be unavoidable. Id. at 24. Dr. Thomas agrees that it would be a priority to treat patients with fibrosis levels of 3 and 4 before those with levels 0-2. Id. at 33. However, stage 2 still shows that the disease has progressed. (Thomas Trans., p. 27, d/e 427.)

Some State's medicaid programs cover treatment at any stage, some state's medicaid programs do not cover for stages 1 and 2, and other states start at later stages. Id. at 23. Dr. Cotler testified that the State of Illinois covers Medicaid patients only once they reach stage 4. (Cotler Trans. 2, p. 99, d/e 428.) That appears to have changed in December 2016: direct-acting antivirals are approved for patients with stage 3 or 4. Ill. Dept. Healthcare and Family Services website, www.Illinois.gov/hfs. Plaintiffs brought to the court's attention a Washington State's district court order granting Medicaid recipients a preliminary injunction to treat their Hepatitis C without regard to fibrosis level. *B.E. v. Teeter*, C16-227-JCC, 2016 U.S. Dis. LEXIS 70021 (Western District of Washington, 5/27/16 Order). Plaintiffs point to a statement by the Center for Medicaid & Chip Services (U.S. Department of Health and Human Services) expressing concern that states limiting treatment to only stages 3 and 4 were in violation of the rules regarding Medicaid drug coverage. (d/e 424-2, p. 2.)

Dr. Thomas has heard that several states have been able to obtain a price of $20,000.00 per treatment, which is less than a quarter of the average wholesale price of $88,000.00. Id. at 27. However, the guidelines acknowledge that prisons might be in a weaker bargaining position. Id. at 30. Dr. Meeks thought the cost of treatment was $60,000.00 per patient, paid to UIC. (Meeks Trans., p. 37, d/e 428.) Dr. Meeks does not believe the money goes through Wexford. Id. at 40. The pricing information provided by

the IDOC does not enable the court to determine how much it would cost to treat the average inmate with a fibrosis level of 2.

8. *Andrew Batey, M.D.* Dr. Batey is the other court-recruited expert on treatment of Hepatitis C. Dr. Batey is a practitioner in the Carle Clinic Foundation in Urbana, Illinois. He is triple boarded in gastroenterology, hepatology and internal medicine. Seventy percent of his patients are under treatment for liver diseases. Dr. Batey supports the AASLD protocols. Dr. Batey recommends treatment for all inmates with Hepatitis C having at least one year to serve on their sentence. (Dr. Batey's 1/5/15 letter)("[I]t is my opinion that ALL patients (assuming no contraindications to medicines) should be considered for therapy irrespective of the stage of fibrosis.").

The defendants' brief in opposition to the plaintiffs' request for temporary relief quotes Dr. Batey as testifying that waiting to treat until fibrosis level 3 or 4 is reached does not raise a risk of serious harm to the patient. (d/e 40, p. 10.) That is an incomplete representation of Dr. Batey's opinions. It comes from a discussion with Dr. Batey in the transcript of the complications from medications that may arise at different levels of fibrosis. Dr. Batey's testimony is simply stated as the earlier you begin treatment after diagnosis, the better off the patient will be. Dr. Batey testified that eradicating the virus is more likely with a lower viral load and that the virus causes the cells of the liver to become inflamed, leading to scarring and hardening of the liver. A fibrosis level of 0 means no scarring. A fibrosis level of 4 means the liver is completely scarred. (Batey Trans., p. 24-25, d/e 376.) If treatment begins at fibrosis level 1 or 2, the liver can regenerate healthy tissue and the fibrosis can revert back to a level of 0. Id. at 25-26. Reversion is still possible, but more difficult, at stage 3 or 4. Id. at 26. One of the risks of waiting is that it is not possible to predict the progression in any one patient, so monitoring instead of treating could lead to unnecessary scarring of the liver. Id. at 47. Another risk of waiting to stage 3 is that the test can "understage," meaning that a patient with stage 3 is actually at stage 4. Id. at 49. Dr. Batey

acknowledged that the cost of the treatment would likely make it prohibitive to treat everyone and that universal treatment at every stage was currently a hope rather than a reality. Id. at 30, 33-34, 63.

9. *Martin Gary Prosky, M.D.* Dr. Prosky is a board-certified gastroenterologist and hepatologist. About one-quarter of his patients have some kind of liver disease, mostly Hepatitis C. (Prosky Trans., p. 181, d/e 376). Dr. Prosky testified that the earlier treatment begins, the better the chance is of curing the disease and avoiding complications. Id. Dr. Prosky recommends that treatment be initiated immediately regardless of fibrosis level if an inmate has at least 6-9 months to serve. (Prosky Trans., p. 185-86, d/e 376). He testified that the risk of waiting is decreased effectiveness of the treatment and the possibility of irreversible liver disease, cancer and cirrhosis complications. (Prosky Trans. 2, p. 37, d/e 427.) He agreed with Defendants that the cure rate is high even at stage 4, but disagreed that no harm occurred by waiting because by stage 4 "you have allowed them to get to the stage of cirrhosis, their lifelong risk of liver cancer and other problems are now irreversible". (Prosky Trans. 2, p. 62, d/e 427.) Dr. Prosky testified that Hepatitis C is a "major public health problem" and the "leading cause for liver transplantation in the United States." Id. at 47. Dr. Prosky believes the six to seven months' time should be sufficient for work-up, treatment, and follow-up: 4 weeks work-up, 12 weeks treatment, follow-up in 12 weeks. (Prosky Trans. 2, p. 51-52, d/e 427.)

III.

What is apparent from the testimony of the physicians called by the defendants is that their opinions on appropriate medical protocols for IDOC inmates are driven by the availability of funding. On the other hand, the plaintiffs' expert witness and the court's two recruited experts gave their opinions without regard to where the infected person was and without regard to the availability of funding. In other words , the court's experts and the plaintiffs'

expert based their opinions only on medical grounds while the defendants' opinions included the availability of funding. That is not a medical reason but a pragmatic, political and societal reason. *See Roe v. Elyea*, 631 F.3d 843, 863 (7th Cir. 2011) ("Although administrative convenience and costs may be, in appropriate circumstances, *permissible factors* for correctional systems to consider in making treatment decisions, the Constitution is violated when they are considered *to the exclusion of reasonable medical judgment* about inmate health.")(emphasis in original); *Berry v. Peterman*, 604 F.3d 435, 441 (7th Cir. 2010) ("[C]ourts may consider the 'cost of treatment alternatives [when] determining what constitutes adequate, minimum-level medical care,' . . . 'but medical personnel cannot simply resort to an easier course of treatment that they know is ineffective.'")(quoted cites omitted).

IV.

The legal principles in a §1983 case such as this are well established. It is a violation of the Eighth Amendment to the United States Constitution for a person acting under color of state law to display deliberate indifference to a serious medical condition of a prisoner. *Petties v. Carter*, 836 F.3d 722, 727 (7th Cir. 2016). A serious medical condition is one diagnosed by a physician or one that is so obvious that even a lay person could see it. Stated another way, it is a violation of the Eighth Amendment for a person acting under state law to show conscious disregard of a substantial risk of serious harm. *Rasho v. Elyea*, 850 F.3d 318, 324 (7th Cir. 2017).

V.

There is no dispute that Hep C is a serious medical condition or that it is present in significant numbers in the IDOC prison population. There is a sharp dispute as to when treatment should begin.

The plaintiffs, and the court-appointed physicians, consistent with the AASLD Guidelines, say treatment should begin as soon as possible. The defendants' physicians, driven by the availability of funding for treatment, say that treatment should begin only when the inmate reaches a fibrosis level of 3. They defend that opinion by pointing out that Hepatitis C is a slow advancing disease normally and that no real liver damage will be incurred by waiting to treat until fibrosis level 3. They also support their opinion by observing that the liver is an organ that often can and does regenerate itself.

Drs. Thomas, Batey and Prosky all say that treatment should begin as soon as possible because to wait until a inmate's fibrosis level is 3 is to run the risk that the level is really 4 because of the inaccuracy of the fibrosis level test and the inability to predict how fast the disease will progress in any one patient. Too, and quite serious, is the beginnings of cirrhosis of the liver. In addition, in inmates who have an accompanying condition such as diabetes or HIV or others, the inmate is at risk of further liver complications developing. Cancer is an example. Those are serious risks not to be ignored.

VI.

The IDOC has outsourced its responsibilities for health care of its prisoners to the corporate entity, Wexford. The record is unclear as to the precise arrangements the IDOC has with Wexford. It appears that Wexford was retained on a fixed budget to supply the personnel and care for the prisoners. It is Wexford personnel who test the prisoners for the presence of the Hepatitis C virus and monitor the fibrosis level in those who are infected. It is Wexford that will inform Drs. Young and Patel of the need for treatment of Hepatitis C inmates and Wexford that will administer the pharmaceuticals provided by Drs. Young and Patel at UIC. IDOC pays the UIC Hospital for the pharmaceuticals, but who IDOC pays for the work-up labs and other testing is unclear. Drs. Young and Patel know nothing about the business arrangement of paying. What is obvious, however, is that the prisoners are totally under the

control of Wexford for all their medical needs. The prisoners cannot get referred for Hepatitis C treatment unless the Wexford doctors make the referral.

That raises the following conundrum: *Quaere:* If the State of Illinois decides, as a matter of policy, not to fund the treatment of its prisoners with Hepatitis C fully, and IDOC implements that policy by limiting the funds provided to Wexford, which in turn follows protocols for treatment that delay treatment until the disease is in full progress, are those actions under color of state law that infringe a prisoner's rights under the Eighth Amendment? *See Glisson v. Indiana Department of Corrections,* 849 F.3d 372 (7th Cir. 2017).

VII.

Which leads the court back to the question raised at the beginning of this order: If basing the time to begin treatment, not on a purely medical reason, but on a financial, political, societal basis, how can the defendants be anything but consciously disregarding a substantial risk of medical harm? Can the State of Illinois be excused from the federal constitutional requirement that it not be deliberately indifferent to a prisoner's serious medical condition? Certainly the plain wording of Article VI §2 of the U.S. Constitution must have some impact: "This Constitution, . . . shall be the supreme law of the land[.]" Or the Fourteenth Amendment: "No State shall . . . deprive any person of life, liberty, or property, without due process of law." If a state may not subject its prisoners to cruel and unusual punishment, and deliberate indifference to a serious medical condition is cruel an unusual punishment, then how can the state not provide treatment because it is too expensive and the state does not want to raise the money? Is it because they are convicted felons and unworthy?

VIII.

In final analysis, the question to be resolved by the court at this juncture of the case is this:

Quaere: Within reasonable medical certainty, at what fibrosis level reading, in a patient infected with the Hepatitis C virus, raises a substantial risk of serious harm to the patient if left untreated?

The court makes the following findings of fact:

The accepted medical treatment of patients with Hepatitis C is given by the Drs. Thomas, Batey and Prosky based on purely medical grounds.

The court finds that all inmates should be tested for Hepatitis C upon admission to the Illinois Department of Corrections. Inmates who test positively should be tested immediately to determine fibrosis level. The court further finds that inmates who test positively and have at least one year to serve on their sentence from admission to release date should be offered treatment with direct acting antiviral drugs as soon as possible after diagnosis, and, in any event, no later then testing at a fibrosis level of 2.

But this finding is too general to meet the specific requirements of a preliminary injunction order. The court has no information on which of the plaintiffs these findings would apply to and who would be eligible for treatment. There is no information about fibrosis levels, contributing conditions, sentence length, etc., so the court cannot determine which of the plaintiffs should be referred for treatment.

IX.

The court is not, and needs to be, fully informed of the precise relationship between the IDOC and Wexford. A troublesome question that lurks in that information is what the State of Illinois is

trying to do by outsourcing its medical treatment of prisoners. Is it intended to put a cap on expenses? Is it to avoid liability or shield itself from liability for medical treatment of its prisoners? The court needs to be fully informed to render a proper decision in this case.

Enter this 6th day of April, 2017.

/s/Harold A. Baker

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Harold A. Baker
United States District Judge

1. The current IDOC guidelines screen all offenders for Hepatitis C antibodies. A diagnosis of Hepatitis C is confirmed at the inmate's parent facility and further work-up is done. If an inmate has less than 12 months left on his sentence, he is not treated. Inmates are referred to the UIC Telemedicine Liver Clinic to be considered for treatment if they have certain other conditions or cirrhosis, if they have an "APRI score" greater than or equal to 2, or if they have a fibrosis level of 3 or greater. Otherwise, the inmate if monitored every six months. IDOC Hepatitis C Guideline, Def.'s Ex. 12.)

2. The current AASLD guidelines call for the treatment of all patients with Hepatitis C unless they have short life expectancies that will not be helped by that treatment or other treatment. Prior AASLD guidelines prioritized treatment because "the infrastructure . . . did not yet exist to treat all patients immediately." www.hcvguidleines.org ("When and in whom to Initiate HCV Therapy")(last visited 4/4/17). The prioritization guidelines have been removed because "from a medical standpoint, data continue to accumulate that demonstrate the many benefits, with the liver and extrahepatic, that accompany HCV eradication." Id.