UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

GREGORY ATKINS, et al., on behalf of themselves and all others similarly situated,	)	
Plaintiffs,	)	
v.	)	**NO. 3:16-cv-1954**
TONY C. PARKER and DR. KENNETH WILLIAMS,	)	
Defendants.	)	

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This case, at its heart, is about the adequacy of medical treatment for state inmates with chronic Hepatitis C ("HCV") viral infections. Plaintiffs challenge the failure of current Tennessee Department of Corrections ("TDOC") policies and protocols to timely provide Direct Acting Antiviral drugs ("DAAs") to treat all HCV inmates constitutes deliberate indifference to their serious medical needs in violation of the Eighth and Fourteenth Amendments. Plaintiffs and their class seek prospective injunctive and declaratory relief under 42 U.S.C. § 1983 against TDOC Commissioner Tony C. Parker and Chief Medical Officer Dr. Kenneth Williams ("Defendants"). In response, Defendants contend TDOC's 2019 HCV treatment policies and protocols are improved, objectively reasonable, and the result of subjective medical judgment.

The Court held a bench trial on July 16, 2019 through July 19, 2019. Based on the record before the Court, the Court finds that Defendant's HCV treatment policies as written and as applied are not perfect, but Plaintiffs have failed to prove, by a preponderance of the evidence, that TDOC's current HCV treatment policy and protocols violate Plaintiffs' Eighth Amendment rights.

The Court enters the following Findings of Fact and Conclusions of Law in accordance with Rule 52(a) of the Federal Rules of Civil Procedure.[1]

FINDINGS OF FACT

I. The Class and Claim

1. Plaintiffs are a class of TDOC inmates diagnosed with HCV who have not yet received treatment at the time of trial. (Doc. No. 219.) Specifically, the class consists of:

> All persons currently incarcerated in any facility under the supervision or control of [TDOC] or persons incarcerated in a public or privately owned facility for whom [TDOC] has ultimate responsibility for their medical care and who have at least 12 weeks or more remaining to serve on their sentences and are either currently diagnosed with [HCV] or are determined to have [HCV] after an appropriate screening test has been administered by [TDOC].
>
> (Doc. No. 32.)

2. Specifically, Plaintiffs allege that the practices and procedures implemented by Defendants for the diagnosis, evaluation, and approval for treatment with DAAs of HCV inmates, do not meet the current medical standard of care, subject HCV inmates to a substantial risk of harm or death, and constitute deliberate indifference in violation of the right to be free from cruel and unusual punishment guaranteed by the Eighth and Fourteenth Amendments. (Id.)

3. There are approximately 21,000 inmates in TDOC custody. (Doc. No. 198, Tr. Stip. No. 20.)

4. At the time of trial, there were approximately 4,740 inmates known to be infected with chronic HCV. (Id., Trial Stip. No. 21.)

[1] This is not a complete recitation of the record. Except where the Court discusses differing testimony on a specific issue, any contrary testimony on that matter has been considered and rejected in favor of the specific facts found. Further, to the extent that either a finding of fact or conclusion of law may constitute the other, the Court reaches that conclusion.

5. The number may be higher because a number of inmates have not yet been tested. (No. 250, Tr. Vol. 1 at 115-117 (Wiley); Doc. No. 251, Tr. Vol. 2 at 199-200 (Williams)).

6. As of July 16, 2019, TDOC has prescribed DAAs for approximately 450 inmates (P. Ex. 84; Doc. No. 251, Tr. Vol. 2 at 166 (Williams)), which is approximately 10% of the known number of inmates with chronic HCV. (Id.)

7. At least 109 inmates have died from complications of HCV in TDOC custody since 2009, although (1) DAAs have only been available for part of that time and (2) DAAs would not necessarily have changed all of those specific outcomes given the combination of the long pathology of HCV and the time at which inmates could have been treated by TDOC. (Doc. No. 251, Tr. Vol. 2 at 169-170 (Williams)).

II. HCV

A. Background

8. HCV is a contagious virus spread through contact with infected blood or bodily fluids. (Doc. No. 198, Tr. Stip. No. 1.)

9. The HCV virus travels to and infects the liver, the largest organ in the body, causing an inflammatory process referred to as "hepatitis." (Id.)

10. An HCV infection occurs in two stages: acute and chronic. (Doc. No. 251, Tr. Vol. 2 at 16 (Yao)).

11. For the first approximately six months following initial HCV infection, persons are in the "acute" phase. (Doc. No. 198, Tr. Stip. No. 2; Doc. No. 251, Tr. Vol. 2 at 9-10 (Yao)).

12. During the acute HCV stage, approximately 15 to 25% of patients will spontaneously clear or resolve. (Doc. No. 198, Tr. Stip. No. 3.)

13. For the majority of patients, however, HCV infections do not spontaneously resolve and result in chronic HCV infection. (Id., Tr. Stip. No. 4.)

14. Chronic HCV is a serious health condition that requires medical attention. (Doc. No. 234 at 16-17 (pretrial conf. stip.); Doc. No. 251, Tr. Vol. 2 at 9-14 (Yao)).

15. Chronic HCV is a progressive disease. Specifically, chronic HCV damages the liver by causing progressive scarring of the liver, known as fibrosis. A five-point score is used for measuring the degree of fibrosis: F0 (no fibrosis), F1 (mild fibrosis), F2 (moderate fibrosis), F3 (advanced fibrosis), and F4 (cirrhosis). Doc. No. 251, Tr. Vol. 2 at 33 (Yao)). Chronic HCV also affects other organs in the human body. (Id. at 9-10). Beginning as early as the acute stage and continuing through the chronic stage, HCV patients may experience fatigue, jaundice, nausea, and pain. (Id. at 10.) In advanced stages, HCV patients may experience vasculitis, skin lesions, kidney, heart, and cognitive symptoms. (Id. at 11.) The rate of fibrosis progression is not the same in all HCV patients. (Doc. No. 198, Tr. Stip. Nos. 5-6; Doc. No. 251, Tr. Vol. 2 at 259 (Williams)). The FibroSure score (a combination of age, platelet count, and blood tests) and AST to Platelet Ratio Index ("APRI") are non-invasive methods used to determine a patient's fibrosis stage. (Doc. No. 251, Tr. Vol. 2 at 14 (Yao)). These methods fail to detect severe liver fibrosis a significant percent of the time. (Id.) The FibroScan is a non-invasive, more accurate method of determining a patient's fibrosis stage utilizing sound waves to measure liver stiffness. (Id. at 15; Def. Ex. 2.)

16. Cirrhosis is the late stage (F4) of liver scarring caused by chronic HCV. There are two types of cirrhosis: compensated cirrhosis, which is asymptomatic (i.e., adequate liver function), and decompensated cirrhosis, which is symptomatic (i.e., inadequate liver function). (Doc. No. 198, Tr. Stip. No. 7.) During decompensated cirrhosis, the liver has deteriorated such that it cannot support the other organs required for the body to function. (Doc. No. 251, Tr. Vol. 2

at 13 (Yao)). Individuals with cirrhosis are also at risk of developing primary liver cancer (i.e., hepatocellular cancer). (Doc. No. 198, Tr. Stip. No. 7.) The occurrence of either decompensated cirrhosis or liver cancer is referred to as end-stage liver disease. (Id.)

17. Chronic HCV symptoms can vary and are not dependent on a patient's fibrosis or cirrhosis stage. For example, some patients may have very severe symptoms, but only have mild liver fibrosis, while others may progress to liver cirrhosis but, if compensated, may have normal liver function. (Doc. No. 251, Tr. Vol. 2 at 12 (Yao)).

18. Chronic HCV is a major cause of liver failure. (Id. at 13). When the liver is failing, it cannot process toxins, raising the body's ammonia level and hepatoencephalopathy with attendant mental impairment. (Id. at 12-13.) Chronic HCV is also the number one reason for liver transplantation in the United States. (Id. at 13.)

19. Approximately 20 to 40 percent of chronic HCV patients will progress to F4 cirrhosis and approximately 4% will develop liver cancer. (Id. at 10, 97.)

20. For those patients who progress to decompensated liver cirrhosis, the liver will ultimately fail and be unable to support the body. (Id. at 36-37.)

B. Treating HCV

21. There is no vaccine for HCV. (Id. at 39.)

22. Diagnosis of HCV starts with an antibody screening by means of a blood test. (Id. at 13-14.) If that is positive, a second blood test is conducted for HCV-RNA (ribonucleic acid) to determine whether the virus is active. (Id.)

23. In the past, the standard treatment for chronic HCV infections involved injections of a drug called interferon, which activates the immune system. However, the interferon treatment

process was long, resulted in lower success rates, and caused severe side effects. (Doc. No. 198, Tr. Stip. No. 8.)

24. In 2011, the U.S. Food and Drug Administration ("FDA") approved DAAs to treat HCV. (Id., Tr. Stip. No. 9.) DAAs are taken in pill form once a day and have minimal side effects. (Doc. No. 251, Tr. Vol. 2 at 9-10, 19-21 (Yao)). Upon the approval of DAAs, interferon treatment for HCV was effectively abandoned.[2] (Id. at 21.)

25. There are several different genetic types of HCV, known as "genotypes" (e.g., genotype 1, genotype 2, etc.). (Id. at 15.) DAAs are now available for treatment of all known HCV genotypes (i.e., "pan-genotype" DAAs). (Id. at 21.)

26. The aim of DAAs is to remove detectable HCV-RNA from blood serum. (Id. at 22.) The absence of HCV-RNA after 12 weeks is known as sustained virologic response ("SVR"), or a "virologic cure." (Id.)

27. SVR, also known as a "surrogate outcome," is a "marker" of the end goal of HCV treatment, which is preventing end-stage liver disease and HCV-related mortality. (Id. at 87-88.) The FDA, NIH, and AASLD/IDSA use SVR as the marker for the success of DAA treatment. (Id. at 88.)

28. All things being equal, the HCV virus rarely reappears after SVR. (Id. at 22-23.)

29. To proceed with DAA treatment, a physician needs limited information: (Id. at 14-16) a face-to-face physical examination to evaluate symptoms, (Id. at 44-45) and confirmation that a patient has active HCV-RNA and is chronic (i.e., has had the infection for six months or more).

[2] A previously-used medication called ribavirin is still sometimes used, but only in conjunction with DAAs for patients that have advanced cirrhosis. (Doc. No. 251, Tr. Vol. 2 at 30 (Yao)).

(Id. at 16.) Because of the effectiveness of DAAs, a fibrosis score is less important to treatment or management decision. (Id.)

30. The significant decision is whether DAA treatment is needed for 8 weeks or 12 weeks. (Id. at 16-17.)

C. "Standard of Care" for HCV

31. Dr. Zhiqiang Yao presented his expert opinion regarding the "standard of care" for treating chronic HCV. Dr. Yao, M.D., PhD., is a Distinguished Professor at East Tennessee State University, Quillen College of Medicine and Director of the hepatitis program at the James H. Quillen Veterans' Administration ("VA") Medical Center. He specializes in the treatment of HCV, is board-certified in both internal medicine and infectious diseases, and is a member of the American Association for the Study of Liver Diseases ("AASLD") and the Infectious Diseases Society of America ("IDSA"). In addition to conducting prolific research, Dr. Yao oversees the treatment of 3,000 to 4,000 HCV patients each year. (Id. at 5-9.) The Court finds Dr. Yao highly knowledgeable and credible on the subjects of HCV and its treatment. He explained that the "standard of care" means the "best practice" physicians should follow. (Id. at 121.)

32. According to Dr. Yao, because early treatment of chronic HCV stops the progression of the damage to patient's liver and prevents damage to other organs, there is no reason to not treat mildly symptomatic patients. (Id. at 29, 102.)

33. Dr. Yao believes that the standard of care or best practice, requires a physician to wait six months for the acute phase to spontaneously clear the HCV infection. If it does not, the physician should treat the patient with DAAs "as early as possible" (id. at 21, 103, 107, 121), or "in a timely manner" (Pl. Ex. 8 at 8-10 (Yao Rep.) (emphasis added); P. Ex. 9 at 2 (Yao Supp. Rep.) (emphasis added)), regardless of fibrosis stage. He does not believe that there is any basis

for prioritizing care "*for only* stage F4 and F3 patients." (Id. (emphasis added)). Delaying care, in Dr. Yao's opinion, may have "adverse effects." (P. Ex. 8 at 11 (Yao Rep.))

34. The AASLD, the professional organization primarily comprised of gastroenterologists and hepatologists; the IDSA, the professional organization primarily comprised of infectious disease specialists; the Centers for Disease Control, the National Institute for Health ("NIH"), the Veteran Administration ("VA"), Medicare, state Medicaid programs, and multiple private insurance companies agree that immediate treatment of DAA's is the standard of care for chronic HCV. (Doc. No. 251, Tr. Vol. 2 at 26-27 (Yao)).

35. An AASLD/IDSA panel has published the "Recommendations for Testing, Managing, and Treating Hepatitis C" ("AASLD/IDSA Guideline") since 2014. (P. Ex. 8.) The AASLD/IDSA Guideline contains treatment "recommendations." (Id.) Since 2015, the AASLD/IDSA Guideline has stated that evidence supports DAA treatment for all HCV patients regardless of their liver fibrosis stage (except those with short life expectancies that cannot be remediated by treating HCV or by other directed therapy). (Doc. No. 251, Tr. Vol. 2 at 27-28 (Yao)).

36. A majority of medical providers in the United States who treat HCV follow the AASLD/IDSA Guidance recommendations. (Id. at 101-102.)

37. TDOC called two experts regarding the HCV standard of care. Dr. Martha S. Gerrity is a Professor of Medicine in the Department of Medicine Division of General Medicine at Oregon Health and Sciences University who also works at the Portland VA and the Scientific Resource Center for the Agency for Healthcare Research. (Doc. No. 252, Tr. Vol. 3 at 184-185 (Gerrity)). She is board certified in internal medicine and is an academic general internist with training in clinical epidemiology, clinical research methods and education. (Id. at 184-186.) She is

not a gastroenterologist, infectious disease specialist, hepatologist, expert in the field of HCV, or HCV researcher, and she has never prescribed DAAs. (Doc. No. 252, Tr. Vol. 3 at 219-220 (Gerrity).) Dr. Ronald Koretz is an emeritus professor of clinical medicine at the David Geffen UCLA School of Medicine and former gastroenterologist at the Olive View UCLA Medical Center in Los Angeles County, California. (Doc. No. 253, Tr. Vol. 4 at 5-7 (Koretz).) He is board-certified in internal medicine and gastroenterology, which includes general familiarity with treatment of liver disease. (Id. at 7.) However, he is neither an infectious disease specialist nor a hepatologist, and has never prescribed DAAs. (Id. at 63-67.)

38. Dr. Gerrity offered an opinion criticizing the trustworthiness and methodology of the AASLD/IDSA Guideline. She opined that it is of poor methodological quality and untrustworthy because its authors did not take a systematic approach to make it sufficiently evidence-based. (Doc. No. 252, Tr. Vol. 3 at 184-216 (Gerrity)). The Court finds Dr. Gerrity's opinion weak. Specifically, based on her demeanor at trial she appears to be advocating a personal cause. She did not offer any convincing explanation regarding why she does not accept the AASLD/IDSA Guideline, that has been accepted by the general scientific community. Her testimony was also evasive. For example, when asked if she knew about the National Institutes of Health adherence to the AASLD/IDSA Guideline, Dr. Gerrity responded, "I'm not sure what institute you're describing." (Id. at 230.) She was curiously unfamiliar with the positions of Medicare/Medicaid and World Health Organization, even though she recently prepared an academic report on the AASLD/IDSA Guideline at the request of state Medicaid directors because it was a "very important issue" to them. (Id. at 203-204, 230.) Dr. Gerrity did not provide a sufficiently credible explanation of her opinion, failed to sufficiently discredit Dr. Yao's opinion, and appeared to be advancing a personal, albeit academically-based, agenda.

39. The Court also rejects Dr. Gerrity's opinion because of a conflict of interest. Upon direct examination, Dr. Gerrity led the Court to believe that she was not compensated for her work on this case and attended the trial on her personal vacation. (Id. at 186.) She attempted to lead the Court to believe she was testifying free of any bias and only due to the strength of her beliefs. However, on cross-examination it was revealed that Dr. Gerrity is employed by the Center for Evidence-Based Policy, which encompasses the Medicaid Evidence-Based Decision Project. (Id. at 185, 221, 236.) The State of Tennessee is a member of this group and pays a fee of approximately $120,000 to $150,000 per year that goes, in part, directly to pay Dr. Gerrity's salary. (Id. at 185, 221, 236.) The Court disapproves of her gross lack of candor.

40. Dr. Koretz offered a similar opinion regarding the lack of evidence supporting the AASLD/IDSA Guideline, as well as what he believes to be a lack of proof that DAA treatment actually affects the clinical outcomes of HCV patients. (Doc. No. 253, Tr. Vol. 4. at 12-63 (Koretz)). The Court also declines to credit Dr. Koretz's opinion. His demeanor and tone reflected deeply held extreme personal opinions that affected his conclusions. He rejects the use of SVR as a marker of HCV treatment success. He overenthusiastically believes that there is "no evidence that [DAA] treatment is beneficial for anybody." (Id. at 70-71.) Not only is there no support in the record for these extreme positions, they are directly contradicted by established medicine. The FDA has approved DAAs, and DAAs are accepted, used, and considered successful by the medical community in treating HCV. Dr. Yao testified that he has a 100% SVR (i.e., virologic cure rate) in his HCV practice after DAA administration. Even TDOC's own Medical Director and Associate Medical Director consider DAAs to be a cure for chronic HCV measured by SVR. (Id. at 91-92.) The Court finds that, on balance, Dr. Koretz's personal beliefs have clouded his judgment and call into question his entire analysis.

III. TDOC's HCV Treatment Policy

41. TDOC has written policies and practices for medical treatment of chronic HCV. (Doc. No. 250, Tr. Vol. 1 at 193 (Williams)).

42. TDOC is led by Commissioner Tony C. Parker. (Doc. No. 198, Tr. Stip. No. 12.) Parker is essentially the chief executive officer of TDOC and is charged with overseeing the administrative functions of the Department. (Doc. No. 250, Tr. Vol. 1 at 27 (Parker)). He is vested with ultimate supervisory authority over all TDOC employees. (Id. at 28-29). Parker has ultimate authority over the TDOC Director of Medical Services. (Id. at 27-28, 34, 173-74.) He has no medical training and does not participate in any TDOC medical or clinical decisions. (Id. at 66-67.) Neither does he participate in developing or approving any medical clinical guidelines, protocols or practices, including those regarding HCV. (Id. at 67.) Parker relies on TDOC's medical health care professionals to determine TDOC's policies for medical treatment and making decisions regarding the particular care inmates receive, including the treatment of HCV in TDOC facilities. (Id. at 51-52, 67-80.) He has little substantive knowledge of HCV policy and treatment aside from what he is told by the medical staff. (Id. at 67-89.) While Parker broadly supports the requests of Dr. Williams for funding related to HCV treatment, he does not become involved with the specifics. (Id. at 93 (Parker); id. at 182-83 (Williams)).

43. TDOC's Director of Medical Services and Chief Medical Officer is Dr. Kenneth Williams. (Doc. No. 198, Tr. Stip. No. 10.) He is responsible for developing, updating, and ensuring adherence to TDOC's policies and practices for inmate medical treatment. (Id., Tr. Stip. No. 11; Doc. No. 250, Tr. Vol. 1 at 67 (Parker)). Under the direction of Dr. Williams, Centurion provides contracted medical care in the 10 facilities operated by TDOC, while CoreCivic provides medical care in the facilities it operates under contract with TDOC. (Doc. No. 250, Tr. Vol. 1 at

150-151, 185-190 (Williams)). He manages the medical aspects of these contracts providing front-line care at TDOC facilities subject to TDOC policies and practices. (Id.) Dr. Williams supervises and works closely on HCV treatment policy with TDOC Associate Medical Director Dr. Kenneth Wiley. (Id. at 174 (Williams); Id. at 109 (Wiley)).

44. TDOC's HCV policies and protocols, devised under the leadership of Dr. Williams, are contained in: "Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection" ("2019 HCV Guidance"). (Doc. No. 198, Tr. Stip. No. 14; J. Ex. 38.)

45. The 2019 HCV Guidance replaces the first TDOC HCV policy of 2016, entitled "Chronic HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C" ("2016 HCV Guidance"). (Doc. No. 198, Tr. Stip. No. 13.) The 2016 HCV Guidance reflects TDOC's transition from interferon treatment to administration of DAAs. (Doc. No. 250, Tr. Vol. 1 at 197 (Williams)).

46. The 2019 HCV Guidance is augmented by an HCV treatment workflow outline ("2019 HCV Workflow") that provides a summary of TDOC protocols for medical practitioners. (J. Ex. 40.)

47. TDOC's policies reflect its recognition that HCV inmates may die from the disease. (Doc. No. 250, Tr. Vol. 1 at 170-171 (Williams)). As described by Dr. Williams and Dr. Wiley, TDOC seeks to provide treatment for inmates in a cost effective manner that is most efficient for the greatest number of individual inmates. (Id. at 222 (Williams); Id. at 117-119, 144 (Wiley)). This is consistent with TDOC's belief that it is responsible medicine to address the sickest patients first. (Id. at 117, 145 (Wiley); Doc. No. 251, Tr. Vol. 2 at 214, 259-60 (Williams)).

48. The cornerstone of TDOC's HCV policy and the 2019 HCV Guidance is the TDOC Advisory Committee on HIV and Viral Hepatitis Prevention and Treatment ("TACHH"). This

special committee makes DAA treatment determinations for HCV inmates based upon their medical records. (Doc. No. 198, Tr. Stip. No. 17.) TACHH is chaired by Dr. Williams and was formed by him in 2015 to facilitate the treatment of HCV inmates. (Id., Tr. Stip. No. 18; Doc. No. 251, Tr. Vol. 2 at 139-145, 241 (Williams)). Dr. Wiley has always been a key member, and TACHH includes an infectious disease specialist. (Doc. No. 250, Tr. Vol. 1 at 126-129 (Wiley); Doc. No. 251, Tr. Vol. 2 at 176-177 (Williams)). Notably, Parker is neither involved in, nor familiar with, the details of TACHH. (Doc. No. 250, Tr. Vol. 1 at 59 (Wiley)). TACHH reviews laboratory data, test results, and medical provider reports. (Id. at 130.) TACHH does not interface with patients, but a "complete workup" is done by front-line providers prior to an inmate's referral to TACHH for consideration for DAAs. (Id. at 137-138 (Wiley); Doc. No. 251, Tr. Vol. 2 at 171 (Williams)).

A. The 2019 HCV Guidance

49. The 2019 HCV Guidance applies to all healthcare professionals who treat inmates in TDOC-operated or privately-operated facilities. (Doc. No. 198, Tr. Stip. No. 15.) It is "mandatory" because it provides the baseline that medical practitioners are expected to adhere. (Doc. No. 251, Tr. Vol. 2 at 190-192 (Williams)). A provider may deviate from the 2019 HCV Guidance only with Dr. Williams' permission. (Id.) He does not allow providers to deviate below TDOC protocols. (Id.)

50. The 2019 HCV Guidance controls the testing, evaluation, staging, prioritization, treatment, and monitoring of TDOC inmates with chronic HCV. (Doc. No. 198, Tr. Stip. No. 16; J. Ex. 38.) It is being continuously improved. (Doc. No. 251, Tr. Vol. 2 at 189 (Williams)).

51. Dr. Yao believes that the 2019 HCV Guidance is a "significant" and "positive" improvement over the 2016 HCV Guidance. (Doc. No. 250, Tr. Vol. 1 at 42, 120, 155 (Yao)).

52. Under the 2019 HCV Guidance, inmates are now tested for HCV at intake to TDOC unless they specifically decline to be tested. (Doc. No. 251, Tr. Vol. 2 at 176-179, 199-200 (Williams); J. Ex. 38 at 2.) The new "opt-out" protocol is informed refusal of HCV testing as opposed to informed consent. (Id.) However, inmates may request HCV testing at any time after intake. (J. Ex. at 3; Doc. No. 250, Tr. Vol. 2 at 270 (Williams)). During subsequent periodic health visits, HCV testing is recommended to inmates with clinical conditions or risk factors associated with a higher prevalence of HCV infection. (J. Ex. 38 at 2-3.)

53. Under the 2019 HCV Guidance, inmates undergo a baseline evaluation within two months of a blood test confirming an active HCV infection. (Id. at 4.)

54. The baseline evaluation includes a history and physical examination related to signs, symptoms, and other possible causes of liver disease, the likely date of infection, and any past HCV treatment. (Id.) Lab tests are also performed to detect the presence of coinfections and comorbid conditions, viral load, HCV genotype, and treatment resistance. (Id.) The baseline evaluation also includes blood tests to assess liver fibrosis unless the inmate is already known to have cirrhosis. (Id. at 5-6.) TDOC uses the results of APRI and FibroSure blood tests to assess fibrosis progression. (Id. at 6.) These tests are an improvement in the 2016 HCV Guidance. (Doc. No. 251, Tr. Vol. 2 at 131 (Williams)).

55. TDOC uses FibroScan to scan every HCV inmate in TDOC custody. (Id. at 236.) Once the necessary baseline information is collected, inmate medical records are reviewed for a treatment regime. (Id. at 132.) Of known HCV inmates that have been evaluated and staged by fibrosis level (based upon FibroSure and FibroScan testing), at the time of trial, approximately 63% are in the F0 or F1 stage; 9% are in the F2 stage; and 29% are in the F3 or F4 stage. (Id. at 227.)

1. Prioritization and Treatment

56. TDOC made a significant change to HCV inmates' eligibility for DAAs in May 2019. As opposed to the 2016 HCV Guidance, which provided that only inmates with F3 or F4 fibrosis stages should be referred to TACHH for DAA treatment (P. Ex. 60 at 11), the 2019 HCV Guidance provides that all HCV inmates are eligible to be referred to the TACHH for possible DAA treatment regardless of fibrosis stage. (J. Ex. 38 at 9; Doc. No. 251, Tr. Vol. 2 at 133-134 (Williams)).

57. In keeping with TDOC's policy of treating the sickest first, the 2019 HCV Guidance provides criteria for prioritizing DAA treatment among HCV inmates. (J. Ex. 38 at 9.)

58. The highest prioritization is given to inmates with "advanced pathology" – that is, fibrosis stage F4 or F3 (as diagnosed by an APRI score, FibroSure, FibroScan, ultrasound, or liver biopsy), cirrhosis, coinfection regardless of fibrosis score, and comorbid conditions regardless of fibrosis score. (Id.)

59. Intermediate prioritization is given to inmates with "moderate pathology" – that is, fibrosis stage F2 (diagnosed by the above methods) or comorbid chronic kidney disease. (Id. at 9-10.)

60. Ultimately, which inmates receive DAA treatment is determined by the TACHH, which evaluates HCV inmates and makes treatment decisions that are "patient-specific." (Id.) As Dr. Williams explains, it is "not just whether [inmates] were F1, F2, F3, F4, but also what else was going on [that] was taken into consideration and then a decision was made." (Doc. No. 251, Tr. Vol. 2 at 251 (Williams)). As a result, lower fibrosis stage patients can be approved for DAA treatment. For example, and coincidentally right before trial, TACHH approved multiple F1/F2 inmates for DAA treatment at its May 29, 2019 meeting. (J. Ex. 37.) As Drs. William and Wiley

explained, the 2019 HCV Guidance does not exclude any HCV cases from review on an individual basis for administration of DAAs. (Doc. No. 251, Tr. Vol. 2 at 142-143 (Williams); Doc. No. 250, Tr. Vol. 1 at 158-159 (Wiley)). If patients with lower fibrosis stages have concerning aspects to their condition, they receive more detailed consideration. (Id.)

61. TACHH meets at least once a month, and recently twice a month, to review medical records and make DAA treatment decisions. (Doc. No. 251, Tr. Vol. 2 at 142 (Williams); Doc. No. 250, Tr. Vol. 1 at 129 (Wiley)). During the first monthly meeting it reviews cases of patients in lower stages of fibrosis. (Doc. No. 251, Tr. Vol. 2 at 142, 244, 252 (Williams)). If DAA treatment may be appropriate that case is considered at the second meeting with an infectious disease specialist present (Id. at 142, 252), along with inmates with F3 or F4 stage fibrosis or other complicating factors. (Id.)

62. The number of inmates considered for DAA treatment at TACHH meetings is increasing. (J. Ex. 37; Doc. No. 251, Tr. Vol. 2 at 140-141 (Williams)). Dr. Williams expects that under the 2019 HCV Guidance TACHH will soon consider up to four times as many patients per month for treatment as in the past. (Doc. No. 251, Tr. Vol. 2 at 140-141 (Williams)).

63. Dr. Yao opined that the 2019 HCV Guidance prioritization structure is "under the standard of care" because it does not apply the AASLD/ISLD Guideline and does not explicitly recommend early DAA treatment of all HCV patients. (Doc. No. 250, Tr. Vol. 1 at 42-43, 102, 119, 120-121 (Yao)). However, it is apparent to the Court that while the 2019 HCV Guidance does not "explicitly" recommend immediate treatment of all HCV inmates, neither does it preclude immediate treatment of any HCV inmate with DAAs. And, Dr. Yao concedes that a prioritization structure is "understandable" when there are finite resources and staffing. (Id. at 102.)

64. Dr. Koretz endorsed only the staged treatment of F3 and F4 inmates. However, his analysis takes a weird and somewhat inhumane theoretical approach. He recommends that the sickest HCV inmates not be administered DAAs at all, but placed into long-term (i.e., multi-year) randomized trials, even though many would receive a placebo and die. (Doc. No. 253, Tr. Vol. 4 at 70-75, 87-89 (Koretz)). Dr. Koretz describes his approach as his "dream world." He concedes it is not possible because he "can't do research on prisoners," so he would not "stand in the way" of HCV inmates with F3 or F4 fibrosis scores being treated with DAAs. (Id. at 74-75.) Neither party disputes that treatment of inmates with F3 or F4 fibrosis scores is appropriate.

65. Dr. Koretz's extreme approach is troubling. He is a member of a subgroup of the Cochrane Collaboration, an international, evidence-based medicine group, that has espoused highly controversial views on this particular subject. (Id. at 10, 95-98.) As explained at trial, the European Association for Study of the Liver ("EASL") [3] published an editorial in which it analogized Dr. Koretz's position regarding withholding DAAs in favor of long-term studies to the "ethical anathema of the infamous Tuskegee study conducted by the U.S. Public Health Service in which patients with syphilis were left untreated to observe the natural history even after advent of and proven efficacy of penicillin." (Id. at 95-96.) EASL concluded that "[t]he premise . . . will be viewed as so egregiously mistaken that the conclusions will rightly be disregarded. As the findings do not assist or advance the field, they will not be pertinent to clinical decision-making or guidelines." (Id. at 98.) Dr. Koretz's opinion is too extreme for this Court.

66. TDOC's 2019 HCV Guidance's prioritization structure mirrors that of the U.S. Bureau of Prisons as memorialized in "Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection Clinic Guidance," published in August 2018 ("2018 BOP Guidance"). (P. Ex. 11

[3] EASL is the European counterpart of the AASLD. (Doc. No. 253, Tr. Vol. 4 at 95 (Koretz)).

at 8-9.) The 2018 BOP Guidance states that the "Bureau of Prisons has established priority criteria to ensure that inmates with the greatest need are identified and treated first." (Id. at 8.) Similar to the 2019 HCV Guidance, the 2018 BOP Guidance classifies patients with fibrosis stages F3 or F4 as "high priority"; stage F2 as "intermediate priority"; and F1 or F0 as "low priority." (Id. at 8-9.)

67. This same type of prioritization was historically recommended by the AASLD/IDSA and the VA. (Doc. No. 250, Tr. Vol. 1 at 29-30 (Yao); P. Ex. 8 at 62.) In fact, the AASLD/IDSA Guidelines continue to recommend prioritization when resources are finite:

> Although treatment is best administered early in the course of the disease before fibrosis progression and the development of complications, the most immediate benefits will be realized by populations at highest risk for liver-related complications. Thus, where resources limit the ability to treat all infected patients immediately as recommended, it is most appropriate to treat first those at great risk of disease complications and those at risk of disease complications and those at risk for transmitting HCV or in whom treatment may reduce transmission risk. Where such limitations exist, prioritization of immediate treatment for those . . . is recommended, including patients with progressive liver disease (Metavir stage F3 or F4), transplant recipients, or those with severe extrahepatic manifestations. . . .
>
> Recommendations . . . *If resources limit the ability to treat all infected patients immediately as recommended, then it is most appropriate to treat those at greatest risk of disease complications before treating those with less advanced disease.*

(P. Ex. 8 at 62-63 (emphasis added)).

2. Monitoring

68. Under the 2019 HCV Guidance, all HCV inmates are enrolled in the chronic care clinic and evaluated at least every six months. (J. Ex. 38 at 13.) These monitoring visits include (1) education and review of systems; (2) vital signs and a physical examination; (3) laboratory testing, including a complete blood count ("CBC"), prothrombin time and international normalized ratio ("PT/INR"), a liver panel, serum creatinine; calculated glomular filtration rate ("calculated

GFR"); and (4) calculation of fibrosis progression by APRI, FibroSure and FibroScan scores. (Ex. 38 at 13.) Monitoring of untreated inmates with advanced fibrosis (F3) or cirrhosis (F4) also include an ultrasound to screen for hepatocellular carcinoma. (Id.)

69. The Court finds that TDOC's regular monitoring of HCV inmates is impressive because it utilizes a comprehensive approach and demonstrates a willingness to update an inmates' staging for TACHH priority consideration based on changes in fibrosis level. It critically reflects TDOC's subjective intent to provide ongoing assessment of all HCV inmates.

B. The 2019 HCV Workflow

70. Dr. Williams designed the 2019 HCV Workflow as a set of detailed medical practitioner expectations that translate the 2019 HCV Guidance into practice and help "get[ ] patients in front of TACHH faster." (Doc. No. 251, Tr. Vol. 2 at 270 (Williams); J. Ex. 40.)

71. The 2019 HCV Workflow provides specific steps health care providers must take to (1) test for HCV; (2) diagnose chronic versus acute HCV; and (3) enroll chronic HCV patients in the chronic care clinic. (J. Ex. 40 at 1.) It then provides detailed steps for the implementation of the prioritization plan. (Id. at 2.) It dictates that inmates staged as F4 or F3 fibrosis level will be referred to TACHH with all supporting diagnostic results. (Id.) Inmates staged as F2, F1, or F0 fibrosis level can also be referred for TACHH evaluation, but full supporting documentation need not be sent until requested by TACHH. (Id.)

72. The 2019 HCV Workflow also created specific procedures to ensure (1) prompt communication of TACHH orders to infection control nurses at TDOC facilities; (2) issuance of orders based on TACHH recommendations; (3) follow-up of TACHH orders; and (4) follow-up to verify that DAA treatment has started without any delay. (Id. at 3.)

73. The 2019 HCV Workflow also provides specific procedures for the monitoring of HCV inmates by means of extensive laboratory testing, both before, during, and after DAA administration. (Id. at 1, 4.)

C. TDOC's Progress

74. Plaintiffs have introduced evidence that, prior to the 2019 HCV Guidance and 2019 HCV Workflow, TDOC has been inconsistent and slow in evaluating, staging, and treating inmates with chronic HCV with DAAs. This is born out in the minutes of TACHH meetings that considered and approved a very few inmates for DAA treatment. (Doc. No. 250, Tr. Vol. 1 at 131 (Wiley)).

75. Plaintiffs presented compelling proof through individual inmates that TDOC's treatment of HCV inmates has been erratic, uneven, and poor, resulting in denial of DAA treatment where it was clearly appropriate. There is convincing evidence that TDOC's DAA past treatment protocols have been uneven, and have bordered on deliberate indifference to serious medical needs of individual inmates. The Court finds by a preponderance of the evidence that:

i. Scott Spangler was diagnosed with HCV and F4 cirrhosis in March 2018. (Doc. No. 252, Tr. Vol. 3 at 58-69 (Spangler); P. Ex. 46.) TACHH reviewed his case in August 2018 and denied DAA treatment in lieu of investigation of possible acute hepatic necrosis. (Doc. No. 252, Tr. Vol. 3 at 73 (Spangler); P. Ex. 46.)

ii. Gregory Atkins entered TDOC custody as an HCV inmate in 2005. (Doc. No. 252, Tr. Vol. 3 at 78-85, 97 (Atkins)). Atkins refused FibroSure testing in September 2018, but December 2018 testing showed that he had F4 stage cirrhosis. (Id. at 106-107.) He has never received any treatment despite

seeking it between 2013 and 2017 and being approved for interferon treatment in 2013. (Id. at 79, 83, 86-91; P. Ex. 36.)

iii. Thomas Rollins, Jr. was diagnosed with HCV in 2001 or 2004. (Doc. No. 252, Tr. Vol. 3 at 130 (Rollins)). He had unsuccessful interferon and ribavirin treatment in 2012. (Id.) He has been seeking HCV treatment from TDOC since he became incarcerated in 2016. (Id. at 131-133.) TACHH reviewed Rollins's case in March 2019. (Id. at 151.) The minutes for that meeting staged Rollins at F3 (P. Ex. 47), but his blood tests and medical records reflected only F2. (P. Ex. 43.) TACHH denied treatment with reconsideration in one year. (Doc. No. 252, Tr. Vol. 3 at 143 (Rollins); P. Ex. 47.)

iv. Samuel Hensley was unsuccessful in obtaining treatment for HCV from 2006 to 2017. (Doc. No. 252, Tr. Vol. 3 at 40-47 (Hensley)). His facility-level providers may not have appropriately recorded his symptoms or forwarded his case to TACHH. (Id. at 46-47.) Hensley was approved by TACHH for DAA treatment in May 2018, but it was delayed until December 2018. (Id. at 41-42; P. Ex. 41, 42.)

v. Russell Davis was unsuccessful in seeking treatment for HCV from 2009 to 2017. (Doc. No. 252, Tr. Vol. 3 at 7-26 (Davis)). Davis was tested at the F2 stage in May 2016. (P. Ex. 39 at 361.) He was finally considered by TACHH after reaching F4 cirrhosis stage in 2018, approved for DAA treatment, and received that treatment. (P. Ex. 39; Doc. No. 252, Tr. Vol. 3 at 16, 22, 33-34 (Davis)).

vi. Kevin Profitt was diagnosed with an HCV and Hepatitis B co-infection in August 2017. (Doc. No. 252, Tr. Vol. 3 at 115 (Profitt); P. Ex. 42.) In May 2018, TACHH reviewed his case and recommended that he be treated for Hepatitis B prior to administration of DAAs. (J. Ex. 26 at 4.) In December 2018, TDOC began treating Profitt for Hepatitis B. (Doc. No. 252, Tr. Vol. 3 at 115 (Profitt)). Profitt's body cleared the HCV during Hepatitis B treatment and does not need to be considered further by TACHH. (Id. at 115-119.)

vii. Christopher Gooch unsuccessfully sought treatment after being diagnosed with chronic HCV at intake in May 2016. (Doc. No. 252, Tr. Vol. 3 at 157-165 (Gooch)). His December 2018 FibroScan results indicated F2 fibrosis. (Id. at 165, 173.) In May 2019, his FibroScan results indicated progression to F3 fibrosis. (Id. at 165-167, 174; P. Ex. 38.) Shortly after getting these results (and shortly before trial), Gooch first filled out paperwork for referral to TACHH and is eligible for consideration for DAAs. (Doc. No. 252, Tr. Vol. 3 at 174-175 (Gooch); J. Ex. 38.)

viii. Several of these individual inmates and their relatives complained about their perceived treatment delays, including filing grievances and communicating to TDOC officials such as Parker and Dr. Williams. (See, e.g., Doc. No. 252, Tr. Vol. 3 at 10, 13, 26 (Davis); 141 (Rollins)).

76. The Court credits the testimony of these witnesses, who demonstrated the personal impact of chronic HCV and the need for timely consideration for DAA treatment. However, except

to the extent delays are continuing past May 2019, their testimony concerns events that occurred before the 2019 HCV Guidance and 2019 HCV Workflow.

77. Indeed, several of these witnesses have encountered changed circumstances in 2019. Spangler was never monitored for HCV by the chronic care clinic prior to 2019, but he is currently enrolled for monitoring. (Doc. No. 252, Tr. Vol. 3 at 67 (Spangler)). At the time of trial, Spangler and Atkins have been placed on the agenda of an upcoming TACHH meeting for consideration. (Doc. No. 251, Tr. Vol. 2 at 255 (Williams)). Hensley and Davis achieved SVR (i.e., virologic cure) after DAA treatment approved by TACHH and do not need to be considered further by TACHH. (Doc. No. 252, Tr. Vol. 3 at 33-34 (Davis); 55 (Hensley)).

78. Dr. Williams reassigned the TDOC coordinator of continuous quality improvement to be the TDOC HCV treatment management coordinator, with sole responsibility to move patients to the TACHH for assessment and treatment decision. (Doc. No. 251, Tr. Vol. 2 at 244 (Williams)).

79. Dr. Williams estimates that TACHH will review all F3 and F4 stage HCV inmates for treatment in the next nine to twelve months. (Id. at 228.)

80. In connection with the 2019 HCV Guidance and 2019 HCV Workflow, Dr. Williams also ordered development and implementation of an online recordkeeping resource known as HepCOR, which is intended to supplant older paper recordkeeping. (Doc. No. 251, Tr. Vol. 2 at 237 (Williams)). Using HepCOR, providers, at all points in the delivery of care system, enter HCV inmate records and information online. (Id. at 237-240.) This facilitates the work of TACHH and the delivery of treatment. (Id.) Patient information is in the process of being loaded into HepCOR. (Id. at 272.) Once this is fully implemented, it will assist TACHH. (Id. at 271-72.)

D. Funding for TDOC HCV Treatment

81. In 2015, a course of DAA treatment cost approximately $80,000 for a simple case and $189,000 for a complicated case. (Doc. No. 251, Tr. Vol. 1 at 221 (Williams)). In 2019, a course of DAAs now costs TDOC between $13,000 and $32,000, depending on the brand. (Id. at 222.)

82. TDOC secured $4.6 million in recurring funds for DAA treatment over the course of the 2016-2017 and 2017-2018 legislative years. (D. Ex. 22; Doc. No. 251, Tr. Vol. 2 at 229 (Williams)).

83. At Dr. William's request, TDOC obtained a one-time allocation of $26.4 million for DAA medications for the 2019-2020 fiscal year. (Id. at 167.)

84. TDOC's total budget from all sources for the 2019-2020 fiscal year for DAA treatment is thus approximately $31 million. (Doc. No. 251, Tr. Vol. 2 at 229-230 (Williams)).

85. Dr. Williams anticipates that funding can provide treatment for approximately 1,800 to 1,900 inmates with chronic HCV. (Id.)

86. TDOC has always used all of its budgeted HCV funds to purchase DAAs. (Id. at 230.) In fact, TDOC has run over budget on DAA medication spending. (Id.)

CONCLUSIONS OF LAW

I. Eighth Amendment Deliberate Indifference

87. The Eighth Amendment bars the "inflict[ion]" of "cruel and unusual punishments" to HCV inmates. U.S. Const. amend. VIII.

88. There is no question that TDOC has an obligation to provide "adequate" medical care for HCV inmates. Farmer v. Brennan, 511 U.S. 825, 834 (1994); Estelle v. Gamble, 429 U.S. 97, 103 (1976).

89. In Rhinehart v. Scutt, the Sixth Circuit clarified how the Eighth Amendment framework "appl[ies] in today's prison context." 894 F.3d, 721, 736 (2018). There, an inmate with end-stage liver disease ("ESLD") claimed deliberate indifference by several prison medical provider defendants based on being denied adequate medical care. The Court of Appeals summarized the inmate's Eighth Amendment burden as follows:

> The government has an obligation to provide medical care for those whom it is punishing by incarceration. But mere failure to provide adequate medical care to a prisoner will not violate the Eighth Amendment. In those circumstances, a constitutional violation arises only when the doctor exhibits deliberate indifference to a prisoner's serious illness or injury, that can be characterized as obduracy and wantonness rather than inadvertence or error in good faith[.] To establish a prison official's deliberate indifference to a serious medical need, an inmate must show two components, one objective and the other subjective. *The plaintiff must show both that the alleged wrongdoing was objectively harmful enough to establish a constitutional violation and that the official acted with a culpable enough state of mind, rising above gross negligence.*

Id. at 737 (emphasis added) (citations and internal quotation marks omitted). This is the standard because "only the unnecessary and wanton infliction of pain implicates the Eighth Amendment." Id. quoting Wilson v. Seiter, 501 U.S. 294, 297 (1991)) (internal quotation marks and citation omitted).

A. The Objective Component

90. The Court of Appeals explained that the objective component requires an inmate to prove two things. The first is that they have a "serious medical need," Rhinehart, 894 F.3d at 736 (citing Estelle, 429 U.S. at 106). "[A] serious medical condition carries with it a serious medical need[.]" Rhinehart, 894 F.3d at 737.

91. The second is that "the alleged deprivation of medical care was serious enough to violate the Eighth Amendment." Id. at 737 (citing Farmer, 511 U.S. at 834-35); see also Bostic v.

Biggs, Civil No. 3:14-CV-1068, 2015 WL 1190177, at *3 (M.D. Tenn. Mar. 13, 2015) (same). Where the claim is that a particular treatment should be provided, an inmate must demonstrate that "the inmate's symptoms 'would [ ] be[ ] alleviated by' the treatment and the inmate's condition 'require[s]' that treatment." Id. at 749 (citing Anthony, 701 F. App'x at 464). If that is established, the inmate must further show that the treatment actually being provided is "'so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness.'" Id. (citing Miller v. Calhoun Cty., 408 F.3d 803, 819 (6th Cir. 2005)). To meet this burden, Plaintiffs must present two types of medical proof: (1) that the provided treatment was not adequate medical treatment for the inmate's condition, and (2) the treatment provided had a detrimental effect. Id. (citing Santiago v. Ringle, 734 F.3d 585, 591 (6th Cir. 2013); Blackmore v. Kalamazoo Cty., 390 F.3d 890, 898 (6th Cir. 2004); Napier v. Madison Cty., Ky., 238 F.3d 739, 742 (6th Cir. 2001); Anthony v. Swanson, 701 F. App'x 460, 464 (6th Cir. 2017)).

92. In making this determination in Rhinehart, the Court of Appeals noted the well-established legal principles that: (1) the Eighth Amendment does not require that prisoners receive "unqualified access to health care" of their choice. Rhinehart, 894 F.3d at 750 (quoting Hudson v. McMillian, 503 U.S. 1, 9 (1992); and (2) an inmate is entitled to adequate medical care, but "not the best care possible." (Id. (citing Miller, 408 F.3d at 819). Neither an inmate's "disagreement with the testing and treatment he has received," nor "a desire for additional or different treatment," rises to the level of an Eighth Amendment violation unless the treatment actually being provided is objectively harmful enough to establish a constitutional violation. Id. at 740 (quoting Dodson v. Wilkinson, 304 F. App'x 434, 440 (6th Cir. 2008); Anthony, 701 F. App'x at 464); see also Darrah v. Krishar, 865 F.3d 361, 372 (6th Cir. 2017) ("As a general rule, a patient's disagreement with

his physicians over the proper course of treatment alleges, at most, a medical-malpractice claim, which is not cognizable under § 1983.").

93. The Sixth Circuit applied these principles in Rhinehart. The inmate sought a specific procedure (a TIPS procedure) to treat his ESLD. Rhinehart, 894 F.3d at 750. In its objective component analysis, the Court of Appeals acknowledged that the plaintiffs' expert "testified that a TIPS procedure is the 'gold standard' of treatment for patients with ESLD." Id. However, it found that the "alternative treatment" provided to the inmate, which included "regular monitoring and pain medication," did not rise to the level of constitutional inadequacy. Id. (citing Johnson v. Million, 60 F. App'x 548, 549 (6th Cir. 2003) (holding that an inmate with liver disease could not establish deliberate-indifference claim against his prison healthcare providers when the inmate was repeatedly examined for his pain and prescribed medications, ordered blood tests, and advised about his diet).

B. The Subjective Component

94. The subjective component of deliberate indifference requires Plaintiffs and the class to show that Defendants acted with a sufficiently culpable state of mind. Farmer, 511 U.S. at 834; Rhinehart, 894 F.3d at 738. This requires proof that the defendant "subjectively perceived facts from which to infer substantial risk to the prisoner, that he did in fact draw the inference, and that he then disregarded that risk" by failing to take reasonable measures to abate it. Rhinehart, 894 F.3d at 738 (quoting Comstock, 273 F.3d at 703); Phillips v. Roane Cty., Tenn., 534 F.3d 531, 540 (6th Cir. 2008)).

95. This a "high bar." Id. Plaintiffs and the class must establish that the defendant "*consciously* expos[ed]" them to an "*excessive* risk" of "*serious* harm." Rhinehart, 894 F.3d at 738 (emphases in original) (citation and internal quotation marks omitted). The Sixth Circuit has

described this mental state as "equivalent to criminal recklessness." Id. (quoting Santiago, 734 F.3d at 591 and citing Farmer, 511 U.S. at 834). While a court is entitled to "conclude that a prison official knew of a substantial risk from the very fact that the risk was obvious," Farmer, 511 U.S. at 842, "a plaintiff also must present sufficient evidence from which the court could conclude that a defendant 'so recklessly ignored the risk that he was deliberately indifferent to it.'" Rhinehart, 894 F.3d at 738 (quoting Cairelli v. Vakilian, 80 F. App'x 979, 983 (6th Cir. 2003)). In this case where Plaintiffs challenge the adequacy of their medical treatment, the subjective component "must be determined in light of the prison authorities' current attitudes and conduct, including attitudes and conduct at the time suit is brought and persisting thereafter." Farmer, 511 U.S. at 845 (quoting Helling v. McKinney, 509 U.S. 25, 36 (1993)).

96. The Court of Appeals has explained that, in considering culpable state of mind, courts, especially in an inadequate medical treatment context, must be "deferential to the judgments of medical professionals." Rhinehart, 894 F.3d at 738 (quoting Richmond v. Huq, 885 F.3d 928, 940 (6th Cir. 2018)). A doctor is not immune from a deliberate indifference claim simply because he provided "some treatment for the inmates' medical needs," but, on the other hand, a doctor "is not liable under the Eighth Amendment if he or she provides reasonable treatment, even if the outcome of the treatment is insufficient or even harmful." Id. (citing Farmer, 511 U.S. at 844).

97. In Rhinehart, for example, the plaintiffs could not establish the subjective component of their claim against a doctor who declined to order a medical procedure for the inmate with ESLD. Id. at 751. There, the doctor was familiar with ESLD and the procedure at issue, would evaluate inmates to see if they were a candidate for the procedure, and made his decisions after weighing potential health benefits – "a process that required medical judgment." Id. In Rhinehart,

the Court of Appeals held that because the record showed that the doctor "made a medical judgment in declining to refer [the inmate] for [the] procedure, the [plaintiffs] *cannot* establish the subjective component of their claim against him." Id. (emphasis added).

II. Analysis

98. Plaintiffs proceed under Section 1983 that provides a federal cause of action against government officials who, while acting under color of state law, "deprived the claimant of rights, privileges or immunities secured by the Constitution or laws of the United States." Bennett v. City of Eastpointe, 410 F.3d 810, 817 (6th Cir. 2005) (citing McKnight v. Rees, 88 F.3d 417, 419 (6th Cir. 1996)).

99. The parties have stipulated that Defendants were acting under color of state law at all times relevant to this case. (Doc. No. 234 at 20 (pretrial conf. stip)).

100. Plaintiffs' bring this Section 1983 action against two state officials. The Court considers the culpability of each defendant separately. See Rhinehart, 894 F.3d at 738; Garretson v. City of Madison Heights, 407 F.3d 789, 797 (6th Cir. 2005).

101. While ultimately in charge of TDOC, Parker is not personally involved in administration of TDOC's HCV treatment policies. He has not participated in developing the 2019 HCV Guidance or 2019 HCV Workflow, has only a passing familiarity with TACHH, is not involved in the consideration of patients for treatment with DAAs, and is not involved in the details of Dr. Williams' medical budget requests.

102. As TDOC's Director of Medical Services and Chief Medical Officer, Dr. Williams is directly responsible for all aspects of TDOC inmate medical care and HCV treatment policies. He developed and drafted the 2019 HCV Guidance and 2019 HCV Workflow and is responsible

for overseeing implementation and administration of each. He formed and is chair of TACHH, which decides whether an inmate receives DAA treatment.

A. Commissioner Parker

103. Plaintiffs have not established that Commissioner Parker, a supervisory official, violated their Eighth Amendment rights.

104. "[Section] 1983 liability must be based on more than *respondeat superior*, or the right to control employees." Shehee v. Luttell, 199 F.3d 295, 300 (6th Cir. 1999); Howell v. Sanders, 668 F.3d 344, 351 n.3 (6th Cir. 2012). A plaintiff must prove that a supervisory official "caused" a violation of his or her constitutional rights, Thomas v. Nationwide Children's Hosp., 882 F.3d 608, 612 (6th Cir. 2018), by demonstrating that the supervisory official "either encouraged the [ ] misconduct or in some other way directly participated in it." Shehee, 199 F.3d at 300; Howell, 668 F.3d at 351 n.3. "At a minimum a plaintiff must show that the official at least implicitly authorized, approved, or knowingly acquiesced in [ ] unconstitutional conduct[.]" Shehee, 199 F.3d at 300. Liability also "cannot be based upon 'a mere failure to act.'" Id. (citing Salehpour v. Univ. of Tenn., 159 F.3d 199, 206 (6th Cir. 1998)).

105. Plaintiffs have not established by a preponderance of the evidence that Parker encouraged, actively participated in, or knowingly approved any particular aspect of TDOC's policy concerning treatment of HCV inmates. This is consistent with the conclusions of other courts on liability of the head of the department of corrections.[4]

[4] See, e.g., Pevia v. Wexford Health Source, Inc., No. CV ELH-16-1950 and ELH-17-631, 2018 WL 999964, at *13 (D. Md. Feb. 20, 2018), aff'd sub nom. Pevia v. Comm'r of Corr., 731 F. App'x 243 (4th Cir. 2018) (dismissing claim against Commissioner of Correction due to inadequate involvement in HCV treatment policy as supervisory official); Abu-Jamal v. Kerestes, Case No. 3:15-cv-00967, 2016 WL 4574646, at *12 (M.D. Pa. Aug. 31, 2016) (dismissing claim against Department of Corrections officials not personally involved in "the [HCV] Treatment

106. Plaintiffs have also failed to establish the subjective component of their deliberate indifference claim against Parker. This is because a prison official who lacks medical training does not act with the necessary culpable state of mind when he "reasonably defer[s] to the medical professionals' opinions." Olmstead v. Fentress Cty., No. 2:16-cv-46, 2019 WL 1556657, at *8 (M.D. Tenn. Apr. 10, 2019); see also Spears v. Ruth, 589 F.3d 249, 255 (6th Cir. 2009) (concluding that nonmedical jail personnel are entitled to reasonably rely on medical staff); McGaw v. Sevier Cty., 715 F. App'x 495, 498-99 (6th Cir. 2017) (collecting cases holding same).

107. Parker has no medical training, lacks substantive medical knowledge regarding HCV, and relies exclusively on Dr. Williams, Dr. Wiley, and other TDOC medical health care professionals to create policies and procedures for the treatment of HCV inmates. Because Parker has reasonably relied on these TDOC medical professionals to create the TDOC HCV policies at issue in this case, devise the 2019 HCV Guidance and 2019 HCV Workflow, and direct TACHH, he has not formed a mental state exceeding gross negligence.

108. Plaintiffs' Section 1983 claim against Parker will be dismissed.

B. Dr. Williams

1. Objective Component

109. The class is defined to include all inmates who have or will be diagnosed with HCV. (Doc. No. 32.) As Dr. Yao explained, HCV is a progressive illness from which the liver and other organs are subject to serious risks. These risks are many, including: progressive liver fibrosis potentially leading to cirrhosis; pain; extrahepatic (non-liver) manifestations including bleeding, skin, kidney, heart, and cognitive symptoms; accumulation of fluid in the body; serious infections;

Review Committee, the "development, adoption, or implementation of the [ ] [HCV] protocol or the protocol's application to [the] [p]laintiff").

cancer; multi-organ failure; and death. It is not surprising that Dr. Yao describes HCV as very dangerous. While not all HCV inmates develop the same symptoms, or progress at the same rate, for many the disease will continue to worsen over time.

110. The proof establishes by an overwhelming preponderance of the evidence that chronic HCV is a serious medical condition. (See Doc. No. 219 at ¶ 4 (pretrial conf. stip.)). Other courts agree. See Stafford v. Carter, No. 1:17-cv-00289-JMS-MJD, 2018 WL 4361639, at *12 (S.D. Ind. Sept. 13, 2018) ("[T]he Court concludes, as have many other courts that have considered the issue, that chronic HCV constitutes a serious medical condition."); Pevia, 2018 WL 999964, at *16 (finding chronic HCV "to be sure . . . constitutes a serious medical need"); Hoffer v. Jones, 290 F. Supp. 3d 1292, 1299 (N.D. Fla. 2017) ("Nor should it be surprising that this Court finds chronic HCV to be a serious medical need."); Coleman-Bey v. United States, 512 F. Supp. 2d 44, 47 (D.D.C. 2007) ("[C]hronic [HCV] infection presents a serious medical need as the condition may lead to liver disease, including cirrhosis."). Indeed, courts have so found about the hepatitis C virus regardless of whether infection has reached the chronic stage. See, e.g., Hix v. Tennessee Dep't of Corr., 196 F. App'x 350, 356 (6th Cir. 2006) ("[H]epatitis C likely constitutes a serious medical need sufficient to satisfy the objective component of our Eighth Amendment analysis[.]"); Owens v. Hutchinson, 79 F. App'x 159, 161 (6th Cir. 2003) ("Owens has adequately alleged that he suffered from an objectively serious medical condition – [HCV]."); Parks v. Blanchette, 144 F. Supp. 3d 282, 314 (D. Conn. 2015) (holding that "[i]t is well-established that Hepatitis C is sufficiently serious" for purposes of the objective prong); Hilton v. Wright, 928 F. Supp. 2d 530, 547-48 (N.D.N.Y. 2013) ("It is well-established that HCV is a serious medical condition[.]").

111. Plaintiffs have also demonstrated by a preponderance of the evidence, especially through the impressive testimony of Dr. Yao, that DAAs alleviate HCV by achieving SVR for the vast majority of HCV patients.

112. The Court must determine whether TDOC's HCV treatment policy, as reflected in the 2019 HCV Guidance and 2019 HCV Workflow, is "so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness." The Court cannot make that conclusion.

113. Plaintiffs' rely upon the AASLD/IDSA Guideline and Dr. Yao's expert opinion testimony that favor administering DAAs to inmates with chronic HCV as soon as possible. Plaintiffs then reason that TDOC's HCV treatment policies fall short of the prevailing standard of care because they do not guarantee immediate, universal treatment of all HCV inmates with DAAs. (Doc. No. 255 at 10, 26-28, 42.) Less than that best practice standard of care, Plaintiffs maintain, is a deprivation of medical care that violates the Eighth Amendment. (Id. at 40-43.)

114. More specifically, Dr. Yao opined that treatment with DAAs "as early as possible" after diagnosis of chronic HCV is the generally accepted standard of care or "best practice." He further opined that prioritization of patients or delayed administration of DAAs has no benefit and may be detrimental to HCV patients in the long-term because earlier treatment of chronic HCV stops the progression of the damage to patient's liver and prevents damage to other organs.

115. Notably, however, Dr. Yao also believes that the 2019 HCV Guidance was a "significant improvement" over prior TDOC policies. He concedes that TDOC's prioritization structure is a practical strategy for HCV care when resources are limited. Indeed, Dr. Yao utilized a prioritization method at the VA before Congress approved a new strategy and funding for universal care.

116. The AASLD/IDSA Guideline consists of treatment recommendations, not mandatory practice requirements. (P. Ex. 8.) To the extent that Plaintiffs rely upon the AASLD/IDSA Guideline, the Court finds that its recommendations are helpful understanding the "best possible" practice, and provide "evidence of a preferred public health policy," but do "not necessarily determine the standard for judging [constitutional] deliberate indifference." See Buffkin v. Hooks, No. 1:18CV502, 2019 WL 1282785, at *6 (M.D.N.C. Mar. 20, 2019) (noting that the AASLD/IDSA disclaims that its guidelines "should not be relied on to suggest a course of treatment for a particular individual" and cautioning against use of the AASLD/IDSA Guideline as a legal measure of Eighth Amendment deliberate indifference).

117. Notably, even the AASLD/IDSA Guideline acknowledges the logic of a prioritization system when resources are limited. In such a case, it recognizes that "it is most appropriate to treat those at greatest risk of disease complications before treating those with less advanced disease," because "the most immediate benefits will be realized by populations at highest risk for liver-related complications." (P. Ex. 8 at 62-63).

118. The Court does not take issue with Dr. Yao's view of the "best practice" for treating HCV, as reflected in the AASLD/IDSA Guideline. However, it is well established that HCV inmates are entitled to adequate care, not the "best care possible" or the "gold standard." Rhinehart, 894 F.3d at 750.

119. When considered together, the 2019 HCV Guidance and 2019 HCV Workflow create a multifaceted set of policies and protocols for DAA treatment of chronic HCV inmates that includes: evaluation, staging for referral to TACHH, consideration by and designation for treatment by TACHH, monitoring and regular testing by the chronic care clinic, and use of HepCOR to streamline and facilitate inmate monitoring and treatment. Importantly, the 2019 HCV

Guidance is an improvement from past treatment protocols. It serves the dual goals of maximizing and prioritizing treatment for HCV inmates. First, it allows inmates to opt-out, as opposed to opt-in, of HCV testing at intake. This testing at intake begins the HCV treatment process. Second, it provides that, upon diagnosis, HCV inmates undergo a prompt and more comprehensive baseline evaluation, including blood and fibrosis tests. Third, it provides for referral of "all" HCV inmates, and does not preclude referral of any HCV inmates, to TACHH. Fourth, it implements a flexible prioritization system for TACHH to order DAA treatment. While TACHH utilizes a three-tier prioritization system, lower priority inmates are still eligible for DAAs. While Plaintiffs complain that the prioritization system does not "guarantee" DAA treatment for anyone at any level (Doc. No. 255 at ¶ 15), such a guarantee is not required under current Eighth Amendment jurisprudence. Finally, the 2019 HCV Guidance directs that all HCV inmates be enrolled in the chronic care clinic for close, regular, and comprehensive monitoring. The results of this monitoring and testing are used, in part, to update inmates' TACHH staging for DAA treatment. Treatment by the chronic care clinic continues until an inmate is administered DAAs and achieves SVR.

120. Dr. Williams has requested and obtained an increased budget for treatment of HCV inmates with DAAs and expects that funding, in tandem with the 2019 HCV Guidance and accelerated work of TACHH, to increase the number of inmates that will be administered DAAs.

121. Dr. Williams has devised a reasonable structure for the diagnosis, evaluation, staging, treatment, and monitoring of inmates with chronic HCV. True, Dr. Williams and TDOC have not put forth the "gold standard" of immediate, universal DAA treatment regardless of fibrosis stage recommended by AASLD/IDSA and advocated by Dr. Yao. But the 2019 HCV Guidance and 2019 HCV Workflow are not so unreasonable or so contrary to medical standards that no competent medical professional would make similar choices, particularly given the

resources available to TDOC. Plaintiffs have not established, by a preponderance of the evidence, that the policies and protocols to treat chronic HCV inmates with DAAs set forth in the 2019 HCV Guidance and 2019 HCV Workflow are "grossly incompetent" or "conscience shocking."

122. Other courts have rejected similar claims for DAA treatment on the same basis relied upon by the Court. For example, in Roy v. Lawson, 739 F. App'x 266, 266-67 (5th Cir. 2018), the Fifth Circuit rejected an HCV inmate's claim that the defendants were deliberately indifferent when they failed to refer him for immediate treatment based on a low fibrosis score and instead performed only blood work, labs, and monitoring "despite the high-risk nature of the disease." The Court noted that there was no evidence the inmate was deprived of adequate medical care "particularly in the absence of any medical evidence showing that his condition required immediate care or subjected him to any wanton infliction of pain." In Spiers v. Perry, Civil Action No. 1:17CV281-RHW, 2019 WL 2373199, at *2 (S.D. Miss. June 5, 2019), an HCV inmate complained of being denied DAAs. The Court found that "constant, routine monitoring" was sufficient to defeat a claim of constitutionally inadequate medical care. Id. In Pevia v. Wexford Health Source, Inc., the court rejected the objective component argument that an HCV inmate was entitled to receive a DAA "as soon as [it] became available," because the inmate was stable and being "monitored, as required by existing protocols." Pevia, 2018 WL 999964, at *16. The Court focused on "medical necessity," "not simply that which may be considered . . . desirable." Id. Likewise, in Walton v. Person, Case No. 1:16-cv-00157-TWP-TAB, 2017 WL 2807326, at *5 (S.D. Ind. June 28, 2017), an HCV inmate with no lab tests showing development of fibrosis sued for being denied DAAs. The Court held that "while fears of developing liver damage are understandable," testing and placing inmate on lower end of treatment priority scale was not "so contrary to accepted professional standards." Id. Finally, in Phelps v. Wexford Health Sources,

Inc., Civil Action No. ELH-16-2675, 2017 WL 528424, at *9 (D. Md. Feb. 8, 2017), an HCV inmate claimed his medical treatment was objectively inadequate because he had not been treated with DAAs. The Court rejected the claim because the inmate was enrolled in chronic care clinic, received regular tests and monitoring, and individual treatments could be considered by a special panel. Id.

123. The Court's analysis of the objective component differentiates this case from three cases that found in favor of HCV inmates who challenged state prison HCV treatment policies. These cases are distinguishable on either the particulars of the policies at issue or the objective component analysis. First, in Abu-Jamal v. Wetzel, the court enjoined a Pennsylvania Department of Corrections ("PDOC") HCV policy. No. 3:16-CV-2000, 2017 WL 34700, at *15 (M.D. Pa. Jan. 3, 2017). There, the PDOC policy contained a prioritization system, but it also had two important limitations: inmates had to have cirrhosis to be considered for DAA treatment, and had to have dangerous esophageal varices to be granted DAA treatment. (Id.) The court noted that "[s]imply prioritizing [HCV] treatment so that those in the greatest need are treated first likely would *not* constitute a constitutional violation." (Id. (emphasis added)). However, with those additional requirements, those with mild or moderate fibrosis unacceptably "ha[d] *no chance* of receiving [DAAs]." Id. at *16. Not so here. While TDOC has a prioritization system, no inmate is foreclosed from consideration by TACHH, and there are no exclusions from DAA treatment.

124. In Hoffer v. Jones, 290 F. Supp. 3d at 1305-06, and Stafford v. Carter, 2018 WL 4361639, at *12, HCV inmates challenged the treatment policies of the Florida and Indiana Departments of Corrections, respectively. However, in these out-of-circuit cases, the analysis of the objective component consisted of no more than deeming chronic HCV to be a serious medical need. Hoffer, 290 F. Supp. 3d at 1299; Stafford, 2018 WL 4361639, at *11-*12. Those courts did

not discuss the further issue, required in the Sixth Circuit where the adequacy of care is at issue, the degree to which there has been an objective deprivation of medical care. This is likely because those cases arrived in a different posture. For example, in Hoffer, the court was faced with a "sordid" state of affairs in which funding was essentially "not available" to treat anyone with HCV and only 13 of perhaps as many as 20,000 inmates had been treated with DAAs. Hoffer, 290 F. Supp. 3d at 1293, 1298. And in Stafford, the Department of Corrections had "not stated that it [wa]s their intention to treat even the individuals who [we]re categorized as high priority." Id. at *17-*18. Again, not so here. It is TDOC's current policy to treat all HCV inmates. The 2019 HCV Guidance and 2019 HCV Workflow are a set of treatment policies and protocols intended and designed to steadily increase the number of HCV inmates treated with DAAs. This case does not fit within Abu-Jamal, Hoffer, or Stafford.

125. Plaintiffs have not satisfied the objective component of the Eighth Amendment deliberate indifference analysis by a preponderance of the evidence.

2. Subjective Component

126. Plaintiffs have also not met their burden on the subjective component of Eighth Amendment deliberate indifference.

127. The proof does not establish, by a preponderance of the evidence, that Dr. Williams has acted with a culpable state of mind equivalent to criminal recklessness. Indeed, the proof is the opposite. Dr. Williams has used, and is using, his medical judgment to provide reasonable care for TDOC HCV inmates through creation, administration, and modification of TDOC policies and treatment protocols for HCV inmates. All of this is a process that involves his reasoned medical judgment. Id.

128. Because the evidence reflects that Dr. Williams' medical judgment has been consciously exercised regarding TDOC's HCV treatment policies and protocols, the Court cannot conclude that Dr. Williams has acted or will act with a culpable state of mind approaching "criminal recklessness" regarding the inmates' HCV treatment. See, e.g., Roy, 739 F. App'x at 266-267 (finding that "[t]he true nature of [plaintiff's] complaint is a challenge to the medical judgment exercised by prison medical staff in determining the appropriate course of his [HCV] treatment, which does not give rise to a constitutional violation"); Loeber, 487 F. App'x at 549 ("Plaintiff's disagreement with the course of treatment employed fails to support an inference that Defendants acted with disregard for the harm posed to Plaintiff by Hepatitis C."); Parks, 144 F. Supp. 3d at 315 ("If medical judgment was consciously exercised, even if that judgment was 'objectively unreasonable,' the defendant's conduct does not constitute deliberate indifference."); King v. Calderwood, Case No. 2:13-cv-02080-GMN-PAL, 2016 WL 4771065, at *6 (D. Nev. Sept. 12, 2016) (concluding disagreement over DAA treatment does not amount to deliberate indifference unless the medical director chose a course of treatment that was "medically unacceptable" under the circumstances).

CONCLUSION

There is room for much continued improvement in TDOC's treatment of HCV inmates with DAAs. The Eighth Amendment is not frozen in time. The evidence at trial made clear that HCV is serious and progressive health condition; that this area of medicine continues to evolve; that DAAs are a virologic cure; and that DAAs are becoming increasingly more affordable. The Court notes that Dr. Williams made a number of promises and projections about anticipated success under the 2019 HCV Guidance. The time it takes to treat HCV inmates with DAAs should continue to dwindle. In time HCV should be no different than other illnesses such as HIV and

tuberculosis for which treatment lingered in nascent stages before reaching a critical mass. Time will tell whether TDOC implements the 2019 HCV Guidance in the dedicated manner it has represented and continues to accelerate approval of inmates for treatment with DAAs. It would behoove TDOC to do so and to engage Dr. Yao to assist in maintaining this progress, lest treatment that is not grossly inadequate today be subject to that renewed claim in the future.

The Court will issue an appropriate order.

WAVERLY D. CRENSHAW, JR.
CHIEF UNITED STATES DISTRICT JUDGE