Case No. 19-11921

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

CARL HOFFER, et al.,
individually and as class representative,

Appellees/Plaintiffs,

vs.

MARK INCH, Secretary of the
Florida Department of Corrections,

Appellant/Defendant.

On Appeal from the United States District Court
for the Northern District of Florida

NO. 4:17-CV-214-MW-CAS

APPELLEES' ANSWER BRIEF

DANTE P. TREVISANI
Florida Bar No. 72912
dtrevisani@floridajusticeinstitute.org

ERICA SELIG
Florida Bar No. 120581
eselig@floridajusticeinstitute.org

RAY TASEFF
Florida Bar No. 352500
rtaseff@floridajusticeinstitute.org

Florida Justice Institute, Inc.
3750 Miami Tower
100 S.E. Second Street
Miami, Florida 33131
305-358-2081
305-358-0910 (fax)

Hoffer, et al. v. Mark Inch
Case No. 19-11921

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and the rules of this Court, Plaintiffs-Appellees hereby submit this Certificate of Interested Persons and Corporate Disclosure Statement:

1. Trevisani, Dante P., Esq., *Attorney for Plaintiffs/Appellees Carl Hoffer, Ronald McPherson and Roland Molina.*
2. Selig, Erica, Esq., *Attorney for Plaintiffs/Appellees Carl Hoffer, Ronald McPherson and Roland Molina.*
3. Taseff, Ray, Esq., *Attorney for Plaintiffs/Appellees Carl Hoffer, Ronald McPherson and Roland Molina.*
4. Hoffer, Carl, (deceased) *Plaintiff/Appellee*
5. McPherson, Ronald, *Plaintiff/Appellee*
6. Molina, Roland, *Plaintiff/Appellee*
7. Inch, Mark, Secretary of the Florida Department of Corrections, *Defendant/Appellant*
8. Agarwal, Amit, Esq., *Attorney for Defendant/Appellant Secretary of the Florida Department of Corrections*
9. Bowden, Albert, Esq., *Attorney for Defendant/Appellant Secretary of the Florida Department of Corrections*

10. Brodeen, Karen Ann, Esq., *Attorney for Defendant/Appellant Secretary of the Florida Department of Corrections*
11. Moody, Ashley, Esq., Florida Attorney General, *Attorney for Defendant/Appellant Secretary of the Florida Department of Corrections*
12. Percival, James, Esq., *Attorney for Defendant/Appellant Secretary of the Florida Department of Corrections*
13. Wenger, Edward M., Esq., *Attorney for Defendant/Appellant Secretary of the Florida Department of Corrections*
14. Stampelos, The Honorable Charles A., United States Magistrate Judge for the Northern District of Florida
15. Walker, Mark E., United States District Judge for the Northern District of Florida
16. Berg, Jr., Randall C., Esq. (deceased), *Attorney for Plaintiffs in United States District Court, Northern District of Florida case*
17. Neff, Lance, Esq., *Attorney for Defendant in United States District Court, Northern District of Florida case*
18. Rigoni, Jarod, Esq., *Attorney for Defendant in United States District Court, Northern District of Florida case*

STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs-Appellees, for themselves and the class they represent ("Plaintiffs"), respectfully submit that oral argument will not be necessary for the disposition of this case. Although the record is substantial, the resolution rests on a straightforward application of settled Eighth Amendment principles.

TABLE OF CONTENTS

PAGE(S)

TABLE OF AUTHORITIES

Cases

Statutes

STATEMENT OF JURISDICTION

As Plaintiffs allege violations of the Eighth Amendment, the district court's jurisdiction was conferred by 28 U.S.C. § 1331 (federal question), and 42 U.S.C. § 1983 (violation of civil rights). This Court's jurisdiction is conferred by 28 U.S.C. § 1291. The district court's final judgment was entered on April 18, 2019. DE 465. The Secretary's Notice of Appeal was filed on May 16, 2019. DE 476.

STATEMENT OF THE ISSUES

1. Whether the district court correctly held that the Secretary of the Florida Department of Corrections (the "Secretary") violated the Eighth Amendment by failing to provide treatment to incarcerated people with earlier stages of chronic hepatitis C solely because of costs, despite conceding that it is inappropriate and inconsistent with the standard of care to withhold treatment based on disease severity.

2. Whether the district court complied with the requirements of the Prison Litigation Reform Act (PLRA), 18 U.S.C. § 3626 (a)(1)(A), by making the necessary particularized findings but not repeating the analysis under subheadings corresponding to each statutory prong.

STATEMENT OF THE CASE AND FACTS

I. Introduction

Hepatitis C is a serious disease that is highly prevalent in this nation's prisons and jails. Left untreated, it can cause irreversible liver damage and death. In 2013, new medications called direct-acting antivirals (DAAs) arrived on the market. They had little to no side effects and had a 90% to 95% cure rate. But this revolution in medicine did not reach the people incarcerated in Florida's prisons, because for four years the Florida Department of Corrections (FDC) refused to treat almost anyone with the disease, despite knowing that this decision put thousands of people at substantial risk of serious harm to their health. The reason for the FDC's refusal to treat hepatitis C was purely financial, and in fact the FDC never even requested the funding necessary to provide even a minimal level of treatment.

After hundreds of preventable hepatitis C-related deaths and the suffering of countless more, Plaintiffs filed this class action lawsuit. The district court certified the class and issued a preliminary injunction, finding that the Secretary had all but admitted deliberate indifference, and imposed a treatment plan. The Secretary eventually conceded to the relief ordered in the preliminary injunction. After further discovery, the district court issued an order on cross-motions for summary judgment, readopting its prior findings, and entered a final injunction imposing a similar treatment plan. As relevant here, the district court ordered that individuals at lower

levels of disease severity be treated within two years of diagnosis. This requirement was well-supported by the record, particularly because the Secretary conceded that it is inappropriate to withhold treatment from patients at lower severity levels.

In sum, the district court entered a targeted injunction aimed at correcting a systemic and statewide constitutional failure. The district court correctly granted summary judgment for Plaintiffs, and this Court should affirm that order.

II. Hepatitis C

Hepatitis C kills approximately 19,000 Americans every year and is the most common bloodborne viral infection in the United States. DE 142-1-28[1] ¶ 14; DE 340-1 at 2. In 2013, hepatitis C killed more Americans than 60 other infectious diseases combined, including HIV and tuberculosis. DE 340-1 at 2. The disease is known as "the silent killer" because it can cause irreparable liver damage in its victims long before outward symptoms appear. DE 35-4 at 1; *see also* DE 142-1-28 ¶ 53.

Between 20% and 50% of individuals diagnosed with hepatitis C will spontaneously clear the disease. DE 340-19 at 53. Those for whom the disease does not spontaneously clear have "chronic" hepatitis C. DE 142-1-28 ¶ 21. This case only concerns this latter category of patients, and the underlying order only requires

[1] Plaintiffs' exhibits introduced at the preliminary injunction hearing are cited by referring to the Exhibit List (DE 142-1) followed by the exhibit number. This citation refers to exhibit 28 at paragraph 14.

treatment for prisoners who have been diagnosed with this more serious type of disease.[2] *See* DE 465 at 4; DE 152 at 1-2.

While the prevalence of hepatitis C in the general population is about one percent, the prevalence among people in prison is far higher. DE 340-1 at 2. Between 16% and 41% of all prisoners in the United States have hepatitis C. DE 142-1-28 ¶ 19. In this case, both experts agreed that at least 20,000 of the 98,000 prisoners in the Florida Department of Corrections (FDC) have hepatitis C, but the number could be as high as 40,000. DE 340-19 at 69-70; DE 361-3 at 95.

The principal consequence of chronic hepatitis C is infection of the liver, which causes liver scarring. DE 142-1-28 ¶ 10. This scarring is called "fibrosis." *Id*. Liver scarring results in many serious health problems, including difficulty fighting infections and filtering toxins from the blood, severe itching, fluid accumulation in the abdomen or legs (called ascites), bleeding from enlarged veins (called varices), cognitive impairment, organ failure, and death. DE 142-1-28 ¶¶ 10-11. Patients with liver scarring are also at greater risk for liver cancer, which often has a terminal prognosis. DE 142-1-28 ¶ 13; DE 119 at 6.

---

[2] In his brief, the Secretary states that the injunction requires "DAA treatment for 'all current and future prisoners in FDC custody who have been, or will be, diagnosed' with Hepatitis C." Appellant's Br. at 6. To be clear, the class definition is narrower than that, and only includes "all current and future prisoners in FDC custody who have been diagnosed, or will be diagnosed, with *chronic* hepatitis C virus." DE 152 at 1-2 (emphasis added).

The extent of fibrosis is measured in five stages: F0 (no scarring), F1 (mild scarring), F2 (moderate scarring), F3 (severe scarring), and F4 (extensive scarring or "cirrhosis"). DE 361-3 at 166. Cirrhosis "disrupt[s] the normal architecture of the liver," preventing it from carrying out its functions. DE 340-19 at 155. It can be irreversible. DE 340-5 at 67. "Decompensated" cirrhosis occurs when the liver has truly failed, and the patient begins to experience more serious symptoms such as swelling of the lower extremities, ascites (fluid accumulation in the abdomen), and bleeding varices. DE 340-19 at 31-32.

Among patients with chronic hepatitis C, 30% have a stable chronic infection, meaning they will not progress to another fibrosis level as a result of hepatitis C; 40% have slow fibrosis progression, meaning they will progress to another fibrosis level over several years; and 30% experience "rapid progression," which may occur over a period of months or even weeks.[3] DE 119 at 5; *see also* DE 100-1 at 22. Patients in the latter category are "on the fast track to liver failure and death." DE 340-19 at 65. All patients have a 10% risk of advancing to a greater stage of hepatitis C each year. DE 119 at 6.

[3] Plaintiffs' expert testified that she has personally seen patients progress from F0 to F2 in a matter of weeks. DE 100-1 at 22. The Secretary's expert testified that he treated a young man who had progressed to F4 by age 25, implying that the disease progressed very quickly. DE 340-19 at 65.

While chronic hepatitis C is easy to diagnosis, it can be difficult to stage accurately without the proper technology, in part because the disease progresses silently. DE 142-1-28 ¶¶ 28-37, 53. Staging is performed using blood serum tests (known as proprietary indices) along with imaging studies to estimate fibrosis level. DE 142-1-28 ¶¶ 30-31, 33, 36; *see also* DE 119 at 7. Proprietary indices only identify about 70% of patients with liver scarring.[4] DE 340-34 ¶ 3. Imaging may include abdominal ultrasounds or a method called elastography, which is far more accurate than ultrasounds at staging hepatitis C. *Id*. ¶ 6; DE 119 at 7. Moreover, modern testing methods are unable to accurately identify whose infection will be stable and whose will progress. DE 340-19 at 57, 160.

Before 2013, hepatitis C was difficult to treat and required injectable medications with severe side effects. DE 142-1-28 ¶ 38. The old treatment regimen also only cured about one third of patients. *Id*. However, beginning in late 2013, new medicines called direct-acting antivirals (DAAs) arrived on the market and revolutionized hepatitis C treatment. *Id*. ¶ 39. These drugs are easy to take (typically

[4] While the Secretary's expert disputed the accuracy of proprietary indices, he provided no data to support that opinion, and he admitted that indices are "less effective" for identifying F2 and F3 patients. DE 369-3 at 2. The Secretary's expert also testified that indices have misdiagnosed patients as F1 when they really had advanced liver scarring and that indices and ultrasounds are the "down-and-dirty" method of staging, DE 340-19 at 75, and also wrote in his report that no single test is adequate to stage a patient. DE 119 at 6-7. Another key witness also agreed that proprietary indices are generally less accurate than other staging methods like elastography. DE 340-14 at 54.

one pill per day for eight to twelve weeks), have minimal side effects, and cure 90% to 95% of patients. *Id*.

In response to the revolutionary DAA medications, the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) formed a panel of experts to conduct an extensive, evidence-based review of the testing, management, and treatment of hepatitis C. *See* DE 361-3 at 67-68. The results of that review have been published in a comprehensive document (the "AASLD Guidelines"), which recommends immediate DAA treatment for all patients with hepatitis C, regardless of fibrosis level, absent contraindications. DE 142-1-6 at 24. The AASLD Guidelines also specifically recommend that incarcerated people should be treated at all stages of the disease. DE 340-16 at 3.

In fact, since these drugs first became widely available, the medical standard of care for treating hepatitis C has been immediate treatment with DAAs for all patients at all stages of the disease. DE 142-1-28 ¶ 40; DE 361-3 at 66-67; DE 340-19 at 154; DE 142-1-6 at 24. As a result, the Florida Agency for Health Care Administration (AHCA), which is responsible for administering the Florida Medicaid program, has approved treatment for all adults with hepatitis C at all stages since May 2016. DE 11-1 at 1. Similarly, the U.S. Department of Veterans Affairs has been treating all veterans with hepatitis C at all stages since March 2016. DE 35-2.

Treatment with DAAs has been shown to improve mortality among all patients with hepatitis C. DE 142-1-28 ¶ 43-44; DE 340-19 at 58. Significantly, DAAs have a higher cure rate for patients in the earlier stages of the disease. DE 142-1-28 ¶ 45. Early treatment also prevents liver-related diseases, cancers, and deaths. *Id*. ¶¶ 45-47; DE 142-1-6 at 25-26. From a public health perspective, early treatment also greatly reduces the spread of hepatitis C and the long-term costs of treating patients with advanced liver disease. DE 142-1-28 ¶ 48; DE 361-3 at 81-82; DE 142-1-6 at 29-30.

When DAAs first became available, they cost approximately $84,000 for a single course of treatment. DE 340-1 at 2-3. In September of 2017, however, the price had fallen to the range of $25,000 to $37,000. DE 340-5 at 165; DE 340-22 at 35. In part because of this lawsuit, the FDC negotiated a deal with the drug company Merck for an "aggressive discount" for DAAs, although it refused to disclose the actual price. DE 340-6 at 269. FDC has also negotiated a "significant" rebate for DAAs through Medicaid that was awaiting approval in June of 2018. *Id*. at 213-215.

III. The FDC's "Long and Sordid History" of Refusing to Treat Hepatitis C

As the district court found, the FDC has a "long and sordid history" of refusing to provide treatment for hepatitis C. DE 153 at 17. For four years, from late 2013 until the district court issued its preliminary injunction order in November 2017, the

Secretary treated just 13 prisoners with hepatitis C (which includes the three named Plaintiffs). DE 153 at 12 (citing DE 340-22 at 47-48 & DE 142-1-11). FDC officials were aware of at least 5,000 prisoners with the disease. DE 340-12 at 107-108. But the Secretary wasn't even prioritizing treatment for the sickest patients; he treated almost no one. DE 153 at 12. This resulted in hundreds of preventable deaths, including Mr. Hoffer's. *See* DE 142-1-31. The Secretary's own expert admitted that "preventable deaths from [hepatitis C] are occurring" as a result of the FDC's failure to treat hepatitis C patients. DE 119 at 3.

The reason for the lack of treatment was purely financial. When DAAs first arrived in 2013, FDC officials chose not to add them to their approved list of medications available to prisoners. DE 340-16 at 53; DE 340-18 at 25. An attempt was made in late 2013 to treat twelve people; they were assembled and evaluated but never given DAAs because funding was not made available. DE 340-18 at 20-27. As the years went on, FDC officials recognized that people were dying from hepatitis C because they were not being treated. *Id*. at 55. Yet, still no funding was made available for treatment. DE 340-22 at 40-47.

In fact, the money was never even requested. Twice (in 2015 and 2016), an FDC official prepared a legislative budget request for DAA funding, but neither was actually submitted to the Legislature. DE 340-22 at 44-47; DE 340-19 at 26-27. These budget requests spelled out that "[t]he Department has no funding to provide

treatment to inmates with Hepatitis C who meet current national treatment criteria" and that "[i]nmates with Hep C are at a very high risk for developing Cirrhosis and Liver Cancer if left untreated, and they can also spread the Hep C virus to others." DE 340-13 at 2. Further, the budget request stated that "[f]ailure to treat the eligible inmates puts the Department at risk of litigation, including class action suit." *Id*. Despite these admonitions, the Secretary chose not to request funding for hepatitis C or to allocate any general funding for it. *See id*.; DE 340-22 at 44-47.

Indeed, prior to hepatitis C treatment being revolutionized in late 2013, FDC was paying about 1 to 2.7 million dollars per year for hepatitis C treatment. DE 340-12 at 18. However, after DAAs came on the market, spending on hepatitis C treatment fell precipitously. *See id*.

IV. The *Hoffer* Lawsuit

Plaintiffs Carl Hoffer, Ronald McPherson, and Roland Molina filed this case on May 11, 2017. DE 1. All three had chronic hepatitis C and sought treatment for years. DE 142-1-28 ¶ 62; DE 153 at 9. All three were very sick because of their untreated hepatitis C. DE 361-3 at 136-42. Carl Hoffer died of liver failure during the course of this lawsuit, and while Mr. McPherson and Mr. Molina eventually received DAA treatment, they will require lifelong medical care due to their permanent liver damage. *See* DE 340-16 at 158-163; DE 142-1-28 ¶ 62.

Plaintiffs sought DAA treatment not just for themselves, but for the thousands of other FDC prisoners with hepatitis C. DE 1. They brought a claim under the Eighth Amendment, alleging that the Secretary had been deliberately indifferent to the serious medical needs of incarcerated people with hepatitis C. *Id*. ¶¶ 144-151. And they brought claims under the Americans with Disabilities Act and Rehabilitation Act, alleging that the Secretary had discriminated against them by failing to provide them with medical services because of their disabilities caused by untreated hepatitis C. *Id*. ¶¶ 152-171.

Because patients were suffering and dying from lack of treatment, Plaintiffs moved for class certification and a preliminary injunction on May 23, 2017. DE 10; DE 11. On October 19, 2017, the district court began a five-day evidentiary hearing on the pending motions. DE 153 at 1. The evidentiary hearing was "focused on ensuring that the sickest inmates were treated first and [the district court] understood that—as a practical matter—it was unrealistic to order FDC to treat everyone immediately." DE 465 at 25. Plaintiffs argued that treatment was required for everyone, but in terms of the emergency treatment needed to justify a preliminary injunction, treatment was most urgent for F2-level patients and above. *See* DE 361-3 at 144-46, 171.

Three days before the hearing, the Secretary filed a Motion for a Case Management Conference, informing the district court that the FDC's Health

Services Director had sent a letter to its medical contractor requesting that they begin treating some people with hepatitis C. DE 128; DE 128-1. The Secretary indicated that the treatment policy had been recently revised, and therefore the focus of the upcoming hearing should be on what the Secretary's current plan was. *Id.*

The district court declined to limit the scope of the evidence presented, and the hearing began on October 19, 2017. *See* DE 134. Given that the Secretary had agreed that more patients should receive treatment, much of the evidence was undisputed. During the evidentiary hearing, the Secretary's own expert, Dr. Daniel Dewsnup, when asked whether he believed the FDC was meeting the standard of care, responded, "I don't believe it's being met at all." DE 340-19 at 122. In fact, he agreed that the AASLD Guidelines—which recommend immediate universal treatment—should be applied "if we had the money and we [had] the system capacity." DE 340-19 at 120. But he believed that, in prison, treatment for F0- and F1-level patients could be delayed due to the financial and logistical issues present in a correctional setting. DE 340-19 at 152. He further stated that "we're going to have to treat [everyone] eventually even if they are Stage 0 or Stage 1." DE 340-19 at 120. Plaintiffs' expert, Dr. Margaret Koziel, also emphasized that the standard of care was immediate treatment at all fibrosis levels, and that treatment for patients at

earlier stages of the disease is beneficial and reduces mortality.[5] DE 142-1-28 ¶ 43-44; DE 361-3 at 134-135; *see also* DE 100-1 at 16-17.

Further, Dr. Dewsup agreed "completely" with Dr. Koziel that successful treatment "tends to decrease mortality in every stage of Hepatitis C[,]" including F0 and F1, although he believed the evidence to be weaker for those stages.[6] DE 340-19 at 58. He acknowledged that scientific evidence had "repeatedly" confirmed that curing hepatitis C is associated with increased survival and improved quality of life. DE 340-5 at 56-57. He also opined in his report that once patients reach F2, they are at substantial risk for decompensated cirrhosis and liver cancer. DE 119 at 6.

On November 17, 2019, the district court granted Plaintiffs' Motions for Class Certification and Preliminary Injunction. DE 152; DE 153. It certified a class of

[5] The Secretary mischaracterizes Dr. Koziel's testimony, claiming that she testified that DAA treatment is "often impracticable or impossible." *See* Appellant's Br. at 8. Rather, Dr. Koziel testified that DAA treatment is necessary for all patients with chronic hepatitis C and that even if her patients have no health insurance, she advocates for them to get treatment. DE 361-3 at 110-11. The Secretary further misstates her testimony by claiming that she "only 'really start[s] to get agitated' and concerned" about F3 patients to the exclusion of her other patients. *See* Appellant's Br. at 15. Rather, Dr. Koziel testified that once patients are at F3 or above, treatment is extremely urgent because most of these patients have already suffered irreparable liver damage that will require lifelong medical intervention. DE 361-3 at 91.

[6] Dr. Dewsnup also testified that for "stable chronic infection" patients—that is, the 30% who never progress to another fibrosis level—he could not say from the scientific literature that improved mortality rates were the result of eradicating hepatitis C. DE 340-19 at 57-61. He nonetheless believed that there are "good reasons to treat this group." *Id*. at 58.

"all current and future prisoners in the custody of the Florida Department of Corrections who have been diagnosed, or will be diagnosed, with chronic hepatitis C virus (HCV)." DE 152 at 14. In granting the preliminary injunction, the district court found that, "although FDC ha[d] tried to moot this case by promising to change its practices going forward," a preliminary injunction was necessary "to ensure that inmates with HCV receive medical care in a timely manner consistent with constitutional requirements." DE 153 at 1-2.

The district court found that Plaintiffs had demonstrated a likelihood of success on the merits of their Eighth Amendment claim. *Id*. at 14. The court first found that chronic hepatitis C is a serious medical need. *Id*. at 15. With respect to the deliberate indifference prong of the inquiry, the court found that "[t]here is no question that [the Secretary] has knowledge of a risk of serious harm . . . ." *Id*. at 16. Regarding whether the Secretary had disregarded that risk with more than mere negligence, the court agreed that the Secretary had "'been deliberately indifferent under nearly every formulation of the standard.'" *Id*. at 16-17 (quoting DE 11 at 17). The court noted that the Secretary's own expert "all but admitted that [the Secretary] ha[d] been deliberately indifferent to Plaintiffs' (and the class's) serious medical needs.[]" *Id*. at 28. Although the court found that funding was no excuse for a failure to provide treatment, it also recognized that funding issues may still hypothetically excuse some delay. *Id*. at 18 n.15. But that was immaterial, because the Secretary

had failed to act since 2013, and had not argued that he should not have to provide treatment because of costs. *Id*.

The district court also found that, despite the Secretary's attempts to moot the case by amending the hepatitis C policy, serious constitutional problems still remained, requiring the entry of an injunction. *Id*. at 19-24. The court found that the other requirements for a preliminary injunction were met. *Id*. at 26-28.

The district court then issued broad orders to the Secretary, requiring the FDC to comply with its own expert's recommendations and to formulate a plan going forward to ensure that patients were treated by certain deadlines according to their fibrosis level. *Id*. at 29-30. After receiving the Secretary's plan, the district court ordered the Secretary to comply with it, and specifically ordered the treatment of prisoners with decompensated cirrhosis by December 31, 2017, treatment of prisoners with cirrhosis (F4) within six months, and treatment of prisoners with moderate to severe liver scarring (F2-F3) within one year. DE 185 at 4, 12-13. The district court later modified the F2 deadline to two years. DE 214. The court did not order treatment for individuals at F0 and F1 in the preliminary injunction order, unless the individuals had a serious comorbid condition such as HIV. The Secretary did not appeal the district court's class certification and preliminary injunction orders.

On May 8, 2018, in a somewhat extraordinary move, the Secretary filed a motion for summary judgment against himself, requesting that the court convert the preliminary injunction into a permanent injunction, and consenting to all the relief ordered in the preliminary injunction. DE 270 at 2. In the motion, the Secretary conceded that chronic hepatitis C "constitutes a serious medical need" and that FDC's "failure to treat inmates with cHCV [chronic hepatitis C] was due to lack of funding." *Id*. at 17-18. The Secretary admitted that the FDC "was not adequately monitoring all inmates with cHCV [chronic hepatitis C] prior to the preliminary injunction." *Id*. at 28. Moreover, the Secretary admitted that "the present-day standard of care is to treat cHCV [chronic hepatitis C] patients with DAAs as long as there are no contraindications or exceptional circumstances" and that "[i]t is inappropriate to only treat those with advanced levels of fibrosis." *Id*. at 8. The Secretary did not raise cost as a defense for failing to treat prisoners with hepatitis C.

On June 22, 2018, Plaintiffs moved for summary judgment. DE 342. Among other things, Plaintiffs argued that F0- and F1-level patients should be treated because the FDC had conceded that it was inappropriate to withhold treatment from them, yet was proposing to do so solely for financial reasons. *Id.* at 30-31. Plaintiffs argued that, although treatment for this category of patients may not have been necessary in the preliminary injunction because that order was designed to quell an

emergency, going forward there was no medical reason to withhold treatment from F0- and F1-level patients. *Id*. at 30-31. In his response, the Secretary did not deny that treatment was being withheld solely for financial reasons. DE 370 at 17-18. Plaintiffs also argued that all patients should be treated because a significant number of patients with significant fibrosis are not identified with FDC's current staging methods. DE 342 at 31. In support, Plaintiffs cited evidence showing a significant portion of the people that FDC has identified as F0 or F1 likely have more advanced stages of the disease. *See* DE 340-43 at 1-2; DE 340-19 at 75; DE 119 at 6-7.

On April 18, 2019, the district court issued its Order on Cross-Motions for Summary Judgment. DE 465. The court found that "no triable issues of fact remain," and "expressly incorporate[d] all findings from its prior order granting Plaintiffs' motion for preliminary injunction." *Id*. at 5-6.

As relevant here, the district court found that "FDC has not put forth any medical reason (nor does the record otherwise reveal a medical reason) why F0 and F1 inmates should not be treated." DE 465 at 24. The court found that withholding treatment *only* because of the cost is per se deliberate indifference. *Id* at 23. Moreover, the court found that both parties' experts agreed that successful treatment of hepatitis C tends to decrease mortality rates. *Id*. The district court concluded that "even F0 and F1 inmate have serious medical needs, FDC is aware of those needs, and FDC's decision not to treat those inmates—without *any* medical reason for that

decision—constitutes deliberate indifference." *Id*. at 27 (emphasis in original). The court therefore ordered the Secretary to treat F0- and F1-level patients within two years of being staged at that level. *Id*. at 62. For those who had been previously staged, the deadline began running on the date of the Order. *Id*. at 66.

Finally, pursuant to the Prison Litigation Reform Act (PLRA), the district court found that its order was "narrowly drawn, extends no further than necessary to effect the changes this Court concludes are constitutionally required, and is the least intrusive means of effecting such changes." *Id*. at 59. The Secretary filed a Notice of Appeal on May 16, 2019. DE 476.

After the Secretary filed his opening brief in this Court arguing that the district court did not make the findings required by the PLRA, in an abundance of caution and to streamline the appellate process, Plaintiffs filed in the district court a Motion for Clarification or alternatively an Indicative Ruling, requesting the district court to make more particularized findings. DE 514. The district court denied the motion, finding that it "did not raise an issue substantial enough to merit issuance of an indicative ruling" because it had "already made the required findings." DE 521 at 7. The court ruled that its "sixty-eight page Order—together with its thirty-two page Order granting Plaintiffs' motion for preliminary injunction [. . .]—illustrates that this Court's consideration of the factors required by the PLRA is interwoven with its analysis of the facts and legal issues throughout the case." *Id*. at 5.

STANDARD OF REVIEW

The decision to grant an injunction and the scope of an injunction are reviewed for an abuse of discretion. *Prison Legal News v. Sec'y, Fla. Dep't of Corr.*, 890 F.3d 954, 964 (11th Cir. 2018). A grant of summary judgment is reviewed de novo. *Ellis v. England*, 432 F.3d 1321, 1326 (11th Cir. 2005). Mere conclusions and unsupported factual allegations are legally insufficient to raise a genuine dispute of material fact precluding summary judgment. *Id*.

SUMMARY OF ARGUMENT

The district court properly granted summary judgment for Plaintiffs, and denied the Secretary's summary judgment motion, on the issue of providing treatment to patients at the F0 and F1 fibrosis levels.

First, the district court correctly found that the Secretary refused to provide treatment *solely* for financial reasons. The Secretary conceded that it was inappropriate to withhold treatment based on fibrosis level, yet proposed to do so anyway to save money. This was clear deliberate indifference to serious medical needs, in violation of the Eighth Amendment and consistent with this Court's longstanding treatment of the issue. Moreover, the district court actually did consider costs in its analysis, and carefully crafted a remedy that allows the Secretary to delay treatment for two years—rather than provide immediate treatment as the standard of care requires.

Second, the district court correctly found that F0- and F1-level patients face a substantial risk of serious harm, such that refusing to provide them with treatment violates the Eighth Amendment. The Secretary waived any challenge to this conclusion by conceding that it was medically inappropriate to withhold treatment from F0- and F1-level patients, and conceding that chronic hepatitis C at any stage qualifies as a serious medical need. While the Secretary claims that his expert's testimony creates a conflict in the evidence, his expert actually agreed with Plaintiffs' expert that treatment tends to decrease mortality at all fibrosis stages, although he could not say the decrease was caused by viral eradication. This is not a sufficient conflict to preclude summary judgment. Further, even if some F0- and F1-level patients face a lower risk, it is not possible to identify those individuals with sufficient accuracy to mitigate the substantial risk to the entire group.

The district court's injunction should also be upheld as a proper exercise of its remedial power. Having found the Secretary to be deliberately indifferent because of a systemic and statewide failure to provide any treatment to hepatitis C patients for years, the district court was well within its authority to fashion a remedy aimed at correcting the violation—including by requiring the treatment of F0- and F1-level patients within two years of diagnosis.

Finally, the district court's final order fully complies with the Prison Litigation Reform Act (PLRA). As a threshold matter, no findings are required for

matters that the Secretary conceded, which comprise the majority of the final order. But even without those concessions, the district court clearly made the required findings by carefully analyzing each proposal and only ordering them if they were constitutionally required. Even though the district court did not repeat this analysis under subheadings corresponding to each statutory prong, such formulaic recitations are not required.

ARGUMENT

I. The district court correctly determined that refusing to provide treatment for patients at the F0 and F1 fibrosis levels violates the Eighth Amendment.

The district court correctly determined that refusing to provide treatment for patients at the F0 and F1 fibrosis levels violates the Eighth Amendment. This conclusion was properly based on two considerations. First, the refusal to provide medical care solely because of costs is per se deliberate indifference to serious medical needs. Second, refusing to provide treatment to F0- and F1-level patients subjects them to a substantial risk of serious harm.

A. The Eighth Amendment prohibits the refusal of medical treatment *solely* because of costs.

As a threshold matter, the Secretary plainly mischaracterizes the district court's holding. The court did not rule that "*any* consideration of the 'cost of treatment' in making medical decisions is 'per se deliberate indifference.'" *See* Appellant's Br. at 12 (emphasis in original; quoting DE 465 at 23). Rather, the

district court properly ruled that withholding treatment "*only* . . . due to the cost of treatment" is "per se deliberate indifference." DE 465 at 23 (emphasis added). The Secretary's distortion of the district court's holding defeats his argument on this point.

And the district court's conclusion—that treatment was being withhold solely for financial reasons—was clearly correct. The Secretary *conceded* that "the present-day standard of care is to treat cHCV [chronic hepatitis C] patients with DAAs as long as there are no contraindications or exceptional circumstances" and that "*[i]t is inappropriate to only treat those with advanced levels of fibrosis*." DE 270 at 8 (emphasis added). Despite this acknowledgment that it was medically necessary to treat hepatitis C patients at *all* fibrosis levels—including F0 and F1—the Secretary still refused to provide treatment. Having made this concession, the Secretary cannot argue that he made a reasoned medical judgment.[7] The only reason for denying treatment to all F0 and F1 patients is the cost of the medications, a non-medical reason. This is per se deliberate indifference. *See H.C. by Hewett v. Jarrard*, 786 F.2d 1080, 1086 (11th Cir. 1986) ("[D]elay of necessary treatment for

[7] This concession also precludes the Secretary from arguing that he was merely following the advice of his expert. Even without this concession, however, such an argument would fail because 1) Dr. Dewsnup recommended a delay, not a complete denial of treatment, DE 340-19 at 114, 120, and 2) Dr. Dewsnup recommended delay in prison for financial and logistical reasons. *Id*. at 120; DE 340-5 at 121-122.

non-medical reasons also established deliberate indifference sufficient to establish a constitutional violation").

The district court's holding is therefore entirely consistent with *Harris v. Thigpen*, 941 F.2d 1495 (11th Cir. 1991). Indeed, the *Harris* court explicitly rejected the argument that the Secretary is now making, stating that "[w]e do not agree that financial considerations must be considered in determining the reasonableness of inmates' medical care . . . ." *Harris*, 941 F.2d at 1509 (quotations/citations omitted). Despite ruling against the prisoner-plaintiffs, the *Harris* court made clear that costs will never "excuse the failure of correctional systems to maintain a certain minimum level of medical service necessary to avoid the imposition of cruel and unusual punishment." *Id*. The plaintiffs in *Harris* failed to prove deliberate indifference because their record only "evidence[d] isolated incidences of medical malpractice" that did not rise to the level of a constitutional violation. *Harris*, 941 F.2d at 1506. Unlike in *Harris*, in this case, the Secretary has conceded deliberate indifference and requested that the district court make the preliminary injunction against him permanent. *See* DE 270.

Moreover, the district court's order is consistent with longstanding Eighth Amendment jurisprudence holding that refusing medical care *solely* because of cost is deliberate indifference. *See, e.g.*, *Allah v. Thomas*, 679 F. App'x 216, 220 (3d Cir. 2017) (withholding hepatitis C treatment from prisoner "*solely* because it was cost-

prohibitive" is deliberate indifference) (emphasis in original); *Roe v. Elyea*, 631 F.3d 843, 863 (7th Cir. 2011) (While "administrative convenience and cost 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); *Ancata v. Prison Health Servs., Inc.*, 769 F.2d 700, 705 (11th Cir. 1985) ("Lack of funds for facilities cannot justify an unconstitutional lack of competent medical care and treatment for inmates.").

Moreover, the district court actually *did* consider costs. In its Preliminary Injunction Order, the district court "recognize[d] that issues of funding might excuse some delay." DE 153 at 18 n.15. The court noted, for example, that "if DAAs were released yesterday, this Court would not expect FDC to wave a magic wand and suddenly treat thousands of inmates overnight." *Id*. But the court found this was not a case in which costs could excuse delay because the "FDC has had since late 2013 to respond to this problem, and it has only just recently started doing what it should have done years ago." *Id*. In fact, when considering costs, the district court cited to the very cases the Secretary now claims the court ignored. *Id*. (citing *Ralston v. McGovern*, 167 F.3d 1160, 1162 (7th Cir. 1999) (Posner, C.J.) & *Reynolds v. Wagner*, 128 F.3d 166, 175 (3d Cir. 1997) (Alito, J.)); Appellant's Br. at 16-17. In addition to incorporating these findings from the Preliminary Injunction Order (DE

465 at 6), in the Order on Cross-Motions for Summary Judgment, the district court also found that because "FDC has been able to begin or complete treatment of almost 5000 inmates within the past fifteen months, FDC should be able to begin treating the ~4000 known F0 and F1 within the next two years." DE 465 at 26-27. Indeed, the district court explicitly found that, "FDC can no longer use resource limitations and implementation difficulties as an excuse to delay treatment."[8] DE 465 at 25. Contrary to the Secretary's claim, the district court perfectly understood the nuances of this issue and faithfully applied the law.

The Secretary improperly relies on *Hudson v. McMillian*, 503 U.S. 1, 9 (1992), for the proposition that, as a general matter, prisoners are not entitled to "unqualified access to health care." Appellant's Br. at 16. *Hudson* stands for the narrower proposition that the Eighth Amendment is only violated when treatment of a *serious* medical need is denied: "Because society does not expect that prisoners will have unqualified access to health care, deliberate indifference to medical needs amounts to an Eighth Amendment violation only if those needs are 'serious.'" *Hudson*, 503 U.S. at 9 (quoting *Estelle v. Gamble*, 429 U.S. 97, 103-104 (1976)). In this case, the Secretary conceded that chronic hepatitis C at all stages is a serious

[8] In addition, the district court did not order immediate treatment for F0- and F1-level patients (as would be consistent with the standard of care), but ordered treatment within two years, which certainly takes into account the Secretary's costs of administration. DE 465 at 26-27.

medical need. DE 270 at 17. Likewise, the Secretary's reliance on *Zingg v. Groblewski*, 907 F.3d 630, 638 (1st Cir. 2018), is misplaced. Appellant's Br. at 17. In *Zingg*, the First Circuit held that the prisoner-appellant had failed to provide any evidence that his jailor had the requisite knowledge of a "significant risk" to his health to prove deliberate indifference. 907 F.3d at 638 (quotations/citations omitted). In this case, it is undisputed that the Secretary had actual knowledge that thousands of prisoners had chronic hepatitis C but failed to treat nearly anyone for years, resulting in preventable deaths. DE 340-22 at 47-48; DE 142-1-11; DE 119 at 3.

Presumably, the Secretary argues that the district court misapplied the law on the consideration of costs because he wishes to argue on remand that he cannot afford to treat F0- and F1-level patients. But the Secretary never raised this argument below, either in his Motion for Summary Judgment (DE 270) or in his Response to Plaintiff's Motion for Summary Judgment (DE 370), and he therefore may not raise it for the first time on appeal. *Access Now, Inc. v. Sw. Airlines Co.*, 385 F.3d 1324, 1331 (11th Cir. 2004) ("This Court has repeatedly held that 'an issue not raised in the district court and raised for the first time in an appeal will not be considered by this court.") (quotations/citations omitted).[9]

[9] What's more is that there is scant evidence in the record upon which the Secretary could base such an argument. The evidence of the price of DAAs is from October of 2017. DE 153 at 7. As of June of 2018, the FDC had reached an agreement with

B. Refusing treatment for F0- and F1-level patients with chronic hepatitis C violates the Eighth Amendment by subjecting those patients to a substantial risk of serious harm.

To establish an Eighth Amendment violation, Plaintiffs need not show that individuals at the F0- and F1-severity levels are currently suffering from symptoms qualifying as a serious medical need, nor must they establish that they will definitely suffer from those symptoms in the future. Rather, it is sufficient to show that they are exposed to conditions that "pose an unreasonable *risk* of serious damage to [their] future health." *Helling v. McKinney*, 509 U.S. 25, 35 (1993) (emphasis added). *See also Farmer v. Brennan*, 511 U.S. 825, 834 (1994) (plaintiffs can succeed on an Eighth Amendment claim by showing they are "incarcerated under conditions posing a substantial *risk* of serious harm.") (emphasis added); *Brown v. Plata*, 563 U.S. 493, 505 (2011) (affirming system-wide relief for Eighth Amendment violation predicated on "deficiencies in the provision of medical and mental health care that, taken as a whole, subject sick and mentally ill prisoners in California to 'substantial risk of serious harm'") (quoting *Farmer*, 511 U.S. at 834); *Board. v. Farnham*, 394 F.3d 469, 479 (7th Cir. 2005) ("The Eighth Amendment protects a detainee not only

---

the drug company Merck for an "aggressive discount" on DAAs. DE 340-6 at 269. The agreement is definite, despite the Secretary's claim. *See* Appellant's Br. at 5 n.3. The only reason why the exact price is not in the record is that the Secretary refused to disclose it. DE 340-6 at 282. Further, the Secretary was awaiting rebates from Medicaid for DAAs and has been able to work through the large treatment backlog. *Id*. at 213-15; DE 465 at 25. Thus, a remand for a consideration of these issues would not change the result.

from deliberate indifference to his or her *current* serious health problems, but also from deliberate indifference to conditions posing an unreasonable risk of serious damage to *future* health.") (emphasis in original). For the reasons that follow, there was no genuine dispute of fact that individuals at F0 and F1 face a substantial risk of serious harm.

1. The Secretary conceded that it is inappropriate to withhold treatment for F0- and F1-level patients.

While the Secretary attempts to paint this case as a mere dispute among medical experts as to the proper course of treatment, that is far from accurate. In fact, the Secretary *conceded* that the "present-day standard of care is to treat cHCV [chronic hepatitis C] patients with DAAs as long as there are no contraindications or exceptional circumstances." DE 270 at 8. The Secretary further conceded that "[i]t is *inappropriate to only treat those with advanced levels of fibrosis*." *Id.* (emphasis added). Thus, the Secretary knows that F0- and F1-level patients require treatment, yet has deliberately chosen not to provide it. The Eleventh Circuit "has consistently held that knowledge of the need for medical care and intentional refusal to provide that care constitute deliberate indifference." *Mandel v. Doe*, 888 F.2d 783, 788 (11th Cir. 1989).[10] The Secretary's concession resolves any so-called conflict in the

[10] As this and other citations make clear, the Eleventh Circuit has described numerous ways in which officials can be deliberately indifferent, *see Baez v. Rogers,* 522 F. App'x 819, 821 (11th Cir. 2013), more than simply failing to provide "minimally adequate care." Appellant's Br. at 15. Plaintiffs do not have to show

evidence and conclusively establishes his deliberate indifference. *See First Interstate Bank of Nevada, N.A. v. Chapman & Cutler*, 837 F.2d 775, 781 (7th Cir. 1988) ("[B]y conceding the issue below, it failed to present it to the district court and has thus waived it for purposes of this appeal.").

The Secretary's proposal also constitutes deliberate indifference because it allows hepatitis C patients to progress to the F2 stage, at which point they will have moderate or significant fibrosis that impairs the functioning of their liver, DE 361-3 at 166 & DE 142-1-28 ¶¶ 21-27, and be at risk for liver cancer and decompensated cirrhosis—a risk that Dr. Dewsnup believed to be substantial enough to recommend treatment. DE 119 at 6. Thus, the Secretary's proposal, rather than preventing the harms of hepatitis C, essentially guarantees that they will occur. *See McElligott v. Foley*, 182 F.3d 1248, 1255 (11th Cir. 1999) (deliberate indifference can be shown by a delay, even for a period of hours).

Indeed, the overwhelming weight of record evidence demonstrates the medical necessity of early treatment. *See* DE 340-16 at 2-3 (the AASLD Guidelines unequivocally recommend treatment for all incarcerated people regardless of

---

that the Secretary's conduct was "outside the boundaries of modern medicine." *Id.* at 22. The out-of-circuit case the Secretary relies on for this proposition, *Kosilek v. Spencer*, 774 F.3d 63 (1st Cir. 2014), is readily distinguishable. In *Kosilek*, the plaintiff's expert acknowledged that professionals could "reasonably differ as to what is at least minimally adequate treatment" for gender dysphoria. *Id.* at 87. In contrast, in this case the Secretary conceded that the standard of care was to provide treatment to all hepatitis C patients, regardless of fibrosis level.

fibrosis stage); DE 142-1-6 at 25-26 (the AASLD Guidelines, under the heading "Benefits of Treatment at Early Fibrosis Stages (Metavir Stage Less Than F2)[,]" describes numerous studies showing the medical necessity of treating hepatitis C at early fibrosis stages); DE 142-1-28 ¶¶ 45-47 (early treatment prevents liver-related diseases, cancer, and deaths); *Chimenti v. Wetzel*, No. CV 15-3333, 2018 WL 3388305, at *11 (E.D. Pa. July 12, 2018) (quoting an expert witness and stating: "'Delaying treatment for patients until they develop advanced liver disease leads to significant suffering, increased risk of cancer, need for liver transplants, and death.'").

The Eighth Amendment requires prison officials to provide medical treatment that avoids serious consequences, not simply treat them after a prisoner becomes dangerously ill. In the same way that incarcerated people can "successfully complain about demonstrably unsafe drinking water without waiting for an attack of dysentery[,]" *Helling*, 509 U.S. at 33, they can complain about failing to treat hepatitis C without waiting for it to advance to a more serious and possibly deadly phase.

2. Dr. Dewsnup's testimony does not create a genuine dispute of material fact.

The Secretary's reliance on the testimony of his expert to create a factual dispute fares no better. In the first place, the Secretary's proposal does not even comport with his own expert's recommendations. While Dr. Dewsnup testified that,

in his view, it was permissible to *delay* in providing treatment to F0- and F1-level patients, he did not testify that it was permissible to completely refuse treatment altogether, which is what the Secretary proposes to do.[11] *See* DE 340-19 at 120 ("[I]n Stage 0 and Stage 1 . . . I think those people don't need to be treated immediately. Those people can be deferred."); *id*. at 114 ("[T]he F0s and F1s . . . we can say, okay, look, it's safe to wait for a bit."). Indeed, as the district court correctly noted, Dr. Dewsnup testified that the FDC was "going to have to treat [them] eventually even if they are Stage 0 or Stage 1." *Id*. at 120; DE 465 at 24. The Secretary's proposal—to never treat F0 and F1 patients—is a far cry from his own expert's recommendation, and therefore offers no cover for the Secretary's conduct. *See Bingham v. Thomas*, 654 F.3d 1171, 1176 (11th Cir. 2011) ("A complete denial of readily available treatment for a serious medical condition constitutes deliberate indifference."); *McElligott*, 182 F.3d at 1255 ("[D]eliberate indifference may be established by a showing of . . . a decision to take an easier but less efficacious course of treatment.").

[11] While the Secretary proposed to put individuals on a treatment schedule once they have advanced to F2, or if they have certain comorbid conditions, it remains true that individuals who stay at F0 and F1 with no comorbidities will never receive treatment. In contrast, the district court's modest order permits treatment to be delayed *for two years*—a delay that has no medical justification, but was imposed to accommodate the financial and logistical realities of prisons.

The Secretary attempts to create a false conflict in the evidence by pointing to only one piece of Dr. Dewsnup's testimony that the Secretary wrongly claims the district court misinterpreted. Appellant's Br. at 21; DE 465 at 24. Dr. Dewsup agreed "completely" with Dr. Koziel that successful treatment "tends to decrease mortality in *every stage of Hepatitis C*[,]" although he believed the evidence to be weaker for stages F0 and F1. DE 340-19 at 58 (emphasis added). He also emphatically agreed that curing hepatitis C was associated with increased survival and improved quality of life. DE 340-5 at 56-57 ("Scientific evidence has confirmed that repeatedly."). The only caveat in Dr. Dewnsup's testimony was that he believed that, for patients at stages F0 and F1 who have a stable chronic infection, the scientific literature was not dispositive as to the cause of that decrease in mortality—he speculated that the cause could be the avoidance of substance abuse.[12] DE 340-19 at 60. But Dr. Dewsnup never affirmatively testified that curing hepatitis C did *not* cause a decrease in mortality; he merely testified that he *did not know* whether it

[12] Dr. Koziel fiercely criticized the implication that staying sober was the key to healing a hepatitis C patient, a notion she called "so medically wrong as to be offensive." DE 361-3 at 105. She faulted the Secretary's proposed treatment guidelines for giving "an impression that sobriety is the end all and be all of the treatment and management of patients with Hepatitis C, when, in fact, it is the administration of drugs, of therapeutic agents that have a high cure rate that actually alters the course of Hepatitis C." *Id.*

caused such a decrease because he lacked the scientific data.[13] *Id*. at 58 ("[W]e don't know if having the sustained viral response affects their mortality rate.").

This is not a genuine factual dispute. Dr. Koziel testified that treatment averted serious negative outcomes; Dr. Dewsnup testified that treatment was associated with averting negative outcomes but didn't know the cause.[14] He did not testify that Dr. Koziel was wrong, only that he lacked the data to render an opinion. "[A] party may not avoid summary judgment solely on the basis of an expert's opinion that fails to provide specific facts from the record to support its conclusory allegations." *Evers v. Gen. Motors Corp*., 770 F.2d 984, 986 (11th Cir. 1985). *See also Cordoba v. Dillard's, Inc.,* 419 F.3d 1169, 1181 (11th Cir. 2005) ("Speculation does not create a genuine issue of fact; instead, it creates a false issue, the demolition of which is a primary goal of summary judgment.") (quotations/citations omitted). Dr. Dewsnup's speculation is insufficient to create a genuine dispute of material fact precluding summary judgment.

---

[13] In fact, Dr. Dewsnup acknowledged that the greater scientific community did not demand this level of certainty. DE 340-5 at 128 (noting that the drafters of the AASLD Guidelines recognized that, "even though we didn't have perfect outcome studies, we should go ahead and treat."); DE 340-19 at 58 (there are "good reasons" to treat F0- and F1-level patients).

[14] This association is important, even if the cause is unknown. For instance, successful treatment could still be a contributing cause to decreased mortality. Perhaps curing hepatitis C helps people remain sober. There was no testimony indicating that the decrease in mortality would occur if patients remained sober but did *not* receive hepatitis C treatment.

The Secretary presses this argument further by blatantly mischaracterizing the testimony of Plaintiffs' expert, Dr. Koziel. Appellant's Br. at 20. The referenced exchange is four lines of a 206-page transcript in which Dr. Koziel confirmed that treating everyone with hepatitis C with DAAs is the "best possible management for [h]epatitis C." DE 361-3 at 177. She also said that, as a physician, it was her job to advocate for the best medical care for her patients. *Id.* The Secretary's implication—that there is some other adequate form of treatment that is not the "best"—is simply untrue. Dr. Koziel did not testify that there was some other form of acceptable treatment.

The Secretary's other misleading point—that Dr. Koziel allegedly only becomes concerned when a patient reaches F3—is similarly based on out-of-context testimony. That testimony was given in response to the district court's question about a hypothetical patient without insurance. *Id*. at 89-91. Dr. Koziel was describing how she would approach an insurance company that was refusing coverage, not how she generally approaches treatment for all her patients. She also made clear that there was "an increased risk of mortality even in the early stages[,]" and that she advocated for treatment for all her patients, not just those with advanced disease. *Id*. at 91. And in this hypothetical scenario, which she clarified later in her testimony, *id*. at 110-111, she explained that waiting until a patient progresses to F3 should cause "panic" because "irreversible complications" would ensue to the point

where she could no longer make the patient "completely whole again." *Id*. at 91. If this is the standard of medical care the Secretary aspires to, it surely fails under the Eighth Amendment. *See McElligott*, 182 F.3d at 1255 ("[D]eliberate indifference may be established by a showing of grossly inadequate care as well as by a decision to take an easier but less efficacious course of treatment.").

Finally, the Secretary's reliance on Dr. Dewsnup's testimony is still deliberate indifference because his opinion was based on financial and logistical issues that exist in prisons, rather than medical considerations. That is, his opinion that treatment for individuals at F0 and F1 should be delayed while in prison was based on his understanding of a *prison* standard of care—not one applicable to the community at large. DE 340-19 at 152 ("However, I think it is a better standard of care for in prison, given the issues that we face."); *id*. at 62 ("That's what goes into the standard of care in the community and the standard of care in corrections, which are—which are different in this case."). In fact, he agreed that the AASLD Guidelines—which recommend immediate universal treatment—should be applied in prison "if we had the money and we [had] the system capacity." *Id*. at 120; *see also* DE 340-5 at 121-122 ("agree[ing]" that treatment will be delayed for some prisoners because of "administrative" rather than "medical" considerations and that prioritization would not be needed if DAAs were the price of aspirin). Because this recommendation was that "necessary medical treatment [be] delayed for non-

medical reasons, a case of deliberate indifference has been made out." *Ancata*, 769 F.2d at 704. *See also Hewett,* 786 F.2d at 1086 (noting that "delay of necessary treatment for non-medical reasons also established deliberate indifference.").

3. The inability to identify high-risk patients means all F0- and F1-level patients face a substantial risk of serious harm.

Even assuming that Dr. Dewsnup's opinion creates a genuine dispute of material fact because some F0- and F1-level patients face a lower risk of harm, it was undisputed that many individuals within this group still face an unreasonably high risk, and that those individuals cannot be identified with sufficient accuracy. This is true for two reasons. First, Dr. Dewsup's testimony—that he could not say that F0- and F1-level patients tend to die from viral complications versus substance abuse—was limited to a group of patients with a "stable chronic infection," which comprises only 30% of the patient population. DE 340-19 at 55-56, 58. Thus, there remains a full 70% of the patient population for whom this opinion does not apply, and for whom treatment causes decreased mortality. Even Dr. Dewsnup admitted that at least some F0 and F1 individuals should be treated immediately because their disease is progressing rapidly. *Id*. at 161 ("[A]nybody in F0 and F1, once we've demonstrated that they are a progressor, even if they only went from F0 to F1, I think they are at some risk . . ."). And modern testing methods are unable to accurately identify whose infection will be stable and whose will progress. *Id*. at 57, 160. Some

patients—the 30% in the rapid progression group—could progress to the next fibrosis level in a matter of months. *See* DE 100-1 at 22; *see also* DE 340-19 at 65.

Second, as Dr. Dewsnup acknowledged, there is a risk that those found to be at F0 or F1 have been erroneously staged—and could actually be at a more advanced stage—because of the imprecise nature of the staging process. *Id*. at 168 (performing more sensitive staging in Oregon resulted in detecting double the number of people with cirrhosis); *see also id*. at 201. This is especially true because FDC is not using elastography, the most accurate staging method. DE 340-6 at 129-130. All of this means that, even if some F0- and F1-level patients face a lesser risk of harm, doctors cannot identify who those individuals are with enough certainty to say the risk of serious harm is not substantial to the entire group. The Secretary's proposal therefore knowingly condemns a large portion of the patient population.

4. The Secretary waived any argument that chronic hepatitis C is not a serious medical need.

Although not explicit, it appears that the Secretary is arguing that chronic hepatitis C at stages F0 and F1 is not a serious medical need. But the Secretary has already conceded this point, as the district court found. DE 465 at 4. In his Motion for Summary Judgment, while noting his belief that the risk of harm did not become measurable until an individual reaches F2, the Secretary stated that the district court "concluded that cHCV [chronic hepatitis C] constitutes a serious medical need. *Defendant does not dispute this*." DE 270 at 17 (emphasis added). Dr. Dewsnup

agreed. DE 340-5 at 114. The Secretary cannot now argue that hepatitis C is not a serious medical need. *See Baumann v. Savers Fed. Sav. & Loan Ass'n*, 934 F.2d 1506, 1510 (11th Cir. 1991) ("In general, this court will not address an argument unless it has been raised in the district court.").

Nor could he. Hepatitis C, even at F0 and F1, qualifies as a serious medical need because, when "left unattended, [it] 'pos[es] a substantial risk of serious harm.'" *Taylor v. Adams*, 221 F.3d 1254, 1258 (11th Cir. 2000) (quoting *Farmer*, 511 U.S. at 834). *See also Danley v. Allen*, 540 F.3d 1298, 1310 (11th Cir. 2008) (a medical need is serious if "a delay in treating the need worsens it"). This Court has repeatedly confirmed this. *See Loeber v. Andem*, 487 F. App'x 548, 549 (11th Cir. 2012) ("That Hepatitis C presents a serious medical need is undisputed."); *Brown v. Johnson*, 387 F.3d 1344, 1351 (11th Cir. 2004) ("HIV and hepatitis meet either of the[] definitions" of a serious medical need and "defendants wisely do not deny that [Plaintiff] has serious medical needs.").

5. The district court's final injunction is a proper exercise of its remedial power.

Finally, even if F0- and F1-level patients do not face a substantial risk of serious harm, the district court's final injunction would still be a proper exercise of its remedial power. The district court correctly found an Eighth Amendment violation for the entire class (defined as all individuals with hepatitis C, regardless of fibrosis level) based on a widespread and systemic failure to treat incarcerated

people with hepatitis C due to a lack of funding. DE 465 at 4. The Secretary conceded liability for deliberate indifference to serious medical needs based on this widespread failure. DE 270 at 18; DE 465 at 4. The only remaining question, therefore, is the scope of the remedy necessary to correct the constitutional violation.

"Once a right and a violation have been shown, the scope of a district court's equitable powers to remedy past wrongs is broad, for breadth and flexibility are inherent in equitable remedies." *Swann v. Charlotte-Mecklenburg Bd. of Ed.*, 402 U.S. 1, 15 (1971). Even for prison-related injunctions, which are restricted by the Prison Litigation Reform Act (PLRA), courts have "substantial flexibility" in fashioning injunctive relief, as "the scope of a district court's equitable powers . . . is broad." *Plata*, 563 U.S. at 538 (quotations/citations omitted; ellipses in original). Significantly, "[t]he PLRA does not require that prospective relief exactly map onto the requirements of the Eighth Amendment." *Graves v. Arpaio*, 623 F.3d 1043, 1050 (9th Cir. 2010). Indeed, "[a] remedy may be deemed to be properly drawn if it provides a practicable 'means of effectuati[on]' even if such relief is over-inclusive." *Handberry v. Thompson*, 446 F.3d 335, 346 (2d Cir. 2006) (citation omitted; brackets in original).

Moreover, the Supreme Court has approved prison injunctions that "have positive effects beyond the plaintiff class" and have "collateral effects." *Plata*, 563 U.S. at 531. Applying these rules in *Plata*, the Supreme Court held that a statewide

injunction requiring the release of 46,000 prisoners to remedy deficient medical care was consistent with the PLRA, even though the majority of prisoners would never develop serious medical issues and would therefore never be subjected to harm. *Id*. at 531-32. Those healthy individuals were not "remote bystanders in California's medical care system. They [were] that system's next potential victims." *Id*. at 532. So too here. Florida prisoners with F0- and F1-level hepatitis C must be protected from the state's unconstitutional practices, lest they become the system's next victims. The district court's requirement to treat their serious medical conditions within two years of diagnosis was well within its remedial authority.

C. This Court should affirm the district court's grant of summary judgment for Plaintiffs.

This Court should affirm the district court's grant of summary judgment for Plaintiffs. Even if this Court determines that there is a genuine dispute of material fact as to whether F0- and F1-level patients face a substantial risk of serious harm, this Court should still affirm because the Secretary's plan impermissibly refuses treatment solely for financial reasons. If the Court rejects both of these arguments, the proper remedy would be to remand the case to the district court for further proceedings, not order the grant of summary judgment for the Secretary. At the very least, if there is a dispute of fact, Plaintiffs have shown that there is ample evidence in the record showing that F0- and F1-level patients face a substantial risk of serious harm.

II. The district court's final order complies with the Prison Litigation Reform Act because it made the required findings even though it did not repeat the analysis under subheadings corresponding to each statutory prong.

After the Secretary filed his opening brief in this Court, raising the issue of compliance with the Prison Litigation Reform Act (PLRA), Plaintiffs filed, in the district court, a Motion for Clarification or alternatively a Motion for Indicative Ruling. DE 514. In the motion, Plaintiffs requested the district court, in an abundance of caution and to avoid the needless waste of judicial resources, to make more detailed findings. The district court denied the motion, finding that it "did not raise an issue substantial enough to merit issuance of an indicative ruling" because it had "already made the required findings." DE 521 at 7.

As a threshold matter, the PLRA findings were not required for any matter the district court addressed in the preliminary injunction order, because no such findings are required "concerning any facts or factors about which there is not dispute." *Cason v. Seckinger*, 231 F.3d 777, 785 n.8 (11th Cir. 2000). The Secretary conceded all the issues found in the preliminary injunction order—that is, every relevant issue except treatment for F0- and F1-level patients—and therefore cannot now argue that the entire injunction should be vacated. DE 270 at 8, 17-18, 28.

Even without this concession, however, the final order still fully complies with the requirements of the PLRA. The relevant portion of the statute states that a "court shall not grant or approve any prospective relief unless the court finds that

such relief is narrowly drawn, extends no further than necessary to correct the violation of the Federal right, and is the least intrusive means necessary to correct the violation of the Federal right." 18 U.S.C. § 3626(a)(1)(A). It further states that a "court shall give substantial weight to any adverse impact on public safety or the operation of a criminal justice system caused by the relief." *Id.*

The Secretary argues that the district court's findings were insufficiently detailed by isolating one sentence that referenced the PLRA. Appellant's Br. at 26-27; DE 465 at 59. But this argument ignores the remaining 68 pages (plus 32 pages in the order granting a preliminary injunction) of "[p]articularized findings, analysis, and explanations" of how the injunction complies with the statute's requirements. *Cason*, 231 F.3d at 785. In fact, the district court later clarified that its "consideration of the factors required by the PLRA is interwoven with its analysis of the facts and legal issues throughout the case." DE 521 at 5. For instance, the district court did not adopt wholesale all the reforms Plaintiffs requested; rather, it carefully analyzed each proposal and declined to order several because they were not constitutionally required. *See* DE 465 at 22 (declining to require elastography for every patient); *id*. at 37 (declining to require shorter treatment deadlines); *id*. at 39 (declining to require re-evaluations every six months); *id*. at 42-43 (declining to require FDC to provide post-release continuity of care); *id*. at 45 (allowing for temporary ineligibilities and declining to require quarterly re-evaluations). It also permitted the Secretary to

exercise his discretion to choose among constitutional alternatives. *See id.* at 17 (allowing the FDC to choose between opt-in or opt-out testing). In sum, as the district court stated in its order on Plaintiffs' Motion for Clarification, this analysis confirms that the district court found that the injunction was narrowly drawn, extended no further than necessary, and was the least intrusive means necessary to correct the described constitutional violations. DE 521 at 6-7.

The district court also gave "substantial weight to any adverse impact on public safety or the operation of a criminal justice system." 18 U.S.C. § 3626(a)(1)(A). Notably, in contrast to the previous sentence, this portion of the statute does not require the court to make findings. Further, it "does not require the court to certify that its order has no possible adverse impact on the public." *Plata*, 563 U.S. at 534. But the district court did find that the relief would promote the rehabilitative goals of the criminal justice system, DE 465 at 59, and would "actually *serve* the public interest." DE 153 at 28 (emphasis in original). The order therefore contains all the findings required by the PLRA.[15]

[15] Although the Secretary has not argued that the substance of the order fails the needs-narrowness-intrusiveness test, in an abundance of caution Plaintiffs note that it clearly does comply. The Secretary consented to the vast majority of relief ordered, thereby rebutting any argument that it fails this test. The injunction is narrowly drawn because the "scope of the remedy" is "proportional to the scope of the violation." *Plata*, 563 U.S. at 531. An order does not fail the narrow tailoring requirement "simply because it will have collateral effects." *Id.* at 531. It extends no further than necessary to correct the constitutional violation because the district court only ordered the relief necessary to correct the FDC's deliberate indifference

The PLRA does not require, as the Secretary seems to suggest, that every part of the court's analysis be repeated under a separate subheading for each statutory subsection; such a requirement would be unnecessary and superfluous. *See Armstrong v. Schwarzenegger*, 622 F.3d 1058, 1071 (9th Cir. 2010) ("[W]here a court has explained clearly the factual circumstances underlying an order and its understanding of the relevant law as applied to the facts," requiring more would "give rise to unwarranted challenges to the findings no matter how detailed those findings were and would unduly delay resolution of the already complicated proceedings necessary to remedy the underlying constitutional violations."); *Benjamin v. Fraser*, 156 F. Supp. 2d 333, 342 (S.D.N.Y. 2001) (no reason to impose a "painfully exacting standard" that would "elevate[] formalism over substance and construe[] the PLRA as devising pitfalls for conscientious courts who have convened hearings, weighed extensive quantities of evidence, rendered detailed opinions, and drafted narrow and specific remedial orders."). Just as a criminal sentence is reviewed based on the entire record, and not simply on the district court's summary statement, a prison injunction must be viewed in its entirety as well. *Cf. United States v. Suarez*, 939 F.2d 929, 934 (11th Cir. 1991) ("When evaluating a district

---

to serious medical needs. And for F0- and F1-level patients, it allowed the Secretary to delay treatment for two years, despite the standard of care that recommends immediate treatment. For the same reasons, it was the least intrusive means necessary to correct the constitutional violation.

court's reasons for imposing a particular sentence, an appellate court may consider the record from the entire sentencing hearing and need not rely upon the district court's summary statement made at the closing of the sentencing hearing.").

This Court's decision in *Cason* is not to the contrary. In *Cason*, the district court order on appeal appears to have contained only a simple statement referencing the PLRA findings, and nothing more. *Cason*, 231 F.3d at 784. In fact, that statement—that the relief complied with the PLRA—was referring to a *prior* order. *Id.* Thus, the order on appeal contained no findings to analyze, and bears no resemblance to the district court's order under consideration here, in which the court extensively analyzed each form of relief that Plaintiffs requested.

Moreover, as the Secretary acknowledges, *Cason* confronted a different statutory subsection. Appellant's Br. at 26 n.7. The subsection at issue in *Cason* precludes a court from terminating prospective relief "if the court *makes written findings based on the record*" that the needs-narrowness-intrusiveness requirements are met. 18 U.S.C. § 3626(b)(3) (emphasis added). In contrast, the subsection at issue here states that a court must not grant prospective relief "unless the court *finds*" that the needs-narrowness-intrusiveness requirements are met. § 3626(a)(1)(A) (emphasis added). Thus, while 3626(b)(3) may require more particularized written findings, 3626(a)(1)(A) merely requires a court to "find" that the relief complies. That is, while a written statement may be required, the more particularized written

findings are not if it is clear that the court actually found the requirements to be met.[16]

In sum, the district court made the required PLRA findings, despite the fact that it did not specifically place them under a heading for each subsection of the statute. The order therefore complies with the PLRA.

CONCLUSION

For the foregoing reasons, this Court should affirm the district court's permanent injunction in its entirety. Alternatively, if the Court finds the Secretary did not violate the Eighth Amendment by refusing treatment solely because of costs and that there is a genuine dispute of material fact as to whether F0- and F1-level patients face a substantial risk of serious harm that precludes the entry of summary

[16] Plaintiffs acknowledge that this Court has said that this difference in wording is immaterial, *United States v. Sec'y, Fla. Dep't of Corr.*, 778 F.3d 1223, 1228 (11th Cir. 2015), and Plaintiffs make this argument to preserve it. Moreover, in that case, the district court did not even mention the PLRA, and the case was ultimately dismissed as moot because the preliminary injunction at issue had expired, in part because it had not been made permanent. *Id.* at 1228. Thus, the Court's statement comparing the two subsections was arguably not essential to the holding of that case, and is therefore dicta. *See CSX Transportation, Inc. v. Gen. Mills, Inc.*, 846 F.3d 1333, 1338 (11th Cir. 2017) ("The holding of an appellate court constitutes the precedent, as a point necessarily decided. Dicta do not: they are merely remarks made in the course of a decision but not essential to the reasoning behind that decision.") (quotations/citations omitted). Moreover, the Fifth Circuit has noted that the difference in wording between the two PLRA subsections is significant. *Gates v. Cook*, 376 F.3d 323, 336 n.8 (5th Cir. 2004).

judgment, it should remand the case for further proceedings, rather than order the Secretary's motion for summary judgment to be granted.

Respectfully submitted,

s/Dante P. Trevisani
Dante P. Trevisani
Florida Bar No. 72912
dtrevisani@floridajusticeinstitute.org
Erica Selig
Florida Bar No. 120581
eselig@floridajusticeinstiute.org
Ray Taseff
Florida Bar No. 352500
rtaseff@floridajusticeinstitute.org
Florida Justice Institute, Inc.
100 SE 2nd Street, Suite 3750
Miami, Florida 33131
305-358-2081
305-358-0910 fax

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). This brief contains 11,883 words.

s/Dante P. Trevisani
Dante P. Trevisani

CERTIFICATE OF SERVICE

I certify that on October 18, 2019, I served upon opposing counsel the foregoing document by filing it via the ECF filing system and mailed paper copies to opposing counsel.

s/Dante P. Trevisani
Dante P. Trevisani