IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

LLOYD BUFFKIN, KIM CALDWELL, and ROBERT PARHAM, et al.,	)	
Plaintiffs,	)	
v.	)	1:18CV502
ERIK HOOKS, ABHAY AGARWAL, KENNETH LASSITER, PAULA SMITH, and NORTH CAROLINA DEPARTMENT OF PUBLIC SAFETY,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

OSTEEN, JR., District Judge

This matter is before this court for review of the Memorandum Opinion and Recommendation ("Recommendation") filed on November 30, 2018 by the Magistrate Judge in accordance with 28 U.S.C. § 636(b). (Doc. 38.) In the Recommendation, the Magistrate Judge recommends that Plaintiffs' motion to certify class, (Doc. 3), be granted and that "the class be defined as 'all current and future prisoners in DPS custody who have or will have chronic hepatitis C virus and have not been treated with direct-acting antiviral drugs.'" (Doc. 38 at 32.) The Magistrate Judge further recommends that Lloyd Buffkin and Robert Parham be named class representatives, that Plaintiffs' counsel be appointed class counsel, and that Plaintiffs' motion

for preliminary injunction, (Doc. 26), be granted.

(Recommendation (Doc. 38) at 32–33.)

Finally, the Magistrate Judge recommends that this court issue a preliminary injunction that:

> order[s] Defendants to: (1) provide universal opt-out HCV screening to all persons who are or will be in DPS custody; (2) cease denying DAA treatment for the contraindications, other than patient refusal, set out in Step 4a of DPS Policy #CP-7; and (3) treat Plaintiffs and all members of their class with DAAs according to the current standard of medical care set out in the AASLD/IDSA Guidance, regardless of an individual's fibrosis level.

(Id. at 33.)

The Recommendation was served on the parties to this action on November 30, 2018. (Doc. 39.) Defendants timely filed objections, (Defs.' Resp. and Objs. to Recommendation ("Defs.' Objs.") (Doc. 40)), and Plaintiffs replied, (Doc. 43.) Defendants object to the following three findings in the Recommendation: (1) that Plaintiffs have standing, (2) that Plaintiffs are adequate class representatives, and (3) that Plaintiffs can demonstrate a high likelihood of success on the merits, as required for this court to issue a preliminary injunction. (Defs.' Objs. (Doc. 40) at 2.)[1]

[1] All citations in this Memorandum Order to documents filed with the court refer to the page numbers located at the bottom right-hand corner of the documents as they appear on CM/ECF.

This court has appropriately reviewed the portions of the Recommendation to which objections were made. This court adopts the Magistrate Judge's findings and recommendation regarding Plaintiffs' motion for class certification (as supplemented herein), and this motion will be granted. Because this court finds that Plaintiffs have not demonstrated a likelihood of success on the merits as to certain aspects of their requested class-wide injunction, this court declines to adopt the Magistrate Judge's findings regarding this issue and Plaintiffs' motion for a preliminary injunction will be granted in part and denied in part, as set forth herein.

I. BACKGROUND

A detailed factual background is clearly and succinctly set forth in the Recommendation, (see (Doc. 38) at 1–7), and this court will not repeat those facts here. Plaintiffs are state prisoners who receive medical care from the North Carolina Department of Public Safety, or DPS. (Complaint ("Compl.") (Doc. 1) ¶¶ 1, 13–15.) Plaintiffs have been diagnosed with and requested treatment for the hepatitis C virus ("HCV"), "a highly communicable disease that scars the liver and presents" other health risks. (Id. ¶ 1.) Plaintiffs allege that they are currently not receiving HCV treatment. (Id. ¶ 3.) The individual Defendants are all employed by the North Carolina state prison system. (Id. ¶¶ 17–20.)

Plaintiffs bring claims under 42 U.S.C. § 1983, alleging: (1) that Defendants' policy of screening only those prisoners with certain risk factors, rather than screening all prisoners under an opt-out system, is deliberately indifferent to the risk that prisoners with HCV will evade detection and will not receive the necessary treatment, (id. ¶¶ 36, 80–82), and (2) that Defendants' policy of providing direct-acting antiviral ("DAA") drug treatment only to certain prisoners based on FibroSure test scores and contraindications is deliberately indifferent to the risk that individuals who do not meet the policy criteria may still suffer serious health consequences from HCV. (See id. ¶¶ 95–98, 108.) Plaintiffs further allege that Defendants violated the Americans with Disabilities Act ("ADA") by discriminatorily withholding medical treatment from Plaintiffs while providing treatment to prisoners with other health issues. (Id. ¶¶ 112–17.)

II. PROCEDURAL HISTORY

Plaintiffs moved to certify a class on June 15, 2018, (Doc. 3), and filed a brief in support of their motion, (Doc. 4). Defendants responded in opposition, (Defs.' Resp. in Opp'n to Pls.' Mot. to Certify Class ("Defs.' Opp'n Resp.") (Doc. 31)), and Plaintiffs replied. (Pls.' Reply to Defs.' Resp. in Opp'n to Pls.' Mot. to Certify Class ("Pls.' Reply") (Doc. 35).) Plaintiffs moved for a preliminary injunction on September 14,

2018, (Doc. 26), and filed a brief in support of their motion. (Pls.' Br. in Supp. of Mot. for Prelim. Inj. ("Pls.' Inj. Br.") (Doc. 27).) Defendants responded in opposition, (Defs.' Resp. to Pls.' Mot. for Prelim. Inj. ("Defs.' Inj. Resp.") (Doc. 32)), and Plaintiffs replied, (Doc. 34). The Magistrate Judge held hearings on these motions on October 29, 2018, and November 5, 2018. (Docs. 41, 42.) This court then conducted an additional hearing on the motion for a preliminary injunction on March 8, 2019. (See Minute Entry 03/08/2019; Doc. 50.)

III. STANDARD OF REVIEW

This court is required to make "a de novo determination of those portions of the [Magistrate Judge's] report or specified proposed findings or recommendations to which objection is made." 28 U.S.C. § 636(b)(1). This court "may accept, reject, or modify, in whole or in part, the findings or recommendations made by the [M]agistrate [J]udge . . . or recommit the matter to the [M]agistrate [J]udge with instructions." Id.

This court applies a clearly erroneous standard to any part of the Magistrate Judge's recommendation not specifically objected to by the parties. Diamond v. Colonial Life Accident Ins. Co., 416 F.3d 310, 315 (4th Cir. 2005). "A finding is clearly erroneous when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed."

United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948) (internal quotations omitted).

IV. STANDING

A. Arguments

Defendants first object to the Magistrate Judge's conclusion that Plaintiffs have standing to challenge the HCV screening process. (Recommendation (Doc. 38) at 18.) The Magistrate Judge found that, although Plaintiffs are already infected with HCV, they still have standing to challenge HCV screening because there is a higher risk of re-infection if the entire prison population is not screened. (Id. at 17.) Further, the Magistrate Judge found that precluding Plaintiffs from challenging screening would "create[] a catch-22 quandary in that a prisoner would have to know of his or her HCV diagnosis to have standing to challenge [the DPS policy generally], but that same knowledge would preclude a challenge to the HCV screening protocol." (Id. at 18 (footnote omitted).) In objection, Defendants argue that any risk to Plaintiffs of future injury from the current screening policy is simply too speculative and attenuated and does not amount to a substantial or imminent risk. (Defs.' Objs. (Doc. 40) at 6.) Defendants further state that, in their opinion, unscreened inmates (or, presumably, inmates who were improperly diagnosed) would have standing to challenge the screening process

specifically, thus eliminating the quandary identified by the Magistrate Judge. (Id. at 8.)

Defendants further argue that, because all named Plaintiffs either received an initial HCV screening prior to the filing of the complaint or were already aware of their HCV diagnosis, they lack standing to challenge the initial step one screening process. (See id. at 7.) Indeed, the Magistrate Judge found that each named Plaintiff had either received an initial diagnostic screening or otherwise been diagnosed with HCV, but had not received a FibroSure screening for possible DAA treatment, at the time of filing. (See Recommendation (Doc. 38) at 16; Pls.' Reply (Doc. 35) at 7 n.3.) Plaintiffs, however, assert that the two stages of screening should be viewed as a single unitary process and that, because certain named Plaintiffs had not received DAA-specific screening at the time of filing, there is standing to challenge the screening process. (Pls.' Reply (Doc. 35) at 7–8.)

B. Legal Framework

To demonstrate standing, Plaintiffs "must have . . . suffered an injury in fact." Kenny v. Wilson, 885 F.3d 280, 287 (4th Cir. 2018) (internal quotation marks omitted). "An allegation of future injury may suffice if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158 (2014) (internal quotation marks omitted). This

"requirement [] cannot be met where there is no showing of any real or immediate threat that the plaintiff will be wronged again." City of L.A. v. Lyons, 461 U.S. 95, 111 (1983).

In a class action, it is well-established that "the named plaintiff may litigate the class certification issue despite loss of his personal stake in the outcome of the litigation" so long as that plaintiff still adequately represents and protects class interests. U.S. Parole Comm'n v. Geraghty, 445 U.S. 388, 398, 406 (1980). In Geraghty, the Supreme Court held that Geraghty's subsequent release from prison mooted his personal claim but that he could nonetheless continue to pursue class certification. See id. at 404 ("[A]n action brought on behalf of a class does not become moot upon expiration of the named plaintiff's substantive claim, even though class certification" is still pending.). This court interprets the Geraghty holding to mean that, if class certification were denied in this case, Plaintiffs would then be entitled to appeal that determination even if some or all of their individual claims had been mooted. It follows that potential mootness should not be a bar to class certification in the first instance. There must, however, "be a named plaintiff who has . . . a [live] case or controversy at the time the complaint is filed." Sosna v. Iowa, 419 U.S. 393, 402 (1975); see also Pashby v. Delia, 709 F.3d 307, 316 (4th Cir. 2013).

C. Analysis

The Magistrate Judge found standing based primarily on two factors: (1) a "broad application of Policy #CP-7" that makes the policy subject to a class-wide challenge, and (2) the "significant risk of reinfection by virtue of the prison environment." (Recommendation (Doc. 38) at 17.) This court agrees with the Magistrate Judge that Policy #CP-7 is correctly viewed as a unitary screening policy designed to both diagnose HCV and provide treatment to certain prisoners. In other words, just as the Magistrate Judge did, this court finds persuasive Plaintiffs' argument that the screening process as a whole may be challenged based upon denial of either step 1 or step 2 screening at the time of filing. (See Pls.' Reply (Doc. 35) at 6–7, 7 n.3.) Therefore, this court finds that the named Plaintiffs do have standing to challenge the HCV screening process.

The Magistrate Judge further relied upon the alleged re-infection risk to both Plaintiffs and potential class members due to inadequate screening to find standing. (Id. at 8; see also Recommendation (Doc. 38) at 17.) Current estimates place the percentage of North Carolina state prison inmates infected with HCV at approximately 17 to 33 percent. (Compl. (Doc. 1) ¶ 48.) The Magistrate Judge found that the risk of re-infection was

substantial,[2] that the named Plaintiffs were "realistically threatened by a repetition" of this harm because it potentially recurs each time an unscreened inmate enters the prison population, Lyons, 461 U.S. at 109, and that this potential "threat of future harm is imminent and a direct result of Policy #CP-7." (Recommendation (Doc. 38) at 18.)

Defendants respond to the alleged re-infection risk by invoking Clapper v. Amnesty Int'l USA, 568 U.S. 398 (2013), where the Supreme Court held that the plaintiffs lacked standing to challenge government email and phone surveillance because a plaintiff "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending." 568 U.S. at 416; see also A.C.L.U. v. Nat'l Sec. Agency, 493 F.3d 644, 662 (6th Cir. 2007) ("[T]he plaintiffs still allege only a subjective apprehension and a personal (self-imposed) unwillingness to communicate."). For example, the plaintiffs in Clapper could not "create" standing by spending money on travel to conduct in-person meetings (to avoid possible surveillance) and then claiming that

[2] This would be true even for inmates who already have HCV and have not been treated, because, according to Plaintiffs' allegations, the condition may "spontaneously clear itself from a patient's blood within six months of exposure." (Compl. (Doc. 1) ¶ 24.) If this occurs, the individual in question will immediately be at risk for re-infection.

they had been injured by this expenditure, because such an injury was not "fairly traceable" to the challenged statute. Clapper, 568 U.S. at 414–15. Here, Defendants argue that there is in fact no risk of re-infection unless Plaintiffs "choose to engage in a behavior that could result in HCV transmission." (Defs.' Objs. (Doc. 40) at 9.)

This court finds some merit in Defendants' argument, but also does not accept the contention that a person would ever affirmatively choose to become re-infected with HCV rather than simply acting in a negligent or reckless manner toward that risk. Defendants point to no binding case law to support a finding that acting negligently or recklessly with regard to a risk of future harm vitiates standing. Using the facts in Clapper as an example, plaintiffs there could have negligently or recklessly exposed themselves to surveillance by failing to encrypt their communications or otherwise making their communications in an open and obvious manner. Had the plaintiffs then suffered some cognizable injury, this court finds that the analysis in Clapper would not necessarily preclude standing because the injury was not intentionally self-inflicted.

This court adopts the Magistrate Judge's conclusion that Plaintiffs have standing to challenge the entirety of Policy #CP-7, including the HCV screening process. However, this court does so based upon a slightly different analysis and relies

primarily on the fact that the two screening tests are properly viewed as a single, unitary process to determine eligibility for DAA treatment. Having concluded that Plaintiffs have standing for that reason, this court finds it unnecessary to determine whether the risk of future re-infection alone provides standing.

V. ADEQUACY

The Magistrate Judge found that Plaintiffs are adequate representatives of the proposed class, pursuant to Fed. R. Civ. P. 23(b)(4). (Recommendation (Doc. 38) at 14.) Defendants now argue, for the first time, that Plaintiffs do not adequately represent the interests of undiagnosed class members challenging the screening process because Plaintiffs either were properly diagnosed through DPS screening or had been diagnosed prior to their incarceration. (Defs.' Objs. (Doc. 40) at 10–11.) Putting aside the issue of whether Defendants have waived this objection by failing to raise it in their first responsive pleading, this court agrees with the Magistrate Judge's conclusion that Plaintiffs are adequate class representatives.

First, the above analysis applies with equal force here. Because the risk of re-infection exists equally for Plaintiffs and unnamed class members, the claims of these two groups are sufficiently aligned. See Deiter v. Microsoft Corp., 436 F.3d 461, 466–67 (4th Cir. 2006) (stating that adequacy, commonality, and typicality "tend[] to merge"). Second, this court finds no

conflict of interest between Plaintiffs and the unnamed potential class members because the same remedy, an injunction requiring universal opt-out screening, could redress the alleged harm suffered by each group.

VI. LIKELIHOOD OF SUCCESS ON THE MERITS

A. Legal Framework

Plaintiffs have moved for a preliminary injunction.[3] (See Doc. 26.) "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008). Such an injunction "is an extraordinary remedy intended to protect the status quo and prevent irreparable harm during the pendency of a lawsuit." Di Biase v. SPX Corp., 872 F.3d 224, 230 (4th Cir. 2017). To demonstrate a likelihood of success on the merits, "[a] plaintiff need not establish a certainty of success, but must make a clear showing that he is likely to succeed at trial." Id.

[3] Because Plaintiffs address only their deliberate indifference claim, and not their ADA claim, in their motion for a preliminary injunction, this court will not evaluate the question of whether a preliminary injunction should issue based on the ADA claim. (See generally Pls.' Inj. Br. (Doc. 27).)

Plaintiffs allege a violation of the Eighth Amendment prohibition of cruel and unusual punishment, under 42 U.S.C. § 1983. To make out this claim, "a prisoner must show that he had a serious medical need, and that officials knowingly disregarded that need and the substantial risk it posed." DePaola v. Clarke, 884 F.3d 481, 486 (4th Cir. 2018). The deliberate indifference prong is subjective: "a prison official may be held liable . . . only if he knows that inmates face a substantial risk of serious harm and disregards that risk by failing to take reasonable measures to abate it." Farmer v. Brennan, 511 U.S. 825, 847 (1994); see also id. at 844 ("[P]rison officials who lacked knowledge of a risk cannot be said to have inflicted punishment."). The Fourth Circuit has emphasized "that considerations of separation of powers and institutional competence suggest the need for judicial restraint before reaching the stern conclusion that prison administrators' conduct constitutes deliberate indifference." Lopez v. Robinson, 914 F.2d 486, 490 (4th Cir. 1990).

The Magistrate Judge found that Plaintiffs established they are likely to succeed on the merits. He first determined that HCV is a serious medical need and then concluded that Defendants had likely been deliberately indifferent to that need. (Recommendation (Doc. 38) at 23–29.) This court agrees with the Magistrate Judge that the ultimate issue is whether, apart from

any professional medical standard or prevailing practice, Defendants' procedures "provide[] prisoners with constitutionally adequate treatment." (Id. at 26.) However, this determination is ordinarily made at a later stage of litigation, either on a motion for summary judgment or by a jury. As the Supreme Court has observed, it is the rare and special case where the evidence is so overwhelming in one direction that a temporary injunction may issue. See Mazurek v. Armstrong, 520 U.S. 968, 972 (1997) (describing a preliminary injunction as "an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion") (quoting 11A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2948 (2d ed. 1995)). Defendants must have subjective knowledge of a substantial risk of serious harm, and whether this knowledge exists is ordinarily a jury question that requires detailed evidence of Defendants' thought process and risk assessment. See, e.g., Torraco v. Maloney, 923 F.3d 231, 234 (1st Cir. 1991).

B. Injunction as to the Named Plaintiffs

This court finds, based upon the testimony of Plaintiffs' expert witness, Dr. Andrew Joseph Muir, that the three individual named Plaintiffs have demonstrated a likelihood of success on the merits sufficient to justify a preliminary

injunction. These Plaintiffs have presented evidence to show that they have HCV and that they have sought and continue to seek treatment. Dr. Muir testified, both in his affidavit and before this court, that Plaintiffs' medical records demonstrate they are candidates for DAA treatment and should receive DAA treatment beginning immediately. (See Pls.' Inj. Br., Amended Affidavit of Dr. Andrew Joseph Muir ("Muir Aff."), Ex. A (Doc. 27-1) ¶¶ 40–50; Tr. of Prelim. Inj. Hr'g (Doc. 51) at 6.) Even at this late stage of the proceedings — following the filing of the Complaint, a hearing on the motion for a preliminary injunction, a Recommendation, and now a second hearing on the preliminary injunction — Defendants present no evidence to contradict Dr. Muir's testimony that Plaintiffs need and have not received treatment. Defendants have offered no explanation for their failure to treat the named Plaintiffs. In all candor, simply failing to treat Plaintiffs for HCV after the presentation of evidence in this case appears to constitute deliberate indifference standing alone, without regard to events prior to the filing of this lawsuit. Therefore, this court will issue a preliminary injunction ordering Defendants to treat the named Plaintiffs with DAAs.

C. Class-Wide Injunctive Relief

Plaintiffs also seek an injunction requiring Defendants to screen and treat all members of the proposed class with DAAs

according to the standard of medical care set out in the AASLD/IDSA Guidance, regardless of an individual's fibrosis level. (See Recommendation (Doc. 38) at 33.)

1. Medical Standard of Care

Plaintiffs and their expert witness, Dr. Muir, repeatedly reference the American Association for the Study of Liver Diseases/Infectious Diseases Society of America ("AASLD/IDSA") Guidance[4] as "the current standard of care." (See Recommendation (Doc. 38) at 25–26; Pls.' Inj. Br. (Doc. 27) at 24.) For example, Dr. Muir testified that the AASLD/IDSA recommendations "are the standard of care for [] practices [in North Carolina]." (Tr. of Motions Hr'g (Doc. 41) at 53.) Dr. Muir proceeded to testify, without citing to any authority, that "typical screening strategies would include all incarcerated individuals, . . . [that] they should be testing everybody[, and that] . . . expecting people to admit to risk factors is a flawed strategy." (Id. at 55.)

However, the choice between competing treatment options is "a matter for medical judgment" that does not constitute deliberate indifference. See Estelle v. Gamble, 429 U.S. 97, 106

[4] It is not clear from the pleadings exactly when this guidance was amended to its current form; it appears that the guidance is continuously updated and that at least the DAA treatment recommendation dates to 2013. (See Compl. (Doc. 1) ¶ 30; see also Defs.' Opp'n Resp. (Doc. 31) at 3.)

(1976) ("A medical decision not to order an X-ray, or like measures, does not represent cruel and unusual punishment. At most it is medical malpractice . . . ."). Further, an aspirational standard does not necessarily identify the deliberate indifference necessary to a § 1983 claim. Defendants' expert, Dr. Anita Wilson, states that "[t]he AASLD/IDSA Guidance does not create a standard of care" and notes that:

> AASLD/IDSA provides a Medical Information Disclaimer, which reads, in part, "[n]othing contained at HCVguidelines.org [where the guidance is published] is intended to constitute a specific medical diagnosis, treatment, or recommendation. The information should not be considered complete, nor should it be relied on to suggest a course of treatment for a particular individual."

(Defs.' Inj. Resp., Affidavit of Anita Wilson, M.D. ("Wilson Aff.") (Doc. 32-1) ¶ 16.) The AASLD/IDSA Guidance itself refers to "Recommended" treatment approaches as opposed to mandatory treatment methods. (Pls.' Inj. Br., Ex. E (Doc. 27-5) at 14.) Therefore, to the extent that Plaintiffs and Dr. Muir rely upon the AASLD/IDSA Guidance, this court finds that the guidance provides some evidence of a preferred public health policy but does not necessarily constitute the standard for judging deliberate indifference.

Further, Dr. Muir candidly acknowledged in testimony before this court and in testimony before the Magistrate Judge that his opinion is the product of two distinct interests: patient care

for prison inmates and a public policy effort to eradicate HCV as a disease. (See, e.g., Tr. of Prelim. Inj. Hr'g (Doc. 51) at 90, 93 ("This is one of the best and strongest opportunities we really have to move towards elimination of hepatitis C in North Carolina.").) This court finds Dr. Muir credible and has no doubt that Dr. Muir's testimony accurately reflects his beliefs and opinions. Deliberate indifference, however, means indifference to inmate care, not to treatment methods intended to benefit society as a whole (for example, by accomplishing the public policy aspiration of eradicating HCV).

At this stage of the proceedings, this court is left with a definite concern regarding Dr. Muir's opinion that the prison's refusal to implement universal opt-out screening or to administer DAAs to all inmates with HCV is a breach of the correctional standard of care. Specifically, that opinion results not only from considerations of necessary patient care but also from general public health concerns and Dr. Muir's aspiration of eliminating HCV. Therefore, this court finds that Dr. Muir's testimony is not entitled to as much weight as Plaintiffs argue. Because deliberate indifference is directed to the Plaintiffs' individual treatment, this court is not persuaded that Plaintiffs have shown a likelihood of success on the merits, based on Dr. Muir's testimony, sufficient to support the broad injunctive relief requested.

In addition, the AASLD/IDSA Guidance itself also reflects, at least in part, the laudable medical goal of eradicating HCV in society as a whole. For example, the Guidelines state that "the success of the national HCV elimination effort will depend on identifying chronically infected individuals in jails and prisons, linking these persons to medical care for management, and providing access to antiviral treatment." (Wilson Aff., Ex. B (Doc. 48-2) at 11.) Similarly, the Guidelines state that "HCV DAA therapy for chronic HCV is now logistically feasible within the prison setting and would aid the HCV elimination effort." (Id. at 13.) While these goals are commendable and desirable, they are also aspirational objectives and thus do not provide a standard for evaluating deliberate indifference in the prison system.

Dr. Muir also acknowledges that he has no experience practicing medicine in a correctional setting. (Tr. of Motions Hr'g (Doc. 41) at 62.) This is an important fact, because Dr. Muir is attempting to take the standard of care applicable to individuals who voluntarily seek treatment and apply this standard to universal screening and treatment of a prison population. Universal screening of any discrete population is a public health policy decision, not a basis for deliberate indifference under § 1983. Plaintiffs may ultimately prove that Dr. Muir's opinions and the AASLD/IDSA Guidance require certain

levels of treatment in North Carolina prisons. However, this court is not persuaded as to whether this treatment standard constitutes what is necessary for appropriate medical care because the opinions are offered based upon two goals: optimal patient care and eradication of the disease in society as a whole.

2. Availability of Medical Resources

This court finds that the limited availability of medical resources in the prison context has at least some bearing on the deliberate indifference inquiry.[5] Cost and resource scarcity is not a complete defense to a deliberate indifference claim "because prison officials may be compelled to expand the pool of existing resources in order to remedy continuing Eighth Amendment violations." Peralta v. Dillard, 744 F.3d 1076, 1083 (9th Cir. 2014); see also Wilson v. Seiter, 501 U.S. 294, 300

[5] While this factor also bears on the public interest prong of the preliminary injunction analysis, Defendants have not objected to that specific portion of the Recommendation. (See Recommendation (Doc. 38) at 31.) This court reviews any part of the Recommendation that is not objected to under a clearly erroneous standard. This court does not find that the Magistrate Judge's analysis of the public interest factors was clearly erroneous; rather, this court finds that resource availability or scarcity is relevant to the deliberate indifference analysis as well. Diamond, 416 F.3d at 315. Alternatively, this court finds that it may conduct a de novo review of the public interest analysis because the preliminary injunction inquiry is akin to a balancing test, see Amoco Prod. Co. v. Vill. of Gambell, 480 U.S. 531, 542 (1987), and all factors must be considered in arriving at a decision regarding the Magistrate Judge's ultimate recommendation to grant the injunction.

(1991). Some courts, however, have recognized that evidence of resource scarcity may properly be considered to determine knowledge or intent. See, e.g., Peralta, 744 F.3d at 1085 ("The jury had sufficient evidence on which to base a finding that a lack of resources caused any delay in providing dental care."); Ralston v. McGowan, 167 F.3d 1160, 1162 (7th Cir. 1999) ("[T]he civilized minimum is a function both of objective need and of cost.").

Here, both Defendants and Plaintiffs' own expert witness concede that the provision of new medicines and treatment options, especially when these medicines are costly, is always dependent to some degree on resource availability. Dr. Muir testified before the Magistrate Judge that Medicaid modified its coverage to include treatment of HCV with DAAs in 2017, but previously reimbursed for DAA treatment only if the patient had a FibroSure score of F2 or higher. (Tr. of Motions Hr'g (Doc. 41) at 42.) Before this court, Dr. Muir explained that he has participated in DAA clinical trials since approximately 2009 and regularly treated clinic patients with DAAs since approximately 2014, in accordance with his stated standard of care. (Tr. of Prelim. Inj. Hr'g (Doc. 51) at 11.) Dr. Muir then candidly acknowledged that, although he did not treat Medicaid patients with a fibrosis level below F2 with DAAs until Medicaid approved coverage for that treatment in 2017, Dr. Muir himself believes

that his treatment of those pre-2017 Medicaid patients fell below the applicable standard of care. (Id. at 13.)

While this court appreciates Dr. Muir's candor, his testimony merely reflects what is generally true: patient treatment is often a product of resources and circumstances. In an ideal setting, all individuals with HCV could and would be treated with DAAs upon receiving a diagnosis. However, medical care in the prison setting must be adequate, not necessarily ideal, and HCV treatment in the prison system is dependent upon the availability of resources. As the AASLD/IDSA Guidance recognizes:

> To expand HCV testing and prevention counseling and increase access to HCV therapy in correctional institutions, it will be necessary to overcome several important barriers. First, appropriately trained staff are needed to screen inmates for HCV infection and, depending on the result, provide counseling on HCV prevention, linkage to care, and access to antiviral treatment. . . .
>
> Second, unplanned transfers and releases could disrupt ongoing HCV treatment. Most state correctional facilities do not have a process in place to smoothly transition a patient receiving DAA treatment in a prison setting to continuing community-based care without a lapse in antiviral therapy. . . .
>
> Finally, the costs of HCV testing and antiviral treatment in correctional facilities are also formidable barriers.

(Wilson. Aff., Ex. B (Doc. 48-2) at 13–14.) These barriers are consistent with Dr. Wilson's observation that "[i]mplementing the preliminary relief requested by Plaintiffs would require an

extensive overhaul of the Department's health services operations, including logistical considerations, such as patient travel and housing assignments, physical facility capabilities and human resource capabilities." (Wilson. Aff. (Doc. 32-1) ¶ 8.) These considerations, coupled with Dr. Muir's testimony recognizing the limits of his own ability to properly treat Medicaid patients for a period of time, all suggest Plaintiffs' evidence does not establish that implementing the requested relief of universal opt-out screening and DAA treatment within the North Carolina prison system is either reasonable or feasible at this time.

Further, Dr. Muir's testimony as to the appropriate standard of care within the prison system as a whole is of limited applicability in this preliminary proceeding because, as previously mentioned, Dr. Muir has no experience treating patients in a correctional setting. This court also accords very limited weight to Dr. Muir's testimony regarding the potential cost of providing DAAs to a large group of prison patients. Dr. Muir testified before the Magistrate Judge that the wholesale cost of Mavyret, a common DAA drug used to treat HCV, "is in the 25,000-dollar range." (Tr. of Motions Hr'g (Doc. 41) at 45.) Before this court, Dr. Muir further testified that, based on his experience overseeing and providing guidance to pharmacy benefit managers, "it is well known that [the price of DAAs] is lower

than [$25,000 per course of treatment].” (Tr. of Prelim. Inj. Hr’g (Doc. 51) at 88.) However, Dr. Muir conceded on cross-examination that he did not have any basis for concluding that Defendants specifically would be able to obtain any DAA medication at an amount below $25,000. (Id. at 94.) At the current stage of these proceedings, this court finds that Plaintiffs have provided no credible evidence to suggest that the cost to Defendants is anywhere below $25,000 per course of treatment.

3. Prioritization

Plaintiffs next contend that the DPS “policy permit[ting] DAA treatment only for patients at stage F2 and higher, with one exception: patients with a lower level of fibrosis but who are also infected with HIV or hepatitis B may also receive treatment,” is deliberately indifferent to a serious medical need. (Compl. (Doc. 1) ¶ 95.) Dr. Muir asserts that the “[s]tandard of care now would be for [DAA] treatment of all patients regardless of fibrosis stage.” (Tr. of Motions Hr’g (Doc. 41) at 56.) Defendants’ policy of prioritizing certain patients, however, is generally consistent with the AASLD/IDSA Guidance, which recognizes that “in certain settings . . . clinicians may still need to decide which patients should be treated first.” (Pls.’ Inj. Br., Ex. E (Doc. 27-5) at 14.) This is especially true in the prison setting, where other

complicating factors may require such an approach. Further, Dr. Wilson states that the standard of care for DAA treatment allows for the "necessity of prioritizing patients for treatment" and notes the importance of using "patient specific data, including drug interactions" to determine whether DAA treatment is appropriate. (Wilson Aff. (Doc. 32-1) ¶¶ 28, 32.)

Plaintiffs argue, and the Recommendation finds, that "Policy #CP-7 does not create a priority list, but rather determines who will or will not receive treatment at all. An inmate that has a fibrosis level below F2 is ineligible for DAAs." (Recommendation (Doc. 38) at 27.) Plaintiffs are correct that Policy #CP-7 states that only those prisoners with FibroSure scores of F2 or higher "should be referred for treatment" and that other prisoners with HCV should be continuously monitored but should not receive treatment. (See Pls.' Inj. Br., Ex. B. (Doc. 27-2) at 8.) This language is certainly not drafted in the form of a priority list. However, the policy is also not a final determination of who will or will not receive treatment. Instead, Policy #CP-7 is prefaced with the following directive:

> DOP Primary Care Providers are expected to follow this guideline except when in their professional judgment on a case-by-case basis there is reason to deviate from these guidelines. If a deviation is made the PCP will document in the medical record any deviations from this guideline and the reasoning behind the need for any deviation.

(Wilson Aff., Ex. D (Doc. 32-6) at 1.)

Policy #CP-7 is consistent with both Dr. Muir's testimony and the AASLD/IDSA Guidance. Dr. Muir acknowledges that the attending physician must have discretion to deal with individual patient circumstances. (See Tr. of Prelim. Inj. Hr'g (Doc. 51) at 17 ("[Y]ou can't possibly predict all the different other medical issues or other things that may impact a recommendation for a specific patient.").) The AASLD/IDSA Guidance provides that "[n]othing contained at HCVguidelines.org is intended to constitute a specific medical diagnosis, treatment, or recommendation." (Wilson Aff., Ex. B-1 (Doc. 32-4) at 1.) Dr. Wilson states, consistent with the need for individualized treatment recognized by Dr. Muir, that "[t]he AASLD/IDSA Guidance does not create a standard of care to be used in place of individualized medical assessments." (Wilson. Aff. (Doc. 32-1) ¶ 16.)

This court declines to make a specific finding as to whether Policy #CP-7 constitutes a mandatory course of treatment rather than guidance that a physician may properly deviate from where necessary or appropriate in his or her medical judgment. As previously noted, this court is concerned by: (1) the use of aspirational public health goals to establish deliberate indifference in the prison context, and (2) the limited medical

resources available to a correctional institution. For those reasons, this court finds that Plaintiffs have failed to prove a likelihood of success in showing that the current standard of care in the prison setting requires treatment of all prisoners with DAAs. Therefore, Plaintiffs have not justified their request for an injunction ordering Defendants to provide DAA treatment to all prisoners diagnosed with HCV.

However, Plaintiffs do raise substantial doubts about whether Policy #CP-7 is deliberately indifferent to the medical health of prisoners, without regard to the AASLD/IDSA Guidance. First, Plaintiffs contest the accuracy of the FibroSure test itself, (see, e.g., Tr. of Prelim. Inj. Hr'g (Doc. 51) at 72), and Defendants do not appear to defend the accuracy of the test. Further, the fact that Medicaid recently approved treatment with DAAs for all patients suffering from HCV, (see id. at 11), suggests a medical consensus in favor of broader DAA treatment. This court finds that Plaintiffs have failed to satisfy their burden of justifying a preliminary injunction that orders DAA treatment for all prisoners with HCV. However, to address the acknowledged issues with the current policy — including the fact that the policy might be construed to prohibit or prevent doctors from administering DAAs to any prisoner with HCV whose FibroSure score is below F2 — this court will enjoin Policy #CP-7 in its entirety.

4. Relevant District Court Decisions

Under the specific facts of the case, this court does not find Defendants' current treatment approach to be so grossly inadequate that, standing alone, it justifies the sweeping injunctive relief requested by Plaintiffs.[6] This court is aware that another district court recently granted a preliminary injunction on a similar § 1983 claim. See Hoffer v. Jones, 290 F. Supp. 3d 1292 (N.D. Fla. 2017). However, the facts in that case were substantially worse: the Florida Department of Corrections (the "FDC") had allegedly provided DAAs to only thirteen out of approximately 7,000 inmates with HCV. Id. at 1294, 1298. Here, DPS has treated 589 inmates with DAAs, out of

[6] Of the two cases cited by the Magistrate Judge to support this assertion, one found no deliberate indifference by prison officials. Torraco, 923 F.2d at 235–36. The second case dealt with a prison doctor's unilateral decision to terminate an inmate's medication. Smith v. Jenkins, 919 F.2d 90, 92 (8th Cir. 1990). The situation here, where Defendants are actively treating prisoners under a policy that Plaintiffs contend is inadequate, is far removed from the facts in Smith. Smith also found deliberate indifference at the summary judgment stage; given the extraordinary nature of a preliminary injunction, it follows that the weight of evidence needed to establish success in this context is greater.

1,543 total identified HCV cases.[7] (Compl. (Doc. 1) ¶¶ 48–49.) In Hoffer, the FDC's own expert witness testified that the FDC's HCV treatment program was inadequate and "that an injunction is necessary for FDC to respond to this problem with the requisite alacrity." 290 F. Supp. 3d at 1303. In a similar case, Abu-Jamal v. Wetzel, the court also issued a preliminary injunction but based its merits finding on the fact "that the DOC's own expert testified he would recommend" DAA treatment for prisoners not currently receiving such treatment. No. 3:16–CV–2000, 2017 WL 34700, at *18 (M.D. Pa. Jan. 3, 2017). Crucially, in each case, this expert testimony was probative evidence of the defendant's subjective knowledge — an element not present here.[8]

Plaintiffs have not established a likelihood of success on the merits sufficient to require broad injunctive relief based upon deliberate indifference. Plaintiffs have raised legitimate concerns and may ultimately prevail, but this court is not able

[7] Defendants also argue that the DPS procedure for administering DAAs is "qualitatively different than either protocols at issue" in the Hoffer and Abu-Jamal cases, because DPS offers DAA treatment at an earlier stage. (Wilson. Aff. (Doc. 32–1) ¶ 40.) While reserving any judgment on the issue, this court finds the assertion by Defendants' expert suggests at least some disparity between the DPS policy and those at issue in other cases, moving this out of the realm where a preliminary injunction might be appropriate.

[8] Neither the plaintiffs in Hoffer nor the plaintiffs in Abu-Jamal challenged the HCV screening process, only the process of determining which prisoners would receive DAAs.

to say at this point that either (1) the lack of universal opt-out screening for HCV, or (2) a policy of providing DAA treatment only to certain prisoners, with discretion to the attending physician to alter treatment on an individualized basis, is so likely to constitute deliberate indifference that Plaintiffs have met the standard for a preliminary injunction on those requests.

5. Contraindications

While declining to grant the sweeping injunctive relief that Plaintiffs request, this court does find that Plaintiffs have established a likelihood of success in proving that certain specific aspects of Policy #CP-7 constitute deliberate indifference. First, Policy #CP-7 provides that HCV treatment is contraindicated if the "[i]nmate will be incarcerated for an insufficient period of time to complete treatment. Usually a twelve (12) month period would be required to complete assessment and treatment for Hepatitis C." (Pls.' Inj. Br., Ex. B (Doc. 27-2) at 6.) Under this policy, it appears that any prisoner, including a prisoner with a FibroSure score of F2 or higher, is precluded from receiving treatment if HCV is diagnosed within one year of that prisoner's projected release date. However, there appears to be no dispute that DAA treatment is (1) necessary and appropriate for all prisoners with severe HCV (at the F2 or higher level), (2) capable of being fully

administered within eight to twelve weeks with minimal required follow-up, and (3) highly effective. (See Tr. of Prelim. Inj. Hr'g (Doc. 51) at 18–19.) Therefore, this court finds that the current policy is likely deliberately indifferent in the sense that it denies treatment to prisoners with advanced HCV who could in fact complete a full course of DAA treatment before being released. Defendants acknowledged this fact during the March 8, 2019 preliminary injunction hearing. (See id. at 49 (stating that Defendants intend to shorten the release date contraindication).)

This court further finds that the contraindication denying treatment to prisoners with "infractions related to the use of alcohol or drugs in the last twelve (12) months," (Pls.' Inj. Br., Ex. B (Doc. 27-2) at 6), is not justified by any medical reason or legitimate prioritization concern. (See Muir Aff. (Doc. 27-1) ¶ 37.) Defendants have provided nothing to refute Dr. Muir's statement that this contraindication is not justified. Therefore, Plaintiffs have shown a high likelihood of proving that this specific policy is deliberately indifferent to a serious medical need.

This court makes the same general finding with respect to the contraindications that deny treatment due to unstable medical or mental health conditions and life expectancy. Dr. Muir states that the medical or mental health contraindication

is "a holdover from the days of treatment with interferon-based regimens" and is not appropriate for DAA treatment. (Id. ¶ 35.) Dr. Muir further attests that the ten-year life expectancy contraindication "is not the standard for treatment of HCV" and should be shortened. (Id. ¶ 34.) At the March 8, 2019 preliminary injunction hearing, Defendants did not attempt to justify these contraindications or argue that they in fact reflect the current standard of care in a prison context. Instead, Defendants implicitly admitted that all contraindications, except for patient refusal, are problematic under the deliberate indifference standard. (See Tr. of Prelim. Inj. Hr'g (Doc. 51) at 52 ("[T]he contraindications are an issue; that will soon no longer be an issue.").)

Defendants have submitted a copy of an updated HCV screening and treatment policy that is set to take effect on March 25, 2019.[9] (See Docs. 52, 52-1.) This policy appears, on initial review, to be based primarily on guidance promulgated by

[9] This draft policy does not moot the claims presently pending before this court. First, the policy is not yet in effect. And, second, "a defendant's voluntary cessation of a challenged practice moots an action only if subsequent events ma[ke] it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." Wall v. Wade, 741 F.3d 492, 497 (4th Cir. 2014) (quoting Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 189 (2000)).

the Federal Bureau of Prisons.[10] This court finds it inappropriate at the current stage of proceedings to evaluate this new policy in terms of the requested preliminary injunction, especially because Plaintiffs have not had a chance to respond. Rather, this court will instead issue its order based on the existing Policy #CP-7, which has been extensively argued and briefed by the parties.

In light of the proposed new policy, this court will grant the requested class-wide preliminary injunction in part and enjoin Policy #CP-7 in its entirety to address the issues identified in this opinion — namely, the accuracy and reliability of the FibroSure test, the use of contraindications (other than patient refusal), and the potential for the current policy to prevent treatment of prisoners below the F2 level. As previously stated, however, this court declines at this time to order Defendants to provide universal opt-out screening or to provide DAA treatment to all class members. While Plaintiffs have shown some possibility of success on these issues, this

[10] To the extent that Defendants endorse the Federal Bureau of Prisons as the source of the current medical standard of care in a prison setting, (see Doc. 52-1 at 3), Defendants should be prepared at a later stage of this case to justify their argument that universal opt-out screening is not required under this standard. See Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection, https://www.bop.gov/resources/pdfs/012018_hcv_infection.pdf, at 2 ("Testing for HCV infection is recommended for . . . all sentenced inmates.").

court is not persuaded that Plaintiffs have shown a likelihood of success in proving that adherence to the AASLD/IDSA Guidance is necessary to avoid deliberate indifference.

VII. CONCLUSION

For the foregoing reasons, this court finds that the Magistrate Judge's analysis regarding Plaintiffs' class certification motion should be adopted and that motion will be granted. This court further finds that, while the named Plaintiffs are entitled to injunctive relief, Plaintiffs have not shown a likelihood of success on the merits as to certain aspects of their class-wide preliminary injunction request. Therefore, Plaintiffs' motion for a preliminary injunction will be granted in part and denied in part as set forth herein.

IT IS THEREFORE ORDERED that the Magistrate Judge's Recommendation, (Doc. 38), is **ADOPTED IN PART** in accordance with the foregoing analysis.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Certify Class, (Doc. 3), is **GRANTED** and that the class be defined as "all current and future prisoners in DPS custody who have or will have chronic hepatitis C virus and have not been treated with direct-acting antiviral drugs."

IT IS FURTHER ORDERED that Lloyd Buffkin and Robert Parham are named as class representatives and that Plaintiffs' counsel is appointed as class counsel.

IT IS FURTHER ORDERED that Plaintiffs' Motion for Preliminary Injunction, (Doc. 26), is **GRANTED IN PART AND DENIED IN PART** as set forth herein, in that Plaintiffs' request for a preliminary injunction ordering Defendants to provide DAA treatment to the named Plaintiffs is **GRANTED**, Plaintiffs' request for an injunction ordering Defendants to cease denying DAA treatment based on contraindications, other than patient refusal, and to cease denying DAA treatment based solely on a prisoner's FibroSure score, is **GRANTED** in that Policy #CP-7 is hereby **ENJOINED** in its entirety, and Plaintiffs' request for a preliminary injunction ordering Defendants to institute universal opt-out screening and to treat all class members with DAAs regardless of fibrosis level is **DENIED.**

This the 20th day of March, 2019.

William L. Osteen, Jr.
United States District Judge