UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

CHARLES GRAHAM aka CHARLES STEVENSON and RUSSELL L. DAVIS, on behalf of themselves and all others similarly situated,	)	
Plaintiffs,	)	
v.	)	**No. 3:16-CV-1954**
TONY C. PARKER, Commissioner, Tennessee Department of Corrections; DR. MARINA CADRECHE, Assistant Commissioner of Rehabilitative Services, Tennessee Department of Corrections; and DR. KENNETH WILLIAMS, Medical Director, Tennessee Department of Corrections, in their official capacities,	)	**Judge Crenshaw** **Magistrate Judge Brown**
Defendants.	)	

PLAINTIFFS' REPLY TO DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO CERTIFY CLASS

Plaintiffs, through undersigned counsel, submit this reply to Defendants' Response in Opposition to Plaintiffs' Motion to Certify, Dkt. No. 20 ("Response"), under Rule 23 of the Federal Rules of Civil Procedure. The Court should grant Plaintiffs' motion for class certification because Plaintiffs satisfy the requirements of Rule 23 and this action can be most efficiently resolved as a class action.

STATEMENT OF FACTS

Defendants' response seeks to downplay the harm caused by the Tennessee Department of Corrections' ("TDOC" or "Department") failure to treat inmates with the Hepatitis C virus ("HCV") with direct acting antiviral ("DAA") medications now widely available on the market.

Simultaneously, Defendants overstate TDOC's protocol for treating HCV by equating testing and monitoring with treatment.

HCV attacks the liver and causes an inflammation of the liver called hepatitis. The inflammation can significantly impair the liver's ability to filter toxins from the blood, digest essential nutrients, and prevent disease. TDOC's current guidance on the testing, managing and treatment of HCV acknowledges that chronic HCV can also lead to chronic liver disease, liver fibrosis, and death. Complaint, Dkt. 1 ("Compl."), ¶¶ 1, 31; Compl., Exhibit A, Dkt. 1-1. HCV infections occur in two stages. Acute HCV infection is the initial phase within the first six months of contracting the virus. (Declaration of Michael S. Saag, M.D. ¶ 5, Attached as Exhibit "A") [hereinafter Saag Dec.]). During this initial period, roughly 15% to 20% of infected individuals resolve the infection. *Id.*

After this initial period, the infection moves into the chronic phase. *Id*. at ¶ 6. Chronic HCV does not resolve. Infected individuals will have HCV for life if not treated with appropriate medications. *Id*. DAAs can cure the infection. Current guidance from the HCV Guidance Panel, a joint panel comprised of individuals from the American Association for the Study of Liver Diseases ("AASLD") and the Infectious Diseases Society of America ("IDSA") (the "Panel"), recommends treatment with DAAs for all patients diagnosed with chronic HCV. *Id.* ¶¶ 2, 7. The AASLD/IDSA Panel convened in 2013 to address the rapidly changing landscape of HCV treatment due to the introduction of DAA therapies around 2011. *Id.* ¶ 2 The Panel publishes guidance entitled HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, the latest iteration of which was released in October 2016. *Id.*

The current Panel guidance is for every person with chronic HCV to be treated with one of the many DAAs now available. While earlier iterations of the guidance suggested prioritizing

treatment for those in the most advanced stages of the disease, given the rapid advancement in DAAs, there is simply no medical reason not to treat everyone.[1] *Id.* at ¶ 7. TDOC's protocol does not follow the Panel's guidance and instead prioritizes treatment among inmates based on the severity of complications from the virus. In their response, Defendants state that all inmates that test positive for HCV receive "monitoring treatment." This is not treatment. *Id.* ¶ 11. Monitoring serves no purpose unless it leads to treatment with medication. *Id.* The Response admits that TDOC's protocol denies meaningful treatment to all inmates except those with the most advanced damage from HCV. The protocol therefore varies wildly from the accepted and recommended treatment standards for chronic HCV that all person's infected should be treated with DAAs, which have a high likelihood of curing the infection and avoiding any further complications or damage from the virus.

Consequently, Named Plaintiffs and other inmates have not received the necessary medical treatment for HCV, including the latest DAA, and have a substantially increased risk of continued HCV infection, liver disease, liver cancer, cirrhosis, and death. See Compl. Dkt. 1 ¶¶ 1, 31; Compl., Exhibit A, Dkt. 1-1.

ARGUMENT

Defendants attack Plaintiffs' Motion on all four requirements of Rule 23(a) and at least one of the three requirements in Rule 23(b)(2) of the Federal Rules of Civil Procedure. While the court must conduct a "rigorous analysis" to determine if the Rule 23 prerequisites are met, *Gen. Tel. Co. of the Southwest v. Falcon*, 457 U.S. 147, 161 (1982), class certification depends only on the requirements of Rule 23, and not on the plaintiff's likely success on the merits of the case.

[1] The Panel recognizes certain medical exclusions to this general rule, such as: life expectancy < 12 – 18 months owing to other diseases; pregnancy (which by definition is self-limited); and willingness to take or adhere to the medical regimen. Saag Decl. ¶ 7.

Weathers v. Peters Realty Corp., 499 F.2d 1197, 1201 (6th Cir. 1974) (citing *Miller v. Mackey Int'l.*, 452 F.2d 424, 427 (5th Cir. 1971)). Defendants' Response seeks to claim victory on the merits of the case and, thereby, argues that certification of a class would be improper. Defendants are putting the cart before the horse.

A. The Inmate Class satisfies Rule 23(a)(1) because joinder of all Class members would be impracticable.

Defendants argue that Plaintiffs fail to meet the numerosity requirement of Rule 23(a)(1) because the potential class members could each, individually bring their own lawsuit, stating that inmates "can and do bring claims pro se and in forma pauperis." Response, p. 6. While it is undoubtedly true that inmates can and often do bring claims, this argument is universal to all class actions on whatever topic. Numerosity is not defeated simply because individuals can, in theory, bring a separate lawsuit seeking relief.

The purpose of the requirement is to ensure that a Class Action lawsuit is an effective vehicle to resolve many claims at once. For this reason, the Sixth Circuit grants a "presumption that joinder is impracticable" for classes in which the number of class members reaches forty. *Daffin v. Ford Motor Co.*, 458 F.3d 549, 552 (6th Cir. 2006); *City of Goodlettsville v. Priceline.com, Inc.*, 267 F.R.D. 523, 529 (M.D. Tenn. 2010). The Inmate Class numbers well into the thousands of plaintiffs and, therefore, should be presumed to be impractical because of its size alone. *See Daffin*, 458 F.3d at 552; *see also Priceline.com, Inc.*, 267 F.R.D. at 529. In fact, Defendants concede that there are "over 20,000 inmates in the system," a number so high as to make some litigation tasks "extremely taxing." Response, p. 7.

Joinder is impracticable not just because of the substantial size of the putative Class, but because of the situation in which potential Class members find themselves. In fact, courts have often observed that joinder of prisoners is particularly onerous.

> [There are] pervasive impracticalities associated with multiple-plaintiff prisoner litigation, which militates against permissive joinder even if it were otherwise allowed by *Rule 20(a)*. Among the difficulties noted are the need for each plaintiff to sign every pleading, and the consequent possibilities that documents may be changed as they are circulated, or that prisoners may seek to compel prison authorities to permit them to gather to discuss the joint litigation. . . . Moreover, it often results in pleadings being filed on behalf of plaintiffs without their consent.

Proctor v. Applegate, 661 F. Supp. 2d 743, 779-80 (E.D. Mich. 2009) (internal citations and quotations omitted).

It is difficult to imagine that proceeding with thousands of *pro se* litigations, each of whom will commence litigation with his or her own *in forma pauperis* petition, would be an efficient use of the Court's resources. For all these reasons, the Inmate Class satisfies Rule 23(a)(1)'s numerosity requirement. The substantial size of the Class, the geographic diversity of the Class members, and the unlikelihood that the Class members would – or could – bring separate suits, or join together in a non-class suit, weigh in favor of certification under Fed. R. Civ. P. 23(a)(1).

Defendants also attack Plaintiffs' class definition, claiming that it is not definite enough to satisfy Rule 23(a). Defendants complain that the term "currently" is not definite enough without a fixed date and that inmate release dates vary and may require individualized and continuous calculations. Response, p. 7. Defendants are complaining, in essence, that Plaintiffs' class is a "fluid class," meaning that members of the class, including the named Plaintiffs, may become moot because of the transitory nature of the class or because Defendant has the ability to moot claims by providing the requested relief. *See Lebron v. Wilkins*, 277 F.R.D. 664, 667 (M.D. Fla. 2011)("The Court finds that there is specific evidence in the record to conclude that the putative class members are so numerous that joinder would be impracticable, especially where, as here, Plaintiff alleges a class-wide constitutional violation across a highly fluid class of citizens."). Classes made up of individuals in institutions, whether prisons, schools, or medical facilities, all

face this common issue. Class members may leave the institution and no longer be part of the Class. This feature of the class as defined in Plaintiffs' complaint does not weigh against certification. It weighs in favor of certification. *Reynolds v. Giuliani*, 118 F. Supp. 2d 352, 391–92 (S.D.N.Y. 2000)("This case involves a fluid class where the claims of the named plaintiffs may become moot prior to completion of this litigation").

The very nature of injunctive relief often includes an outcome where relief is granted for current and future class members. In *Jackson v., Danberg,* the district court found that the numerosity requirement had been met by a class of sixteen inmates because the nature of the class, and the relief sought, lends itself to an ever changing class. 240 F.R.D. 145, 147 (D.Del. 2007). "[A]lthough the identity of the members of the putative class may change, the defining characteristics and the parameters of the class will remain the same."

The Inmate Class is definite and objectively measurable such that the Court can easily determine whether a particular individual is a member of the Class. The Class is limited in time to persons who are incarcerated in a facility operated or supervised by the Department and who have a current diagnosis of HCV or who are diagnosed with the virus after proper screening by TDOC.

Essentially, inmates either have the virus or they do not. If they have contracted the virus, they are part of the Class. An inmate who meets this objective criteria would be a Class member because they are subject to unconstitutionally deficient medical care by the Department for their HCV.

The size of a potential class and the need to review individual files to identify its members are not reasons to deny class certification. *See Young v. Nationwide Mut. Ins. Co*., 693 F.3d 532, 539–40 (6th Cir. 2012)("Several other courts have found that the size of a potential class and the

need to review individual files to identify its members are not reasons to deny class certification.") Therefore, while some current Class members may be released for varying reasons, Defendants and TDOC should have no trouble determining which inmates have the disease and would be subject to any injunctive relief won at the conclusion of the lawsuit.

B. Plaintiffs satisfy Rule 23(a)(3) because their claim is typical of the class they seek to represent.

Defendants next assert that each Class member's claim relies on the individual merit of their own case and, therefore, fails to meet the typicality and commonality requirements of Rule 23(a)(2) and (3). Response, pp. 9-14. However, injunctive actions, by their very nature, present common questions satisfying Rule 23(a)(2) because there are "questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). They also do not involve an individualized inquiry for the determination of damages. A proposed class satisfies the commonality requirement of Rule 23(a)(2) if the class members' claims "depend on a common contention" and that common contention is "of such a nature that it is capable of classwide resolution." *Wal-Mart Stores, Inc.*, 564 U.S. at 350.

Plaintiffs satisfy Rule 23(a)(2) because there are questions of both law and fact that pertain to all members of the Inmate Class and are capable of class-wide resolution such that it will advance the litigation. Defendants cite several cases concerning HCV treatment to demonstrate the individual proof needed to determine whether treatment was warranted. Response, pp. 10-13. These cases are wholly irrelevant to the question of certifiability. First, these cases go to the constitutionality of individualized courses of treatment provided to particular prison litigants suffering from HCV infection. In other words, these are merits cases that do not inform the Court's analysis of whether the currently proposed Class satisfies the strictures of Rule 23. For example, Defendants repeat throughout their brief that that they provide "monitoring" of the progression of

the disease, which, they argue, is sufficient treatment for many. *See* Response, pp. 2 ("the Department provides ongoing monitoring treatment"), 19 ("monitoring liver constituted treatment"), 20 (same), 22 ("many persons with Hepatitis C require no drug treatment at all, but only monitoring"). Of course, from a medical standpoint, this is patently incorrect. Monitoring is not treatment. Saag Dec., ¶ 11. In fact, "[m]onitoring serves no purpose unless it leads to treatment with medication." *Id*. However, questions about the appropriate type of treatment to provide members of the Class is a merits question to be resolved after both fact and expert discovery. That Defendants already provide some medical attention, even if wholly inadequate, is not relevant to the question of class certification.

Second, many of these cases predate the introduction of DAA medications and the change in treatment standards for those infected with HCV. *See* Saag Dec., ¶ 7 (explaining that "earlier iterations of the guidance suggested prioritizing treatment for those in the most advanced stages of the disease," which differentiation has been mooted by the current guidance). In fact, Dr. Williams himself concedes that the currently accepted medical standard is "to treat all patients diagnosed with HCV." Affidavit of Kenneth Williams, Dkt. No. 20-1, ¶ 5. Because guidance on DAAs is so new, case law that predates this medical advancement are inapplicable given the current treatment standards.

Finally, the cases cited by Defendants are not applicable to the central questions presented in suit. In fact, these cases wholly mischaracterize Plaintiffs' claims in this case. The cases Defendants cite involve requests for specific treatment for an individual inmate with HCV and, often, monetary damages. In this case, however, Plaintiffs make a blanket challenge to the Department's official protocol and system-wide practices for HCV diagnosis and treatment, seeking only non-monetary forms of relief. In other words, Plaintiffs challenge the

constitutionality of the Department's policies, not individual courses of treatment. Whether the Defendants' failure to diagnosis and treat HCV in inmates with the most recent and generally accepted standard of treatment violates the Eighth Amendment to the United States Constitution is a question of general applicability to the Class and does not depend on individualized medical determinations. This question is common to all Class members because all are incarcerated and subject to TDOC's treatment protocols and policies regarding treatment for HCV. *See Saur v. Snappy Apple Farms, Inc.*, 203 F.R.D. 281, 287 (W.D. Mich. 2001) ("In cases involving the question of whether a defendant has acted through an illegal policy or procedure, commonality is readily shown because the common question becomes whether the defendant in fact acted through the illegal policy or procedure.") (citing *Van Vels v. Premier Athletic Ctr. of Plainfield, Inc.*, 182 F.R.D. 500, 507 (W.D.Mich. 1998) (collecting cases)).

Questions of fact further satisfy the commonality requirement. The factual question of whether the Department's treatment protocols and policies adequately screen for, diagnose and treat inmates with HCV applies to all proposed Class members. Questions regarding what is the standard of care for treating HCV likewise apply to all Class members. Resolution of these questions, and others, will involve facts common to all members of the Class and will materially advance the litigation.

For these reasons, courts in this Circuit routinely certify as class actions challenges to a correctional department's policies and blanket practices. *See, e.g.*, *Johannes v. Washington*, No. 14-CV-11691, 2015 WL 5634446, at *6 (E.D. Mich. Sept. 25, 2015) ("As for typicality and commonality, if the legal claims in this case are merely challenges to the constitutionality of MDOC's dental policies in the abstract, there would be *no* difference between any class member's claims . . . . This is the essence of commonality and typicality.") (citing *Wal-Mart*, 131 S. Ct. at

2551 & n.5); *Turner v. Grant Cty. Det. Ctr.*, No. CIV.A. 05-148-DLB, 2008 WL 821895, at *15 (E.D. Ky. Mar. 26, 2008) ("Ordinarily, whether Defendants' alleged policies and/or practices for each class violate the Eighth Amendment would be a question common to Plaintiffs' proposed classes.").

> Cases involving enforcement of a uniform policy or procedure, including those relating to prisoners, are often approved as class actions because they involved questions of fact and law common to all members. Clearly each individual member of the class has a unique situation and has been affected in diverse ways by the alleged discriminatory policy. That there are differences in situation and effect does not preclude a finding by this Court of commonality. That each class member's case is in other ways unique does not affect the commonality of the action, as long as the members of the class have allegedly been affected by a general policy of the defendant, and the general policy is the focus of the litigation.

Dowdy-El v. Caruso, No. 06-11765, 2012 WL 6642793, at *4 (E.D. Mich. Aug. 15, 2012), report and recommendation adopted, No. 06-11765, 2012 WL 6642763 (E.D. Mich. Dec. 20, 2012) (citing *Glover v. Johnson,* 85 F.R.D. 1 (E.D.Mich.1977)) (internal citations omitted) (collecting cases).

For the same reasons, courts across the country routinely certify as class actions challenges to a correctional department's policies and blanket practices. *See, e.g.*, Parsons v. Ryan, 754 F.3d 657, 678 (9th Cir. 2014) (citing *Wal–Mart,* 131 S.Ct. at 2551) ("What all members of the putative class and subclass have in common is their alleged exposure, as a result of specified statewide ADC policies and practices that govern the overall conditions of health care services and confinement, to a substantial risk of serious future harm to which the defendants are allegedly deliberately indifferent."); *Hernandez v. Cty. of Monterey*, 305 F.R.D. 132, 154–56 (N.D. Cal. 2015); *Scott v. Clarke*, 61 F. Supp. 3d 569, 587–88 (W.D. Va. 2014) ("[The] analytical regime concerning 'commonality' does not serve as a barrier to the certification of class actions in cases involving prisoners' claims alleging a pattern and practice of

conduct resulting in unconstitutional conditions of confinement."); *Jones v. Gusman,* 296 F.R.D. 416, 465–67 (E.D.La.2013); *Butler v. Suffolk Cnty.,* 289 F.R.D. 80, 96–101 (E.D.N.Y.2013); *Flynn v. Doyle*, No. 06-C-537, 2007 WL 805788, *4 (E.D. Wis. Mar. 14, 2007) ("The commonality and typicality requirements are also more easily met when the class members only seek injunctive relief, rather than monetary damages…. [W]hen, as is the case here, the plaintiffs only seek injunctive relief, the possibility of individualized determinations is removed.").

Likewise, typicality does not require the claims of the class representative to be identical to the claims of other class members. *See Falcon*, 457 U.S. at 155. A claim is typical if it: (1) arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and (2) is based on the same legal theory as their claims. *Craft v. Vanderbilt Univ.*, 174 F.R.D. 396, 404 (M.D. Tenn. 1996) (citations omitted).

Plaintiffs' claims satisfy Rule 23(a)(3). Plaintiffs' claims are typical of – indeed identical to – the Class claims because all claims involve the constitutionality of the Department's treatment protocols, polices, and practices regarding HCV. Plaintiffs' claims involve the same legal theory as the Class claims. If Plaintiffs establish that the Department's treatment, or lack thereof, of HCV is unconstitutional, and that they are entitled to injunctive and declaratory relief, the claims of the Class will necessarily succeed and the Class members will reap the benefits of the same injunctive and declaratory relief.

C. Plaintiffs satisfy Rule 23(a)(4) because they are members of the Class with common interests to the unnamed Class members and will vigorously prosecute the interests of the Class through qualified counsel.

Defendants assert that Plaintiffs cannot represent the class because they have not submitted "medical records showing their Hepatitis C condition is serious and an alleged delay in treatment is causing harm." Again, Defendants assert that their protocols pass constitutional muster and,

therefore, Plaintiffs cannot represent a class of plaintiffs because their individual complications from HCV may be different from other class members. However, the only relevant inquiry is whether Plaintiffs suffer from chronic Hepatitis C, which they have alleged in the Complaint and which the medical records in TDOC's possession clearly show they do. *See Compl.* ¶¶ *4-5.*

Plaintiffs and the unnamed Class members all suffer from chronic HCV infection and are all subject to the same treatment protocols and policies. Plaintiffs' claims attack the constitutionality of these policies, which withholds treatment from those for whom it is medically indicated. Current medical standards require treatment with DAAs for all inmates who have chronic HCV. Failure to cure HCV may have more or less severe consequences according to an individual's progression, but the fact remains that TDOC protocols run contrary to the most current medical standards and leave all Class members, including the named Plaintiffs, without treatment of their chronic infection. Plaintiffs' interests are coextensive to the unnamed Class members' interests.

Favorable relief in this case will provide relief to all Class members. Plaintiffs seek the same relief as the unnamed Class members, namely to protect their constitutional rights to receive adequate medical care and treatment for a chronic, painful condition that can, and often will, lead to death. Because Plaintiffs' physical health is at stake, they have the highest incentive to vigorously litigate this case to achieve favorable relief from the Court. *See* Compl., ¶¶ 31, 38, .

D. **Plaintiffs Satisfy The Requirement Of 23(b)(2) Because Injunctive And Declaratory Relief Would Provide Relief To All Class Members**

Defendants claim Plaintiffs fail to meet the requirements of Rule 23(b)(2) because an injunction ordering that inmates be treated with DAAs for HCV would be inappropriate because such treatment is not required. Defendants again assert that if the Court assumes that they will ultimately prevail on the merits of the case then Plaintiffs' request for injunctive relief is

unnecessary. While this is certainly true, the standard for certification of an injunctive class does not assume the Defendant will prevail. If Plaintiffs show Defendants have violated the Class members' constitutional rights, then favorable injunctive and declaratory relief would provide appropriate relief to all Class members simultaneously, namely the institution of proper screening and treatment for their disease. The declaratory and injunctive relief sought satisfies the requirements of Rule 23(b)(2) for class certification. Indeed, the Ninth Circuit recently approved of certification under Rule 23(b)(2) in a case in which a class of inmates sought injunctive relief for inadequate medical care. *Parsons v. Ryan*, 754 F.3d 657, 678, 686-87 (9th Cir. 2014).

CONCLUSION

For the reasons set forth in this reply and in Plaintiffs' Memorandum in Support of the Motion to Certify Class, the Court should permit this matter to proceed as a class action under Fed. R. Civ. P. 23(b)(2). Plaintiffs respectfully request that the Court grant Plaintiffs' Motion to Certify Class by certifying the Inmate Class. Plaintiffs also ask that their counsel of record be approved as counsel for the Class.

Dated: November 30, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 30 2016, a true and exact copy of the foregoing document has been served by ECF upon the following counsel for defendants:

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/s/ Thomas H. Castelli
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Defendants.	)	

DECLARATION OF MICHAEL S. SAAG, M.D.

I, Michael S. Saag, M.D., have personal knowledge of the following matters, would so testify in open court if called to do so, and am competent to render this testimony:

1. I am the Associate Dean for Global Health at the University of Alabama School of Medicine. I also serve as the Director for the Center for AIDS Research, University of Alabama at Birmingham. I have been principally involved in HIV research since the 1980s, and approximately 6-8 years ago I transitioned into research on the Hepatitis C Virus ("HCV"), which was a natural transition because many similarities between the two viruses, including the disease progression of both. Of course, unlike HIV, there is now a cure for HCV.

EXHIBIT A

2. I am also a founding Co-Chair and current member of what is commonly known as the HCV Guidance Panel, which is a joint panel comprised of individuals from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) ("Panel"). The AASLD/IDSA Panel convened in 2013 to address the rapidly changing landscape of HCV treatment due to the introduction of direct-acting anti-viral ("DAA") therapies around 2011. I was one of five original co-chairs of the Panel. The Panel publishes guidance entitled HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, the latest iteration of which was released in October 2016.

3. I have reviewed Defendants' Response in Opposition to Plaintiffs' Motion to Certify Class, Dkt. 20. I have also reviewed the Affidavit of Kenneth Williams, Dkt. 20-1.

4. I found interesting Dr. Williams statement that "The Tennessee Department of Correction follows the recommendation of the AASLD to treat all patients diagnosed with HCV." Dkt. 20-1, ¶ 5. In fact, this is precisely the current guidance recommended by the AASLD/IDSA Panel.

5. Generally speaking, HCV infection occurs in two stages. Acute HCV infection is the initial phase within the first six months of exposure to the virus. During this period, roughly 15-20% of infected individuals self-resolve. Therefore, there is no reason to treat the virus during the acute phase of infection.

6. Approximately six months after infection, the remaining 80-85% of infected individuals move into the chronic phase of infection. Chronic HCV does not self-correct; these individuals are infected for life if not treated with appropriate medication.

7. The current Panel guidance is for every person with chronic HCV to be treated with one of the many DAA regimens now available. While earlier iterations of the guidance

suggested prioritizing treatment for those in the most advanced stages of the disease, given the rapid advancement in DAAs, there is simply no medical reason not to treat everyone who has HCV (except those with medical exclusions, such as: life expectancy < 12 – 18 months owing to other diseases; pregnancy (which by definition is self-limited); and willingness to take or adhere to the medical regimen).

8. The Hepatitis C virus replicates very rapidly in the body. In fact, the level of viral replication can reach into the trillions of viral participles per day. This high level of replication causes substantial inflammation. In other words, people with untreated chronic HCV have chronic inflammation. Chronic inflammation shortens life expectancy and leads to a number of secondary conditions, such as heart disease, stroke, liver disease, kidney disease, and cognitive impairment at earlier ages. Approximately 30-50% of individuals with Chronic HCV will develop advanced liver disease over 20 – 30 years, and most people with chronic HCV will develop some symptoms or chronic conditions due to inflammation. The difficulty clinically is that there are no tests can predict whether a given patient with HCV will progress to end stage liver disease nor at what rate; hence, the recommendation in the HCV Guidelines to treat all persons with chronic HCV infection, who do not have exclusions to treatment (supra), regardless of current stage of liver fibrosis.

9. A number of the medical assertions made by Defendants in their Response are wildly inaccurate. For example, Defendants state that the risk of developing liver disease is small, Dkt. 20, p. 4. This is simply incorrect, given the risk ranges from 30-50% and other non-liver disease end points occur at a higher rate. Also, Defendants state that medicine is often not necessary because the disease is not progressing, and so in those cases delay is not harmful, Dkt. 20, p. 14. This is false. Daily viral replication means that the disease – and inflammation and

the chronic illnesses it causes – is always progressing. Hepatitis C is a serious disease, and so of course delay in treatment causes harm.

10. Additionally, Defendants list priorities of treatment based on individual health, for example, people with fibrosis or cirrhosis. Dkt. 20, p. 3. However, current medical standards moot these priorities, as treatment is recommended for everyone with chronic infection (unless a treatment exclusion exists).

11. Finally, Defendants say throughout their Response that they provide treatment in the form of monitoring. Monitoring is not treatment. Monitoring serves no purpose unless it leads to treatment with medication. A good analogy for this argument is cancer: a doctor would not recommend monitoring the progression of cancer until it reaches a late stage to begin treatment, because the risks are much greater at that point. The same is true for HCV; there is no medical reason to delay treatment for chronic HCV with a DAA that can cure the disease.

FURTHER DECLARANT SAYETH NOT

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 29, 2016

/s/ Michael S. Saag
MICHAEL S. SAAG, M.D.