# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF KENTUCKY CENTRAL DIVISION at LEXINGTON

## CIVIL ACTION NO. 10-CV-094-KKC

## THEODORE HOWZE,

### MEMORANDUM OPINION AND ORDER

DEBORAH HICKEY, Warden,

#### \*\*\*\* \*\*\*\* \*\*\*\* \*\*\*\*

This matter is before the Court on Defendant's "Motion to Dismiss or, In Alternative, for Summary Judgment" [R. 16]. Plaintiff having filed a response in opposition thereto [R. 17], and defendant having filed a reply to plaintiff's response [R. 21], this matter is ripe for review. For the reasons explained below, Defendant's Motion to Dismiss or, In Alternative, for Summary Judgment will be granted, and this case will be dismissed.

## BACKGROUND

Plaintiff Theodore Howze ("Howze")<sup>1</sup> has been incarcerated at the Federal Medical Center in Lexington, Kentucky ("FMC-Lexington") since May of 2003. He filed this action, pursuant to the doctrine set forth in *Bivens v. Six Unknown Fed. Narcotics Agents*, 403 U.S. 388 (1971), against defendant Deborah Hickey in her official capacity as FMC-Lexington Warden, alleging that the Bureau of Prisons has been deliberately indifferent to his serious medical needs, in violation of his Eighth Amendment right to be free from cruel and unusual punishment, by the failure of its medical officials to properly treat his Hepatitis C condition. Specifically, Howze claims that he is in need of

PLAINTIFF

DEFENDANT

V.

<sup>&</sup>lt;sup>1</sup> On April 1, 2003, Howze was convicted in the United States District Court for the Western District of North Carolina, pursuant to a guilty plea, of possession with intent to distribute cocaine and cocaine base. He is serving a 240-month sentence and has a projected release date of August 23, 2020. [See Inmate Profile, Attachment A to Defendant's Motion to Dismiss, Or In Alternative, For Summary Judgment - DE #16-3].

interferon treatments for Hepatitis C, as recommended by his physician at FMC-Lexington and by other medical specialists at the University of Kentucky, and that officials at BOP's Central Office in Washington, D.C., have unlawfully denied this request.

For relief, Howze seeks an order compelling the Bureau of Prisons ("BOP") to provide him with the "recommended and prescribed Interferon Treatment." <u>Complaint</u>, p. 8 [R. 5]. Alternatively, Howze seeks release from custody so that he may obtain this interferon treatment in the community, and he seeks any other relief available from the Court. *Id*.

### DISCUSSION

Prior to Plaintiff's arrival at FMC-Lexington in May of 2003, he was arrested and detained in January of 1999 on charges contained in an information filed in the Western District of North Carolina. Plaintiff remained in custody in the Mecklenberg County Jail in North Carolina for approximately forty-five (45) months before being sentenced on these charges on April 1, 2003. At some time unknown to plaintiff, but prior to his arrival at FMC-Lexington, he contracted Hepatitis C, a blood-borne infectious disease caused by the Hepatitis C virus. It affects the liver. See <u>Declaration of Richard Ramirez, M.D.</u>, pp. 1-2 (DE #16-5), attached to defendant's <u>Motion To</u> Dismiss, Or In Alternative, For Summary Judgment (DE #16).

Since plaintiff's diagnosis, physicians at FMC-Lexington have been monitoring regularly his chronic Hepatitis C condition. Plaintiff remained asymptomatic and his liver enzymes, although slightly elevated, remained stable from the time of diagnosis until an increase was noted in August of 2007. [See Supplement to Declaration of Richard Ramirez - DE #16-5; CE\_0043 - DE #16-8]. However, plaintiff remained asymptomatic. In November of 2008, plaintiff's liver enzymes were

lower, showing improvement. [See Supplement to Declaration of Richard Ramirez - DE #16-5; CE\_0036 - DE #16-8].

On May 5, 2009, FMC-Lexington physician, Dr. Maria F. Marrero noted in plaintiff's medical records that his chronic Hepatitis C condition had worsened, evidenced by his increased liver enzymes. Specifically, she stated in her Diagnosis Comments: "Patient with increased liver enzymes once more. All his labs and test requested by the specialist have been done. Needs to follow up to decide on liver biopsy and need of treatment." [See Supplement to Declaration of Richard Ramirez - DE #16-5; CE 0026 - DE #16-7]. Subsequently, on July 28, 2009, plaintiff was examined again by FMC-physician Dr. Maria F. Marrero, who made the following Diagnosis Comments: "Patient still with increased liver enzymes. He saw GI who recommended to start hep C treatment. Apparently he did not realize that it needed approval from Central Office, including a liver biopsy. We have been gathering all the test[s] needed to submit the request to Central Office for approval. Patient has been oriented about this." [See Supplement to Declaration of Richard Ramirez - DE #16-5; CE 0020 - DE #16-7]. Thereafter, plaintiff underwent a liver biopsy at the University of Kentucky Medical Center. At her examination of plaintiff on October 21, 2009, Dr. Marrero noted: "liver enzymes lowered some, but still increased. His liver biopsy was done on 9/15/2009 and we got results this week. We have all paperwork done to give to pharmacy so it can be sent to CO for approval." [See Supplement to Declaration of Richard Ramirez - DE #16-5; CE 0013 - DE #16-6].

Ultimately, medical officials at FMC-Lexington submitted the request to the BOP's Central Office ("CO") in Washington, D.C., for approval of the interferon treatment regimen for plaintiff's Hepatitis C condition. On January 21, 2010, medical officials at BOP's CO denied that request

based on plaintiff's histologic criteria and clinical guidelines. That same day, Certified Physician's Assistant Roberts Williams at FMC-Lexington noted the CO's denial in plaintiff's medical records and scheduled plaintiff for a follow-up appointment on January 25, 2010, to advise him of that decision by the CO. In the "Assessment" section of plaintiff's medical records, on January 21, 2010, Mr. Williams noted:

### **Health Problem Comments:**

Not a candidate for HCV tx due to histologic criteria.

## **Diagnosis Comments:**

LFT's have normalized. Nonformulary request for Hep C treatment was not approved by CO, statin HCV genotype 1 with stage 1 (portal) fibrosis does not meet BOP histologic tx criteria.

[See Supplement to Declaration of Richard Ramirez - DE #16-5; CE\_0009-0010 - DE #16-6].

At his scheduled appointment on January 25, 2010, Mr. Williams informed plaintiff that CO

had denied his request for interferon treatments. In the "Assessment" section of the medical

records, Mr. Williams stated:

#### **Health Problem Comments:**

Not a candidate for HCV tx due to histologic criteria per Central Office. **Diagnosis Comments:** 

Discussed Nonformulary request for Hep C treatment was not approved by Central Office, stating HCV genotype 1 with stage 1 (portal) fibrosis does not meet BOP histologic tx criteria.

[See Supplement to Declaration of Richard Ramirez - DE #16-5; CE\_00069 - DE #16-6].

Thereafter, on March 18, 2010, plaintiff was seen again by a specialist at the

Gastroenterology Clinic at the University of Kentucky, who recommended updating plaintiff's

genotype and viral load. [See Supplement to Declaration of Richard Ramirez - DE #16-5; CE 0005

- DE #16-6]. In April of 2010, medical officials at FMC-Lexington resubmitted the nonformulary

request for approval of interferon treatments for plaintiff to the CO, and the CO again denied that

request. On April 16, 2010, Dr. Marrero examined and consulted with plaintiff. In her Assessment, Dr. Marrero stated:

### **Health Problem Comments:**

Not a candidate for HCV tx due to histologic criteria per central office. **Diagnosis Comments:** same, no change. His Hep C packet for treatment was resubmitted last week and it was denied once more due to fibrosis.

[See Supplement to Declaration of Richard Ramirez - DE #16-5; CE 0002 - DE #16-6].

Thus, although FMC-Lexington physician Dr. Marrero and consulting physicians at the

University of Kentucky recommended interferon treatments for plaintiff's Hepatitis C condition,

and Dr. Marrero twice requested approval for same from BOP's CO in Washington, D.C., that

request has been denied on both occasions. In support of her motion to dismiss, or alternatively, for

summary judgment, defendant has submitted the affidavit of Dr. Richard Ramirez, the BOP's

Regional Medical Director for the Mid-Atlantic Region, to explain the basis for the BOP's denial

decision and his concurrence therewith. The Declaration of Richard Ramirez, M.D., dated June 24,

2010, states in relevant part, as follows:

1. .... In my current position, I consult with medical staff at various federal prisons on clinical medical care issues. I have reviewed the medical records and am familiar with the medical history of federal inmate Theodore Howze (hereinafter "Plaintiff"), register number 09498-058, who is currently incarcerated at FMC Lexington.

2. In this case, Plaintiff's medical records show he has received appropriate medical care for his Hepatitis C condition. Plaintiff has been incarcerated at FMC Lexington since May 2003. He has a medical history of chronic Hepatitis C, which is a blood-borne infectious disease caused by the Hepatitis C virus, affecting the liver. The initial infection is often asymptomatic, but once established, chronic infection can cause inflammation of the liver (chronic hepatitis), which can lead to progressive scarring of the liver (fibrosis), and advanced scarring (cirrhosis). Hepatitis C is spread by blood-to-blood contact.

3. The development of a standard interferon treatment has yielded successful results for some Hepatitis C patients, with many experiencing complete clearing of the virus (although relapse is common). Plaintiff's viral genotype 1 is the least

responsive to interferon therapy of the six Hepatitis C genotype groups. Only approximately 25 to 40 percent of patients with Hepatitis C viral genotype 1 receiving pegylated interferon therapy show any response to the therapy. There are potentially serious side effects from administration of this highly toxic interferon medication, and the therapy can also make the Hepatitis C worse, or lead to lifethreatening complications. In recent years, pegylated interferon in combination with ribavirin, an anti-viral medication, has become a common treatment method for Hepatitis C patients.

4. The medical appropriateness of pegylated interferon therapy for Hepatitis C sufferers greatly varies between patients, depending on factors such as the likelihood of the patients developing cirrhosis of the liver, viral genotype, viral load count, abnormal liver enzyme level, nature and progression of the disease, past success and present likelihood of success of interferon therapy, and the patients' physical condition and tolerance to the therapy. Hepatitis C patients with early stage disease and relatively normal liver enzyme counts, and on the other end of the spectrum, patients with late stage disease and advanced liver cirrhosis, are generally not good candidates for interferon therapy. In general, the ideal candidates for interferon therapy are Hepatitis C patients who are in the middle to later stages of the disease and have high abnormal liver enzyme counts, high viral load count, viral genotypes other than genotype 1, and are highly likely to develop or have liver cirrhosis, but do not have late stage cirrhosis.

5. Plaintiff is currently in the early stages of Hepatitis C, with Stage I fibrosis (scarring) of the liver, viral genotype 1, a near normal liver enzyme count, and a relatively low viral load count recorded in his latest liver biopsy. Plaintiff's primary care physician at FMC Lexington made requests for the therapy on two occasions, to the Bureau's Health Services Division in Central Office, D.C. Approval by the Health Services Division for the ribavirin/interferon therapy is necessary because the therapy drugs are not on the Bureau's drug formulary list, and non-formulary drugs require special approval.

6. On January 21, 2010, Plaintiff's FMC Lexington physician submitted a Non-Formulary Drug Authorization request to the Health Services Division, Washington, D.C., for consideration. This request was reviewed and disapproved on the same day by a reviewing official who determined Plaintiff did not meet the Bureau of Prisons histologic criteria or clinical guidelines for this therapy based upon Plaintiff's September 2009, liver biopsy which showed Plaintiff had fibrosis of the liver (scarring of the liver), specifically HCV genotype 1 with stage 1 portal fibrosis. The reviewer recommended Plaintiff be followed with regular outpatient examinations and laboratory examinations.

7. On April 8, 2010, Plaintiff's FMC Lexington physician submitted a second Non-Formulary Drug Authorization request to the Health Services Division, Washington, D.C., for consideration. This second request with additional information was also denied based on the fact that Plaintiff's Hepatitis C condition did not meet the Bureau's Clinical Guidelines for interferon therapy due to fibrosis of the liver. 8. Specifically, Plaintiff is medically outside of the Bureau's Clinical Guidelines under which interferon therapy is indicated if a Hepatitis C patient has any one of the following disease characteristics: viral genotype 2 or 3; significant liver biopsy results; evidence of compensated liver cirrhosis. [Id.]. However, in Plaintiff's case, he has none of these characteristics. [Id.].

9. First, Plaintiff's liver enzyme count was relatively normal, only modestly elevated above normal. Candidates for interferon therapy typically have liver enzyme counts one and [one] half times or greater than normal. Second, Plaintiff is relatively healthy at this time and he has Stage I fibrosis, a very early stage of Hepatitis C, and appropriate candidates for interferon therapy are typically at least in Stages II or III fibrosis. Third, Plaintiff's viral load count tested in 2009 was only 63,000, while appropriate interferon candidates often have viral load counts of 750,000 to over 1 million.

10. Finally, as described above, Plaintiff's viral genotype is genotype 1, which is the least responsive of the six genotypes to pegylated interferon therapy. Clinical studies show only 25 to 40% of Hepatitis C patients with viral genotype 1 show any response to pegylated interferon therapy.

11. For the reasons described above, I fully concur with the denials of the interferon therapy for Plaintiff by the Health Services reviewer in Central Office, and I respectfully disagree with University of Kentucky specialists who recommend the interferon treatment for Plaintiff. At this time, the potential benefits of interferon therapy for Plaintiff are outweighed by the significant risks of harm caused by the highly toxic interferon therapy drugs. In my medical opinion, the highly aggressive and riskier interferon treatment approach recommended by the University of Kentucky specialists is not medically-indicated for Plaintiff who is a relatively healthy 50 year old man who has had slow-progressing, early stage Hepatitis C for more than a decade without advancement into the middle or later stages of the disease.

12. Plaintiff may eventually be a candidate for interferon therapy, so accordingly, the current treatment regimen for Plaintiff is watching and continuing to test his viral load and liver enzyme levels, and in the future possibly do liver biopsies if indicated. However, at this time, interferon therapy is not medically-indicated based on the Bureau's Clinical Guidelines and the reasons discussed above.

Declaration of Richard Ramirez, M.D., 6/24/10 [DE #16-5], attached to Defendant's Motion to

Dismiss, Or In Alternative, For Summary Judgment - DE #16-3.

### **APPLICABLE LAW**

### Standards for Dismissal/Summary Judgment

Fed.R.Civ.P. 12(b) provides for the dismissal of claims and parties for seven listed reasons.

Subsection (b)(6) provides for dismissal for failure to state a claim upon which relief can be granted.

Thereafter, Rule 12 continues, in subsection (d), as follows:

(d) Result of Presenting Matters Outside the Pleadings. If, on a motion under Rule 12(b) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties shall be given reasonable opportunity to present all material made pertinent to the motion.

*Id.* Thus, the plain language of Rule 12(d) permits a 12(b)(6) motion to be converted into a motion for summary judgment. As the moving defendants herein have submitted the <u>Declaration of Joseph</u> <u>Tang</u>, and the <u>Declaration of Richard Ramirez</u>, M.D., with numerous exhibits appended thereto (which the Court has considered in evaluating the defendant's motion [R. 16)])<sup>2</sup>, summary judgment standards will be applied.

In evaluating a motion for summary judgment, the Court must determine whether there are "no genuine issues as to any material fact and the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). "[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on

<sup>&</sup>lt;sup>2</sup> The Court has also reviewed the exhibits attached to Plaintiff's original pleading, styled as a habeas petition filed under 28 U.S.C. § 2241, the exhibits attached to Plaintiff's later-filed Complaint, and the exhibits attached to Plaintiff's response to defendant's motion to dismiss or for summary judgment, styled "Objection To Defendants Motion To Dismiss Or Summary Judgment." [R. 17].

which that party will bear the burden of proof at trial." *Celotex Corporation v. Catrett*, 477 U.S. 317, 322, (1986).

The Supreme Court has directed that a court must look beyond the pleadings and assess the proof to determine whether there is a genuine need for trial. *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The significant question is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-53, (1986). The moving party has the burden of showing there is an absence of evidence to support a claim. *Celotex*, 477 U.S. at 324-25. After a moving party carries its burden, the non-moving party must go beyond the pleadings to designate by affidavits, depositions, answers to interrogatories, and admissions on file, specific facts showing that there is a genuine issue of material fact for trial. *Id.* With these standards in mind, the Court examines the defendant's motion.

### Eighth Amendment Standards

The Supreme Court has held that "[i]n order to state a cognizable claim [under the Eighth Amendment with regard to medical care] a prisoner must allege acts or omissions sufficiently harmful to evidence deliberate indifference to the plaintiff's serious medical needs." *Estelle v. Gamble*, 429 U.S. 97, 106 (1976). Therefore, a prisoner must show both "deliberate indifference" and "serious medical needs." *Id.* "Deliberate indifference" means that prison medical staff knew of the inmate's serious medical needs, but intentionally disregarded an excessive risk of harm to the inmate, or that prison guards or medical staff intentionally prevented the inmate from receiving prescribed treatment or intentionally delayed or denied him access to medical care. *Estelle*, 429 U.S. at 104-105; *Farmer v. Brennan*, 511 U.S. 825, 837 (1994).

Thus, the Eighth Amendment contains both an objective and a subjective component.

*Wilson v. Seiter*, 501 U.S. 294 (1991). The objective component requires the existence of a "sufficiently serious medical need." *Blackmore v. Kalamazoo County*, 390 F.3d 890, 895 (6th Cir. 2004). A serious medical need is "one that has been diagnosed by a physician as mandating treatment or one that is so obvious that even a lay person would easily recognize the necessity for a doctor's attention." *Id.* at 897. In the present case, the objective component pertains to the medical problems associated with plaintiff's Hepatitis C condition.

The subjective component requires a plaintiff to show that "the official [knew] of and disregard[ed] an excessive risk to inmate health or safety, which is to say the official must both be aware of facts from which the inference could be drawn that a substantial risk of serious harm exists, and he must also draw the inference." *Clark-Murphy v. Foreback*, 439 F.3d 280, 286 (6<sup>th</sup> Cir. 2006) *quoting Farmer*, 511 U.S. at 837. Deliberate indifference may be "manifested by prison doctors in their response to a prisoner's needs or by prison [staff] in intentionally denying or delaying access to medical care or intentionally interfering with treatment once prescribed." *Estelle*, 429 U.S. at 104.

However, no claim of a constitutional dimension is stated where a prisoner challenges only matters of medical judgment or otherwise expresses a mere difference of opinion concerning an appropriate course of treatment. *Estelle*, 429 U.S. at 107; *Sharpe v. Patton, et al.*, No. 08-CV-58-HRW, 2010 WL 227702 (E.D. Ky. 2010). When the cause of action is based on an allegation that the prescribed treatment was inadequate in some way, rather than on an allegation that the prison official failed to provide the plaintiff with any treatment, courts traditionally have been reluctant to second guess the medical official. *Rodriguez v. Lappin*, 08-CV-347-GFVT, 2009 WL 2969510

(E.D. Ky. 2009). Simply put, differences of opinion as to matters of medical judgment, negligent treatment or even medical malpractice are insufficient to establish that one has received inadequate medical care in violation of the Eighth Amendment, as seen in *Alexander v. Federal Bureau of Prisons*, 227 F. Supp.2d 657 (E.D. Ky. 2002), where this Court addressed a prisoner's challenge to his medical treatment and granted summary judgment to the Bureau of Prisons under the following rationale:

... While it appears that the plaintiff has not gotten what he wants, what he wants is not the issue. Ordering a specific type of surgery is not the appropriate function of this Court. The Court agrees with the defendants that, at most the plaintiff has alleged a difference in opinion between the plaintiff and his health care providers regarding the expediency of a specific treatment. This does not generally create a constitutional claim.

## Id. at 666.

Whether an Eighth Amendment claim exists in Hepatitis C cases ultimately depends on whether interferon treatment is medically-indicated for the patient's condition. Courts have recognized that Hepatitis C may require interferon or another treatment regimen in some, but not all, situations. There is no uniform rule applicable to all cases. Each case is different, as noted in *Paulley v. Chandler*, No. 3:99-CV-P549-H, 2000 WL 33975579, \*4 (W.D. Ky. April 18, 2000):

The constitutionality of each prisoner's treatment must be assessed individually, and a conclusion in one case may not foreclose a different conclusion in another. No inequity results from such different outcomes, because each prisoner is considered as an individual. Medical needs are always peculiar to the patient, and the necessary differences in treatment will not establish conflicting or incompatible standards for the board.

## Id.

In *Paulley*, the United States District Court for the Western District of Kentucky granted injunctive relief to the plaintiff inmate, who had alleged that his Eighth Amendment rights were

violated by the denial of interferon treatment for his Hepatitis C condition. In analyzing Paulley's case under the Eighth Amendment, the Court considered the nature of his disease, its seriousness, the treatment options, the potential effectiveness of interferon treatment, prison officials' awareness of the disease and treatments, and whether they denied the inmate the effective options. *Id.* The Court recognized that since each prisoner's condition is different, all of these questions had to be considered in determining whether the prisoner has access to the treatments necessary to satisfy his own medical needs. *Id.* 

Ultimately, in *Paulley*, the district court determined that the plaintiff suffered from cirrhosis of the liver and had a serious risk of death in a short period of time, and that interferon treatment was the only possible effective treatment for the condition. *Id.* Paulley established that prison officials were aware of the seriousness of his condition, but declined to approve the interferon therapy. *Id.* The district court held that denial was a violation of his Eighth Amendment rights, and the Court ordered prison officials to provide the interferon therapy. *Id.* 

On the other hand, in cases similar to this one, the United States Court of Appeals for the Sixth Circuit has found that the denial of interferon treatment did not violate the Eighth Amendment. In *Johnson v. Million*, 60 F. App'x 548 (6<sup>th</sup> Cir. 2003), a state inmate filed an action, pursuant to 42 U.S.C. § 1983, against the prison warden and two physicians alleging a violation of his Eighth Amendment rights by the defendants' failure to properly treat his Hepatitis C. The district court granted summary judgment to the defendants, and the Sixth Circuit affirmed on appeal, noting that prison officials regularly monitored his Hepatitis C condition (every three to four months) and that his condition did not meet the clinical guidelines for interferon treatment. In *Johnson*, the inmate was seen regularly in the prison clinic for his Hepatitis C condition, and no

interferon treatment was recommended or provided. *Id.* Johnson was not provided any treatment because his liver enzyme levels had stayed within normal range, and interferon or other treatments were not medically-indicated. *Id.* For these reasons, the Sixth Circuit affirmed the summary judgment granted to the defendant.

Similarly, in *Edmonds v. Robbins*, 67 F. App'x 872 (6th Cir. 2003), a state inmate filed an action pursuant to 42 U.S.C. § 1983 alleging that the prison physician's failure to properly treat his Hepatitis C violated his Eighth Amendment rights. The district court dismissed the complaint, and the Sixth Circuit affirmed on appeal, reiterating that a difference of opinion between a prisoner and a physician concerning treatment of a condition does not rise to an Eighth Amendment claim. Specifically, the Sixth Circuit in *Edmonds* stated:

The record establishes that Dr. Robbins saw Edmonds on a monthly basis. Dr. Robbins feels that at this time, Edmonds's condition does not warrant medication. This conclusion is supported by hospital personnel. Furthermore, the medical literature which Edmonds filed with the court also establishes that medication is not always required for the treatment of hepatitis C. As Dr. Robbins is testing Edmonds on a monthly basis and Edmonds is receiving emergency care when necessary, Edmonds has not established that Dr. Robbins is subjecting him to cruel and unusual punishment.

# Id. at 873.

Returning to the case *sub judice*, the BOP's Health Services reviewer at the CO reviewed both of plaintiff's requests for interferon treatment and denied same because his Hepatitis C condition fell outside of the Bureau's Clinical Guidelines; therefore, interferon therapy is not medically-indicated at this time. [Declaration of Richard Ramirez, M.D., ¶¶ 5-12 [DE #16-5], attached to Defendant's Motion to Dismiss, Or In Alternative, For Summary Judgment - DE #16-3. Additionally, the BOP's Regional Clinical Director for the Mid-Atlantic Region reviewed plaintiff's medical case and fully concurred with the decision by the CO reviewer to deny the requests for interferon treatment. *Id.*,  $\P$  11.

As discussed above, plaintiff's Hepatitis C condition is currently outside of the Clinical Guidelines for interferon therapy. Id., ¶ 8. Specifically, interferon therapy is indicated if a Hepatitis C patient has any one of the following disease characteristics: genotype 2 or 3; significant liver biopsy results; evidence of compensated liver cirrhosis. Id.; FEDERAL BUREAU OF PRISONS CLINICAL PRACTICE GUIDELINES, p.7, June 2009.<sup>3</sup> However in plaintiff's case, he has **none** of these characteristics. Id.

To reiterate, first, Howze's liver enzyme count was relatively normal, being only modestly elevated. *Id.*, ¶ 9. Candidates for interferon therapy typically have liver enzyme counts one and one-half times or greater than normal. *Id.* Second, he is relatively healthy at this time, with Stage I fibrosis, a very early stage of Hepatitis C. Typically, appropriate candidates for interferon therapy are at least in Stages II or III fibrosis. *Id.* Third, his viral load count, tested in 2009, was only 63,000, while appropriate interferon candidates often have viral load counts of 750,000 to over one million. *Id.* Finally, his viral genotype is genotype 1, which is the least responsive of the six genotypes to pegylated interferon therapy. *Id.*, ¶ 10. Clinical studies reflect that only 25 to 40

<sup>&</sup>lt;sup>3</sup> The BOP's June 2009 guidelines are titled "Guidelines for the Prevention and Treatment of Hepatitis C and Cirrhosis." These guidelines address plaintiff's condition, "Chronic Hepatitis C Infection," and provide a tenstep approach for detecting, evaluating, and treating this condition. Step 5 of this approach includes a table (Table 5) for interpreting liver biopsy results. At the bottom of this table is the following notation: "*Note: The shaded areas with the bolded text indicate a significant liver biopsy result with a degree of fibrosis for which antiviral therapy should be considered.*" (Clinical Guidelines, pg. 7 - DE #16-8) (attached to <u>Defendant's Motion to Dismiss,</u> <u>Or In Alternative, For Summary Judgment</u> - DE #16-3). Plaintiff's liver biopsy scoring, per the Table 5 scoring system, falls outside of the shaded areas of Table 5, which is another indicator that he does not have the degree of fibrosis for which antiviral therapy should be considered at this time.

percent of Hepatitis C patients with viral genotype 1 show any response to pegylated interferon therapy. *Id.* 

For all of the foregoing reasons, Dr. Richard Ramirez, BOP's Regional Medical Director for the Mid-Atlantic Region, and the Health Services reviewer in BOP's CO, agree that interferon treatment for the plaintiff is not warranted at this time, and they disagree with University of Kentucky specialists who recommend interferon treatment for Plaintiff. *Id.*, ¶ 11. At this juncture, the potential benefits of interferon therapy for plaintiff are outweighed by the significant risks of harm caused by the highly toxic interferon therapy drugs. *Id.* In the opinion of these BOP medical professionals, the highly aggressive and riskier interferon treatment approach recommended by the University of Kentucky specialists is not medically-indicated for plaintiff, a relatively healthy 50-year-old man who has had early stage Hepatitis C for more than a decade without advancement into the middle or later stages of the disease. *Id.* 

The BOP has not permanently denied plaintiff's request for interferon treatment. If Plaintiff's condition changes, he may eventually become a medically-appropriate candidate for interferon therapy. *Id.*, ¶ 12. The BOP's current treatment regimen for plaintiff is monitoring his condition, continuing to test his viral load and liver enzyme levels, and in the future possibly do liver biopsies if indicated. *Id*.

Thus, BOP officials have not been "deliberately indifferent" to plaintiff's medical condition. There is no evidence that any BOP clinician or administrator knew of plaintiff's medical need for interferon therapy for his Hepatitis C condition, but consciously ignored the need. In fact, BOP medical professionals have carefully reviewed plaintiff's Hepatitis C condition and determined that interferon therapy is not medically-indicated at this time. Consequently, this case is simply a situation where there is a disagreement among medical professionals regarding the medical appropriateness of interferon therapy for plaintiff's Hepatitis C condition. Plaintiff is not satisfied with the BOP's denial of his request for interferon treatment, and he has a difference of opinion with those BOP medical officials as to what his course of treatment should be. As seen above, differences of opinion regarding diagnosis or treatment are not actionable under *Bivens*, as they do not establish that the defendants have been deliberately indifference," plaintiff has failed to state a Constitutional claim arising under the Eighth Amendment. Consequently, summary judgment will be granted to the defendant, pursuant to Fed.R.Civ.P. 56(c).

## CONCLUSION

Accordingly, IT IS ORDERED as follows:

(1) Defendant's Motion to Dismiss, Or In Alternative, For Summary Judgment [R. 16] isGRANTED;

(2) All claims having been resolved, this action is **DISMISSED** and **STRICKEN** from the docket.

(3) Judgment in favor of the named Defendant, Deborah Hickey, Warden, shall be entered contemporaneously with this Memorandum Opinion and Order.

Dated this 17<sup>th</sup> day of February, 2011.



Signed By: Karen K. Caldwell **United States District Judge**