UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EMILIAN PASZKO and JEFFREY FOWLER, on behalf of themselves and all others similarly situated, Plaintiffs, v. CAROL HIGGINS O'BRIEN, Commissioner of Massachusetts Department of Correction, in her official capacity, and MASSACHUSETTS PARTNERSHIP FOR CORRECTIONAL HEALTHCARE, LLC, Defendants.	)	CIVIL ACTION NO.

CLASS ACTION COMPLAINT

Introduction

1. This is a class action that seeks declaratory and injunctive relief under 42 U.S.C. §1983 for violation of the Eighth Amendment as a result of the deliberate indifference of defendants, the Commissioner of the Massachusetts Department of Correction and the Massachusetts Partnership for Correctional Healthcare, LLC ("MPCH"), to the serious medical needs of plaintiffs and the members of the class, who are infected with the Hepatitis C virus. Over 1,500 state prisoners in Massachusetts have Hepatitis C, but as of the present time only three are being treated for it. For many of them, including plaintiffs and the members of their class, the illness may progress toward end stage liver disease and death. A major advance in treatment was made in 2014, with the introduction of medication regimens that have near-perfect success rates, far fewer side effects, and a much shorter duration. Despite these

advances, defendants have failed and refused to provide this new treatment to plaintiffs and the members of their class.

The DOC and MPCH have instead continued a years-long reduction in the number of patients treated for Hepatitis C; they have knowingly delayed evaluating prisoners, and they have consciously avoided knowledge of their treatment needs. Prisoners who ought to receive the new medications are not receiving them, and a vast number of prisoners with Hepatitis C are not being afforded the necessary testing to determine whether they too should receive treatment.

Plaintiffs Emilian Paszko and Jeffrey Fowler are two such prisoners. They bring this action on behalf of themselves and all other state prisoners with Hepatitis C to remedy defendants' deliberate indifference to their serious medical need for treatment for their Hepatitis C. By not assuming the financial cost of Hepatitis C treatment, defendants are imposing a human cost on the prisoners in their care as well as on the population which will be at risk when these prisoners are released.

JURISDICTION AND VENUE

2. The Court has subject matter jurisdiction over plaintiffs' claims pursuant to 28 U.S.C. §§1331 (federal question jurisdiction) and 1343 (civil rights jurisdiction).

3. Venue is proper pursuant to 28 U.S.C. §1391(b).

PARTIES

4. Plaintiff Emilian Paszko is currently incarcerated at MCI-Shirley Medium in Shirley, Massachusetts, a penal institution operated by the Massachusetts Department of Correction ("DOC"). Mr. Paszko has Hepatitis C, and without treatment, he will suffer from the complications of this disease, up to and including death. He brings this action on his own behalf and on behalf of all prisoners in DOC custody who have Hepatitis C.

5. Mr. Paszko suffers from serious complications from Hepatitis C that have required multiple hospitalizations in the last two years. A gastroenterologist has noted that Mr. Paszko "would certainly be a candidate" for treatment with the newest Hepatitis C medications, if they were available within the DOC.

6. Plaintiff Jeffrey Fowler is currently incarcerated at Old Colony Correctional Center in Bridgewater, Massachusetts, a penal institution operated by the DOC. Mr. Fowler has Hepatitis C and, without treatment, he will suffer from the complications of this disease, up to and including death. He brings this action on his own behalf and on behalf of all prisoners in DOC custody who have Hepatitis C.

7. Non-invasive testing has confirmed that Mr. Fowler has significant liver fibrosis (scarring). In 2014, Mr. Fowler was treated with triple therapy, a medication regimen that preceded today's medication regimens, but that treatment was unsuccessful.

8. Defendant Carol Higgins O'Brien is the Commissioner of the Massachusetts DOC, and she is being sued in her official capacity. The DOC is an agency of the Commonwealth of Massachusetts that is charged with the care and custody of state prisoners and has a constitutional obligation to attend to the serious medical needs of the prisoners in its custody. Defendant O'Brien is aware of the facts alleged below, and she has acted, and continues to act, under color of law, custom and policy with respect to her failure and refusal to provide constitutionally adequate care and treatment to plaintiffs and the members of their class.

9. Defendant Massachusetts Partnership for Correctional HealthCare, LLC ("MPCH") is a Massachusetts corporate entity with a principal place of business in Westborough, Massachusetts. MPCH is the health care provider for the DOC, pursuant to a contract between the two parties. Since July 1, 2013, MPCH has been responsible for providing adequate medical

care to all prisoners in DOC custody. MPCH is aware of the facts alleged below, and has been acting, and continues to act, under color of law, custom and policy with respect to its failure and refusal to provide constitutionally adequate medical care and treatment to plaintiffs and the members of their class.

CLASS ACTION ALLEGATIONS

10. This is a class action under Rule 23(a) and (b) of the Federal Rules of Civil Procedure.

11. Plaintiffs are representatives of a class composed of all prisoners in the custody of the DOC who have Hepatitis C.

12. Membership in the class is so numerous that joinder of all members is impracticable. Over 1,500 DOC prisoners have Hepatitis C at any given time, and the population changes as persons are admitted and released.

13. Plaintiffs' claims involve common questions of law and fact that are typical of the claims of the class as a whole. The claims concern defendants' protocol and practice for treating Hepatitis C, which is applicable to all prisoners with Hepatitis C. Common questions include (1) whether treatment for Hepatitis C is a serious medical need; (2) whether defendants have been deliberately indifferent to the serious medical needs of plaintiffs and the members of their class; (3) whether defendants have failed and refused to provide the necessary staging of Hepatitis C patients in accordance with the prevailing standard of care, including the pretreatment testing and specialist consults that are needed to determine the severity of the disease and the need for treatment; (4) whether defendants have failed and refused to provide treatment for plaintiffs and the members of their class with the newest, most effective medications for Hepatitis C in accordance with the prevailing standard of care; and (5) whether

defendants' failure to provide treatment to plaintiffs and the member of their class in accordance with the prevailing standard of care for treatment of Hepatitis C has put plaintiffs and the members of their class at risk of serious harm.

14. These common questions predominate over any questions affecting only individual class members. Defendants have acted and refused to act on grounds generally applicable to the class so that final declaratory and injunctive relief would be appropriate to the class as a whole.

15. Plaintiffs have a strong personal interest in the outcome of this litigation, and they are represented by competent counsel who will adequately and fairly protect the interests of the class.

16. A class action is superior to any other available method for a fair and efficient adjudication of this controversy. Separate actions by individual members of the class would create a risk of inconsistent or differing adjudications and delay the ultimate resolution of the issues at stake.

FACTS

Hepatitis C Defined

17. Hepatitis C is a blood borne disease caused by the Hepatitis C virus ("HCV"). The virus brings about inflammation that damages liver cells. It is a leading cause of liver disease and liver transplants.

18. There are several different genotypes of Hepatitis C, with subtypes. Genotype 1 is the most common type of Hepatitis C in the United States.

19. Approximately eighty percent of people who become infected with the Hepatitis C virus will develop chronic Hepatitis C.

20. Chronic Hepatitis C patients develop fibrosis (liver scarring), which can worsen liver function until the patient develops cirrhosis. Ultimately, patients may end up with end stage liver disease, cancer, or other serious illnesses. Some patients will need a liver transplant, and others will die.

21. Hepatitis C is transmitted by infected blood. Methods of transmission include intravenous drug use (via shared equipment), tattooing (same), blood transfusions (with infected blood, largely before regular screening of donated blood began), and sex. Intravenous drug use is the most common means of transmission in the U.S.

22. It is widely accepted that the number of reported cases of Hepatitis C nationwide understates its actual prevalence. In 2000, the United States Surgeon General called Hepatitis C a "silent epidemic," and estimated that as much as two percent of the adult U.S. population had Hepatitis C.

23. The last decade has seen a spike in reported cases of Hepatitis C among young people. This increase in new cases of Hepatitis C is largely attributable to the increase in opioid addiction and the resulting use of intravenous drugs.

24. The incidence of Hepatitis C is not diminishing, and its effects are worsening. In 2011, the CDC reported that Hepatitis C had overtaken HIV as a cause of death.

Hepatitis C in Prison

25. The prevalence of Hepatitis C in prison is higher than in the general population. It is estimated to be anywhere from 9.6% to 41.1% of the prison population nationally. As many as half a million people in prison at any given time have Hepatitis C.

26. In 1997, according to one study, 29% to 43% of all people infected with Hepatitis C in the United States passed through a correctional facility.

27. In the Massachusetts Department of Correction, over 1,500 of the ten thousand prisoners are known to have Hepatitis C.

History of Hepatitis C Treatment

28. Treatment exists for chronic Hepatitis C. The available treatments have changed over time.

29. In 1991, a drug called Interferon was approved to be used alone. Seven years later, the FDA approved the use of Ribavirin alongside Interferon, and in 2001, Ribavirin was paired with Pegylated Interferon. This regimen was referred to as combination therapy.

30. Combination therapy was marked by a long duration of treatment – 48 weeks. The medications had significant side effects. Interferon in particular was troublesome, causing such side effects as depression, thrombocytopenia, and loss of bone marrow. While research had shown that combination therapy was very effective against Genotypes 2 and 3, only around 60% of patients with Genotype 1 taking combination therapy achieved a Sustained Viral Response ("SVR") – an undetectable viral load six months after completing treatment, which is considered a cure.

31. The standard of care after 2001 was to treat Genotypes 2 or 3 with combination therapy, and to treat Genotype 1 with combination therapy if the patient had reached a certain stage of liver damage, typically measured by a liver biopsy. If after treatment the virus was not suppressed, or if it was suppressed during treatment but later returned, there was no other treatment available for the so-called nonresponder or relapser.

32. 2011 saw the FDA approval of two protease inhibitors that produced better results when either one was taken with combination therapy, especially for Genotype 1 (SVR of 60-80%).

33. The standard of care evolved to include so-called triple therapy – one of the two protease inhibitors, taken with Interferon and Ribavirin – for Genotype 1 patients. Triple therapy was effective on nonresponders and relapsers, giving them a new option and potential cure.

34. The duration of treatment with triple therapy remained the same as with combination therapy, as did the side effects. The expense increased because of the additional medication.

35. In 2013 and 2014, the FDA approved more new antiviral medications. These medications can now be taken as part of an Interferon-free regimen. The change is dramatic; the worst side effects are avoided. The regimen is a much shorter duration – 12 weeks for some, 24 weeks for others. Best of all, the success rate for these regimens is better than combination or triple therapy – well over 90%, including for nonresponders and relapsers.

36. There have also been changes in how the disease is monitored. To measure fibrosis, providers now generally forego a liver biopsy in favor of non-invasive tests. Blood tests can offer an accurate assessment of liver fibrosis, and these tests can be coupled with certain types of scanning if desired.

37. These new developments in staging the disease, and treating it, have eliminated the barriers to a cure.

History of Hepatitis C Treatment in the DOC

38. The DOC has treated some prisoners for Hepatitis C since approximately 2000, with combination therapy the treatment of choice since 2002.

39. In about 2002, the DOC implemented a Hepatitis C treatment protocol, with input from its health care contractor and the Department of Public Health.

40. The treatment protocol contained directions for screening of prisoners. Those prisoners considered at high risk would be given an HCV antibody test (detecting whether HCV antibodies are present in the blood).

41. If a prisoner tested positive for HCV antibodies, confirmatory testing would be done, including liver function tests and measurement of the viral load (the amount of virus in the blood).

42. Laboratory testing and a medical assessment would be done to determine whether the prisoner should receive a liver biopsy. A biopsy provided the best evidence of whether there was fibrosis of the liver.

43. If the biopsy resulted in a recommendation for treatment, the prisoner did not necessarily receive treatment right away. He or she was instead placed on a wait list. The DOC and its healthcare contractor rationed treatment, authorizing a certain number of "treatment slots" – a maximum number of prisoners who could receive treatment at one time. Prisoners were selected from the wait list for treatment based on the severity of their disease, and other factors.

44. The DOC and its health care contractor paid close attention to the number of prisoners receiving combination therapy and to how much money had been spent on Pegylated Interferon and Ribavirin. Monthly reports calculated both numbers.

45. The DOC's health care contractor had a Hepatitis C program manager – a staff member dedicated to overseeing Hepatitis C treatment in the DOC. The manager followed the number of Hepatitis C cases, managed a database of Hepatitis C prisoners, maintained the wait list, and participated in the determination of who received treatment and when.

46. The treatment protocol contained several exclusions, some of which were tied to

prison issues rather than medical issues. For example, prisoners who were too close to their release date would not receive treatment, the stated concern being that the prisoner would not complete the treatment after release. Moreover, prisoners who received certain types of disciplinary reports would be rendered ineligible for treatment.

47. By 2011, when triple therapy arrived nationally, the DOC and its health care contractor had been convening a Hepatitis C Task Force for two years. The Task Force was comprised of representatives from the DOC, its health care contractor, and the Department of Public Health.

48. The Task Force and its members were well aware of the two new protease inhibitors before their approval by the FDA. Nevertheless, the treatment protocol was not amended in a timely way when triple therapy became available.

49. A sizable number of prisoners in the DOC were nonresponders or relapsers. These patients in particular had had little hope of cure, until the arrival of triple therapy. Most or all of them had not been staged (evaluated) in a long time, and did not know how much farther their liver fibrosis had progressed.

50. New prisoners were also entering DOC custody with Hepatitis C, specifically with Genotype 1, for which triple therapy was superior to combination therapy.

51. Many of these prisoners sought staging and a determination of their eligibility for treatment. Prisoner advocates inquired about how the DOC and its health care contractor planned to implement triple therapy, and especially how it planned to conduct the necessary testing for nonresponders and relapsers – patients who needed to be brought back into the treatment pipeline.

52. For nearly two years, prisoners and their advocates were told only that the treatment

protocol was "under review." Heavy emphasis was placed on the fact that the medications were "new," even though their arrival had been anticipated for years, and even as months passed without a single DOC prisoner receiving triple therapy.

53. In July of 2012, the DOC advised that its task force continued to meet, that its health care contractor was still working on a revised protocol, and that after the protocol was submitted, the DOC would then review it further. There was no timetable for implementation of the new protocol.

54. On October 3, 2012, the DOC issued a Request for Response – a call for bids on a new health care contract. In its Request, the DOC advised that it was still "in the process of implementing a new Hepatitis C protocol."

55. Finally, in 2013, a few DOC prisoners began to receive triple therapy. Very few prisoners were treated.

56. The DOC has for years reduced Hepatitis C treatment, as has MPCH since its arrival in 2013 as Doc's health care contractor. In Fiscal Year 2009 (July 2008 – June 2009), an average of 81 prisoners were taking Hepatitis C medications in any given month. In Fiscal Year 2014, that number had dropped to 16.

57. This dramatic reduction in the number of treatment slots was coupled with a failure to stage Hepatitis C patients. With nonresponders and relapsers joining the treatment-naïve Hepatitis C patients, the situation called for a rigorous, speedy process of conducting the necessary tests. This task should have been made easier since the standard of care permitted non-invasive tests, rather than liver biopsies, to measure liver fibrosis. But such a process never emerged.

58. In late 2013, the FDA approved Sovaldi and Olysio, which brought an even higher

cure rate for Genotype 1 (when taken with Interferon and Ribavirin).

59. Within their joint Pharmacy & Therapeutics Committee, defendants first discussed Sovaldi in April of 2014. In the months leading up to that meeting, defendants had reduced the number of prisoners on triple therapy or combination therapy.

60. By the time of the August 2014 Pharmacy & Therapeutics Committee meeting, defendants reported having an interim guideline for use of Sovaldi, and three prisoners were said to have been evaluated and cleared to begin therapy that month.

61. However, at the September 2014 meeting, it was reported that in all DOC facilities there were only six prisoners taking combination therapy, six prisoners taking triple therapy, and no prisoners taking Sovaldi. The three prisoners referred to in paragraph 60, above, were now said to be ready for treatment "once operational processes are put into place."

62. By October of 2014, there were only five prisoners cleared to start treatment with Sovaldi "once operational processes are put into place." Meanwhile, the number of prisoners receiving combination or triple therapy dropped to six.

63. The FDA approved Harvoni (in October 2014) and Viekira Pak (in December 2014), marking the arrival of the first Interferon-free treatment regimens. These regimens also enjoy near-perfect cure rates.

64. Nevertheless, only two or three prisoners have been treated with one of the new regimens. As of February 2015, there were only three prisoners taking Hepatitis C medications of any kind. Defendants have not changed their protocol to recognize the new reality in Hepatitis C treatment, and they have done nothing to conduct the necessary pre-treatment testing of the many prisoners – the nonresponders, relapsers, and treatment-naïve – who may benefit from treatment now or in the future.

65. Moreover, defendants have not addressed their protocol's outdated treatment exclusions. For example, disqualifying prisoners based on an upcoming release date made some sense under a 48-week combination therapy regimen, but today the standard treatment time is 12 weeks. Prisoners with decompensated cirrhosis of the liver used to be excluded, but the new regimens are effective in these cases. Excluding prisoners who have contraindications to taking Interferon or Ribavirin is no longer necessary or appropriate.

Conscious Disregard of Serious Needs by Delay and Denial

66. In years past using combination therapy, the DOC rationed treatment, delaying care for many prisoners. However, they at least treated eighty or more Hepatitis C prisoners at a time. The DOC provided combination therapy despite its challenges, which included a long duration of treatment, significant side effects (some of which would require abandoning treatment, and some of which could only be treated at further expense), only a moderate chance of success (for Genotype 1), and high-priced medications.

67. Today, the standard of care includes Interferon-free regimens. These regimens are of much shorter duration, lack the worst side effects, and offer a near-certain cure. Defendants, however, are only treating three prisoners with Hepatitis C, and they have treated almost no one with the newest regimens.

68. The high cost of Hepatitis C medication encourages systemic delay – delay in the defendants' approval of new medications, delay in amendments to the treatment protocol, delay in the staging of the many prisoners who need to know whether they should receive treatment, and delay in treatment itself.

69. When prisoners inquire about Hepatitis C treatment, defendants respond vaguely. They indicate that the prisoner will have a chronic disease appointment soon, or that the

Hepatitis C protocol is under review.

70. There is no legitimate excuse for delay in amending the treatment protocol, in staging, or in prescribing treatment. Defendants knew that the Interferon-free regimens were coming long before they were approved by the FDA.

71. In fact, defendants denied triple therapy to many prisoners by pointing to the imminent arrival of Interferon-free regimens. They have saved money by deferring treatment and reducing the number of treatment slots, in anticipation of this time.

72. The DOC and its health care contractor knew before 2011, when triple therapy arrived, that they needed to bring a large number of prisoners who were previously ineligible for treatment – particularly nonresponders and relapsers – back into the treatment protocol, by ordering pre-treatment tests and staging them. They failed to do so then, and defendants are failing to do so now.

73. Defendants' now-outdated treatment protocol contemplated a staging process of twelve months. It is taking far longer than that to work up most prisoners, with some not being ordered the necessary tests or consults at all, despite the staging process being easier and less invasive than ever before.

74. The result of this foot-dragging is that defendants do not know who needs Hepatitis C treatment now, or which prisoners need treatment the most. By their actions, defendants have made a conscious choice not to know.

75. Moreover, to treat only the most severe cases of Hepatitis C is no longer the standard of care. At a minimum, prisoners with a moderate stage of liver fibrosis (including Stage 2 of the Metavir scale, or Stage 3 of the Ishak scale) should be treated. In the past, prisoners with moderate fibrosis might be encouraged to wait for the arrival of new regimens.

Those regimens are now here.

76. Having chosen to delay treatment for so many prisoners from 2011 to 2015, and having saved a significant amount of money in so doing, defendants cannot now be heard to complain about cost, or to delay treatment any longer under the guise of further deliberation.

77. Defendants should be adhering to specific guidelines and deadlines for follow-up testing and evaluation of prisoners who, for whatever reason, have been deemed ineligible for treatment.

Risk of Serious Harm That Results

78. Some 20% of people with Hepatitis C will progress toward cirrhosis, putting them at risk of end stage liver disease, cancer, and death.

79. Hundreds of DOC prisoners are at risk of serious harm, including cirrhosis, end stage liver disease, cancer, and death, if they do not receive timely and adequate monitoring, testing, and treatment.

80. The risk of serious harm and death is not hypothetical. Other prisoners were forced to wait while their untreated Hepatitis C led to their deaths.

CLAIM FOR RELIEF

CRUEL AND UNUSUAL PUNISHMENT IN VIOLATION OF THE EIGHTH AND FOURTEENTH AMENDMENTS TO THE UNITED STATES CONSTITUTION

81. Plaintiffs restate and reallege paragraphs 1-80 as if fully set forth herein.

82. In all relevant aspects, defendants have acted, and are acting, under color of law, custom and policy.

83. By their policies, practices, and acts, defendants are violating the rights of plaintiffs and the members of their class to be free from cruel and unusual punishment guaranteed by the Eighth and Fourteenth Amendments to the United States Constitution and 42 U.S.C. § 1983 as a

result of their deliberate indifference to the serious medical needs of plaintiffs and the members of their class for immediate and effective treatment for Hepatitis C.

PRAYER FOR RELIEF

84. WHEREFORE, plaintiffs request that this Court grant them the following relief:

a. Certify that this action be maintained as a class action of all prisoners in Department of Correction custody who have Hepatitis C;

b. Issue a judgment against defendants, declaring that their acts, omissions, policies, and practices with regard to the treatment of Hepatitis C are cruel and unusual punishment in violation of the Eighth and Fourteenth Amendments to the United States Constitution and 42 U.S.C. § 1983;

c. Issue preliminary and permanent injunctions ordering defendants to implement and adhere to a comprehensive treatment protocol that includes timely and adequate screening of DOC prisoners, timely evaluation, staging, and monitoring of Hepatitis C prisoners, timely treatment with the most effective medications, timely and adequate treatment of side effects to ensure that the Hepatitis C treatment is successful, and elimination of unjustified exclusions from or denials of treatment;

d. Enjoin defendants from taking any action to interfere with plaintiffs' right to maintain this action, or from retaliating in any way against plaintiffs for bringing this action;

e. Award plaintiffs their reasonable attorneys' fees and costs, in accordance with 42 U.S.C. § 1988 and other applicable law;

f. Grant such other and further relief as this Court considers just and proper.

Respectfully submitted,

Plaintiffs Emilian Paszko and Jeffrey Fowler, on behalf of themselves and all others similarly situated,

By their Attorneys,

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