UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

RICHARD WEST and JOSEPH BRUYETTE, individually and on behalf of a class of similarly situated persons; Plaintiffs, v. AL GOBEILLE, Vermont Secretary of Human Services, MICHAEL TOUCHETTE, Vermont Department of Corrections Commissioner, BENJAMIN WATTS, Vermont Department of Corrections Health Services Director, in their official capacities, VERMONT DEPARTMENT OF CORRECTIONS, CENTURION OF VERMONT, LLC, Defendants.	Case No. DECLARATION OF DR. STACEY TROOSKIN, MD, PH.D, MPH IN SUPPORT OF PLAINTIFF'S MOTION FOR CLASS CERTIFICATION

I. Credentials

1. I am a medical doctor and a nationally recognized medical researcher in the field of viral hepatitis.

2. I received my M.D. from the Robert Wood Johnson School of Medicine, my Ph.D. in in Epidemiology from Rutgers University, and my Masters of Public Health from Yale University.

3. I am board certified in internal medicine and have spent my entire career – a total of 18 years -- focusing on issues related to the testing and treatment of Hepatitis C.

4. I am a practicing physician, and care for, on average, 30 patients infected with Hepatitis C every month.

5. I am currently the Director of Viral Hepatitis Programs at Philadelphia FIGHT Community Health Centers in Philadelphia, Pennsylvania. Philadelphia FIGHT is a comprehensive health services organization providing primary medical and dental care, consumer education, advocacy and research. In this role, I oversee the care of more than 125 patients every month via our weekly multidisciplinary HCV case conference. I also oversee our community HCV testing and linkage to care program that includes a partnership with the Philadelphia Department of Prisons (PDP).

6. I am the Community Co-Chair of the Hepatitis C Allies of Philadelphia. The Hepatitis C Allies of Philadelphia is a citywide collective dedicated to improving the continuum of hepatitis C prevention, diagnosis, care, and support services with the goal of eliminating Hepatitis C from the City of Philadelphia.

7. I am a member of the Infectious Disease Society of America (IDSA) as well as the American Association for the Study of Liver Diseases (AASLD). The IDSA is a medical association representing physicians, scientists and other health care professionals who specialize in infectious diseases. The AASLD is a leading organization of scientists and health care professionals committed to preventing and curing liver disease.

8. I sit on the AASLD/IDSA Treatment Guidance Panel, the entity that develops the nationwide standard of care for treatment of chronic Hepatitis C. Panel members are chosen based on their expertise in the diagnosis, management, and treatment of HCV infection.

II. An Overview of Hepatitis C

9. Hepatitis C ("HCV") is a blood-borne infectious disease, which is transmitted through exposure to infected blood. Even a microscopic amount of blood can transmit HCV.

10. The only way to be diagnosed with HCV is through a blood test that identifies HCV antibodies.

11. Chronic Hepatitis C is a widespread communicable disease that scars the liver and can cause cancer, portal hypertension, excruciating pain, and death.

12. Chronic HCV is a widespread infectious disease. Over 3.5 million individuals in the United States are estimated to be infected with chronic HCV, and more than 20,000 people in the United States die due to liver disease caused by chronic HCV each year—more than all the next 60 infectious diseases reported to the CDC combined. This makes Hepatitis C the deadliest infectious disease in the United States.

13. Hepatitis C is a growing public health crisis both in Vermont and throughout the United States. Out of every 100 people infected with the Hepatitis C virus, 75 to 85 will go on to develop chronic HCV, which is an infection that lasts longer than six months.

14. The opioid epidemic has increased the incidence of chronic HCV infection, particularly among younger individuals. New cases of chronic HCV are found disproportionately among people who inject drugs.

15. Vermont HCV surveillance data shows a significant increase in newly-reported cases of chronic HCV infection in the state. Chronic HCV is prevalent in

Vermont, with 723 new cases reported by the U.S. Centers for Disease Control in 2016. *See* Exhibit 1 at page 64.

16. The U.S. Centers for Disease Control and Prevention ("CDC") recognizes that pinpointing an exact number of people infected with chronic HCV is challenging because up to 50% of people living with the infection in the United States do not know they are infected. As such, estimates by the Vermont Department of Health likely do not reflect the number of individuals infected with the disease.

17. Chronic HCV is even more prevalent in prisons. Of the 2.2 million people in American jails and prisons, the CDC estimates that approximately one-third of them are infected with chronic HCV. *See* Exhibit 2.

18. This trend is also prevalent in Vermont prisons. In their January 2018 report, the Vermont Department of Health estimated that there are 150 – 879 cases of HCV among individuals who are incarcerated in the custody of the Vermont Department of Corrections. *See* Exhibit 3 at page 3, Table A.

III. Those living with chronic HCV suffer from a serious medical need and a chronic disability.

19. Individuals infected with chronic HCV suffer from a range of hepatic (affecting the liver) and extrahepatic (affecting other organ systems) symptoms.

20. A common hepatic manifestation of chronic HCV infection symptom is fibrosis, the formation of scar tissue in the liver. This scarring of the liver ranges from mild to severe, with the most severe form of fibrosis being cirrhosis. As cirrhosis progresses, more scar tissue forms, making it difficult for the liver to function.

21. Advanced scarring of the liver (Fibrosis score of F3 or F4) is associated with an increased risk of cancer. Cirrhosis is associated with increased rates of liver transplants, and increased risk of death.

22. Once individuals develop advanced liver disease they must undergo cancer screening at regular intervals for the rest of their life even after they are cured of their chronic HCV infection.

23. A significant number of persons with chronic HCV who have no or mild fibrosis will progress to cirrhosis in the absence of treatment.

24. Currently, there is no way to predict which newly infected patients will develop advanced liver disease.

25. According to the CDC, 40% of those infected with chronic Hepatitis C will develop cirrhosis, and more than 5% will develop liver cancer.

26. Hepatitis C is the most common cause of liver transplants in the United States.

27. Liver damage is only one potentially significant consequence of chronic HCV infection.

28. Chronic Hepatitis C may have extrahepatic manifestations which affect other organ systems.

29. Chronic HCV infection can be associated with myocardial infarction, diabetes, decreased cognitive function, fatigue, joint pain, depression, sore muscles, arthritis various cancers, decreased kidney function, certain types of rashes and autoimmune disease. These extrahepatic manifestations can occur irrespective of the amount of fibrosis in the liver.

30. Delay in treatment can cause damage to the liver and other vital organs. I strongly agree with the current HCV Guidance which provide that "[b]ecause of the many benefits associated with successful HCV treatment, clinicians should treat HCV-infected patients with antiviral therapy with the goal of achieving an SVR, preferably early in the course of their chronic HCV infection before the development of severe liver disease and other complications." By denying or delaying DAA treatment congruent with the standard of care, the Vermont DOC places inmates chronically infected with HCV in imminent risk of harm.

IV. Measurement of Disease Severity

31. Liver damage and scarring related to chronic HCV infection ("fibrosis") is measured in a variety of methods. In addition to the physical exam and history, medical professionals should use a combination of other blood tests and imaging to determine the stage of liver damage caused by HCV.

32. Metavir Fibrosis Score ("fibrosis score"), measures the degree of inflammation (activity grade A0 to A3) and the degree of fibrosis (Fibrosis State F0 to F4). A score of F0 represents no fibrosis (no scarring), F1 is portal fibrosis without septa formation (minimal scarring), F2 is portal fibrosis with few septa (intermediate scarring), F3 is numerous septa without cirrhosis (severe scarring) and F4 is cirrhosis. A parallel scale of measurement is known as "Ishak Stage," named after one of the pathologists who developed it, and it quantifies fibrosis on an ascending scale of 0-6.

33. Metavir Scores can be estimated using noninvasive serological testing as well as transient elastography. Liver biopsy is no longer considered the standard of care

for staging liver disease. All measures of liver fibrosis have limitations. Beyond the limitations of the individual modalities of disease staging, it is important to understand that the progression of liver disease is not linear and therefore difficult to predict an individual's progression through the stages of liver damage over time.

34. Blood tests can provide an "APRI score" determined from a ratio derived from the level of an enzyme in the blood (AST) compared to the AST levels of healthy persons and the number of platelets in the infected person's blood. "APRI" is an acronym for "AST to Platelet Ratio Index." The APRI score provides useful, but often imprecise measures of fibrosis or cirrhosis. Generally, the lower the APRI score (in the scientific literature a cutoff of less than 0.5 is often used), the greater the negative predictive value (and ability to rule out cirrhosis) and the higher the value (the scientific literature often uses a measurement of greater than 1.5) the greater the positive predictive value (and ability to rule in cirrhosis); midrange values are less accurate and less helpful. The APRI score has a sensitivity of 0.81 of using an APRI score of 0.5 or higher to diagnose Fibrosis (defined as a Metavir stage F2 to F4 and Ishak stages 3 to 6 or equivalent). However, a cutoff of 0.5 would fail to identify 19% of people who actually had fibrosis.

35. Similarly, another method of estimating fibrosis using blood testing is known as "Fibrosis-4 or "FIB-4." FIB-4 scores measure liver scarring through a calculation including patient age, platelet count, and liver enzymes. A FIB-4 score of less than 1.45 has been demonstrated in 2 studies to have a negative predictive value of 90 to 95%, suggesting that for every 100 patients with a negative test result

(Fib-4 < 1.45), 90 to 95% will actually have an Ishak score of less than 4 or a Metavir score of less than 3, see exhibits 8-10.

V. Treatment of HCV

36. Prior to 2011, treatment for chronic HCV infection was ineffective and accompanied by severe side effects.

37. Before the advent of all oral Direct Acting Agent (DAA) regimens, the standard of care for chronic HCV treatment was a three-drug treatment consisting of boceprevir or telaprevir, interferon, and ribavirin. This treatment provided, at best, a 70% cure rate, and was accompanied by several adverse side effects, including anemia, insomnia, anxiety, depression, nausea, bone pain, joint pain, muscle pain, memory loss, liver failure, and death.

38. Starting in 2011, the United States Food and Drug Administration approved a series of DAA oral medications for the treatment of HCV capable of curing the infection. These DAAs include Harvoni (ledipasvir-sofosbuvir) ("Harvoni"), Olysio (simeprevir), Sovaldi (sofosbuvir), Viekira Pak (ombitasvir/paritaprevir/ritonavir plus dasabuvir), Zepatier (elbasvir/grazoprevir), Epclusa (sofosbuvir/velpatasvir), Mavyret (glecaprevir/pibrentasvir), and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) to treat chronic HCV infection. These medications result in a sustained virologic response ("SVR") -- meaning elimination of the virus -- for more than 90% of patients, when treated according to the recommended protocol. The FDA designated these drugs as "breakthrough therapies," a classification reserved for drugs that provide substantial

improvement over available therapies for patients with serious or life-threatening diseases.

39. All FDA-approved DAAs are supported by multiple, well-designed, controlled studies or well-designed experimental studies.

40. These medications result in a sustained virologic response ("SVR") in 90% of patients who use the drug according to recommended protocol. SVR means that no trace of the Hepatitis C virus can be detected in the blood.

41. Sustained Virologic Response (SVR) is considered by researchers, physicians and the AASLD/IDSA HCV Guidelines to be a cure of a Hepatitis C infection. I consider SVR to be a cure of Hepatitis C infection.

42. DAA treatment can cure chronic HCV with a daily oral medication taken over the course of 8 to 12 weeks — with mild and treatable side effects.

43. In addition to the curative benefits of SVR, patients who achieve SVR are no longer able to transmit the virus, thereby curbing the incident rate of HCV infection nationwide.

44. In the absence of DAA treatment, individuals infected with chronic HCV may suffer from fibrosis progression.

45. Delaying treatment has a variety of adverse effects including the increased risk of liver damage and cancer, as well as other adverse health outcomes. Delayed treatment also increases the risk of death. Once an individual is cirrhotic, treatment does not eliminate the risk of liver cancer and that individual must continue to be screened for liver cancer every 6 months, indefinitely.

46. One study has shown that delaying treatment until a certain fibrosis score of 3-4 results in a two-to-three times higher rate of liver-related mortality in HIV positive patients, compared with commencing treatment when the score is F2. *See* Exhibit 7.

47. Delaying treatment can also increase psychological stressors including anxiety, illness uncertainty (the inability to determine the meaning of illness-related events), and depressive symptoms. With treatment, patients who are cured of chronic HCV report an improvement in their mental well-being.

48. Because of the many benefits associated with successful treatment of chronic HCV infection, HCV-infected individuals should be treated with DAAs to achieve SVR as early as possible in the course of their chronic HCV infection, before the development of severe liver disease.

VI. DAAs are the Standard of Care in Treatment of HCV

49. As stated above, the Infectious Diseases Society of America (IDSA) is an association of over 11,000 physicians, scientists and public health experts who specialize in infectious diseases. The American Association for the Study of Liver Diseases (AASLD) is the leading organization of scientists and health care professionals committed to preventing and curing liver disease. Together, IDSA and AASLD publish "Guidance for Testing, Managing, and Treating Hepatitis C" (Guidance). The Guidance represents findings that are evidence-based, peer-reviewed, and developed by a panel of experts in the field.

50. The Guidance is published at https://www.hcvguidelines.org/full-report-view.

51. The Guidance constitutes the uniform national standard of care for chronic HCV, whether in the community or in a correctional setting.

52. As set forth in the Guidance, DAA treatments are the standard of care in treating chronic HCV, irrespective of fibrosis score.

53. Medicare and the U.S. Department of Veterans Affairs also utilize coverage criteria consistent with the standard of care, as reflected by the AASLD/IDSA guidelines. It is my understanding that Vermont Medicaid also covers DAA treatment irrespective of disease severity, as per the Guidance. *See* Exhibit 4.

54. Under the Guidance, there is no medical basis for using "prioritization" as an instrument of denying or withholding DAA treatment.

55. The Guidance specifically confirms that DAA treatment should be available for all individuals chronically infected with HCV, and should not be reserved for individuals FIB-4 scores of greater than 1.45, or with individuals based on having reached a certain stage of fibrosis.

56. The Guidance explains that DAA treatments should be provided to all patients with chronic HCV regardless of fibrosis score, except those with short life expectancies who cannot be remediated by DAAs, liver transplants, or other therapy.

57. There is no medical justification for denying DAA treatments to individuals with chronic HCV other than the three criteria set forth in the Guidance, and restated herein.

58. The Guidance specifically addresses treatment of chronic HCV in correctional settings. "Prisons should implement routine opt-out HCV testing. Chronically

infected individuals should receive antiviral therapy according to [the Guidance] while incarcerated. Upon release, patients should be provided linkage to community healthcare for surveillance for HCV-related complications." The Guidance thus makes clear that there is no separate standard of care applicable to a correctional setting.

59. Fibrosis scores are useful only inasmuch as they provide direction for the course of treatment, with cirrhotic patients requiring certain considerations when choosing the DAA regimen, duration of treatment and appropriate supportive care and screenings. For example, a patient with a fibrosis score of F4 will require regular cancer screenings. Denying or delaying DAA treatment based on disease severity cannot be justified on any medical basis.

60. Any structural or procedural barrier to providing DAA treatment contravenes the standard of care.

61. The standard of care does not consider delaying or withholding treatment based on behavioral considerations, including propensity for drug relapse, whether patients will interact with society positively, or show they will adhere to and benefit from treatment, in determining who should receive DAA treatment.

62. Current treatment courses range from 8 to 12 weeks. Denying or withholding DAA treatment based on an incarceration length of 12 to 18 months contravenes the standard of care. Just as the standard of care does not allow delaying DAA treatment based on fibrosis score, it does not permit delaying treatment based on these unreasonable time constraints.

63. Denying or withholding DAA treatment based on concerns that a patient will not adhere to the treatment regimen cannot be justified on a medical basis. Adherence with direct-acting antiviral (DAA) therapy is inherently much easier than with older interferon and peg interferon-based therapies due to markedly better medication side effect profile, easier dosing schedule, and overall shorter treatment duration. DAA treatment, which consists of taking one pill per day, can be accomplished in the community without oversight of the original prescribing physician. That is, upon release, a patient could adhere to the treatment regimen under the oversight of another physician.

64. Studies have shown that patients who receive DAA treatments have high adherence rates irrespective of treatment duration. Studies have shown that adherence rates for DAA treatment regimens are greater than 96%. In fact, SVR numbers remained high even when patients injected drugs during the course of their DAA treatment. *See* Exhibit 5.

65. There is consensus in the medical literature that treating individuals chronically infected with Hepatitis C with DAAs is cost-effective, with some studies even concluding that DAA treatment is the rare medical intervention that may be cost-saving. *See* Exhibit 6.

66. The per-treatment cost of DAA treatment has fallen significantly across the market in recent years, making the cost-effectiveness of treatment at all stages of disease severity even more compelling.

VII. Current Vermont Practice

67. It is my understanding that documents from the Vermont Department of Corrections reveal a policy or practice of only referring individuals infected with chronic HCV for DAA treatment when their FIB-4 scores are greater than 1.45. This policy or practice is at odds with the standard of care. The standard of care for chronic HCV does not countenance disease severity thresholds for treatment of any type. Moreover, the Fib-4 score threshold of 1.45 or higher correlates to Metavir Score of F3 or F4, meaning that the threshold is targeted to identify those with advanced fibrosis, to the exclusion of individuals at Metavir Fibrosis Scores F0 through F2. See Exhibits 8-10.

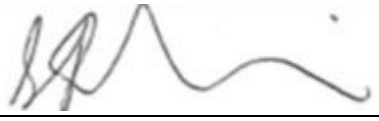
68. To the extent that individuals in DOC custody are still being subjected to the practices and policies of Centurion of Vermont ("Centurion"), the company with whom Vermont DOC contracts for medical care in its corrections facilities, it is my understanding that further restrictions on patients' access to DAA treatment that also contradict the standard of care may be imposed. Centurion guidelines prohibit patients with F-scores of F0 or F1 from receiving DAA treatment. Centurion withholds DAA treatment if the patient has less than a certain minimal threshold of time left before release, has a disciplinary record, has a history of substance abuse or mental health issues, or acquired tattoos while incarcerated. Further, Centurion requires that an inmate with a score of F2-F3 not "have chronic disciplinary issues" in order to receive treatment, and if there is "concern" about a "patient's ability to adhere to and benefit from a standardized treatment regimen…. treatment should not be initiated."

69. The Guidance is clear that DAA treatment must be provided to all individuals infected with chronic HCV, irrespective of fibrosis score, and without any structural or procedural barriers to access. The Guidance applies with equal weight to correctional settings. The Vermont DOC's policies or practices impose barriers to access to DAA treatments that directly contravene the well-accepted standard of care as set forth in the Guidance.

70. In my opinion, the current policies and practices of the Vermont DOC, as described herein and in the Plaintiffs' Complaint, contradict the medical standard of care, and intentionally deny or withhold medically necessary treatment for a serious medical condition without any medical justification whatsoever.

I declare under penalty of perjury that the foregoing is true and correct.

Signed this 20th day of May, 2019.



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