

**IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
No. 1:18-cv-502**

**LLOYD BUFFKIN,
KIM CALDWELL, and
ROBERT PARHAM, individually
and on behalf of a class of similarly
situated persons,**

Plaintiffs,

v.

**ERIK HOOKS, individually and in
his official capacity as Secretary of
the North Carolina Department of
Public Safety,**

**ABHAY AGARWAL, individually
and in his official capacity as Acting
Medical Director, Department of
Adult Correction, North Carolina
Department of Public Safety,**

**KENNETH LASSITER,
individually and in his official
capacity as Director of Prisons,
Department of Adult Correction,
North Carolina Department of
Public Safety,**

**PAULA SMITH, former Medical
Director, Department of Adult
Correction, North Carolina
Department of Public Safety,
individually, and**

**The NORTH CAROLINA
DEPARTMENT OF PUBLIC
SAFETY,**

Defendants.

CLASS ACTION COMPLAINT

1. Plaintiffs are incarcerated by the North Carolina Department of Public Safety (DPS). All have been diagnosed with hepatitis C infection (HCV), a highly communicable disease that scars the liver and presents risks of cancer, portal hypertension, excruciating pain, and death.

2. Plaintiffs have requested treatment that complies with the current standard of medical care: direct-acting antiviral drugs (DAAs) that cure the vast majority of patients infected with HCV.

3. Defendant prison officials have refused to treat Plaintiffs. Unless a patient also has hepatitis B or HIV, DPS only permits DAA treatment when a patient has already suffered significant liver scarring and the risks of further significant injury are higher.

4. There is no medical reason justifying the denial of DAAs to Plaintiffs. Rather, DPS refuses to provide medically necessary treatment simply to avoid the associated costs.

5. Even patients in DPS custody with the most advanced forms of HCV—and at the greatest risk of experiencing the disease’s most horrific outcomes—may not qualify for treatment. Regardless of how advanced a patient’s disease is, DPS policy forbids DAA treatment if the patient has less than twelve months left on his sentence, a life expectancy of less than ten years, or a drug or alcohol infraction committed within the previous twelve months. None of these restrictions are medically justified. They exist only to spare DPS further cost.

6. DPS has also failed to implement medically adequate HCV screening practices. Despite the high concentration of HCV in prisons, DPS has not implemented universal

screening. Instead, DPS employs an outdated, risk-based approach that does not actually require testing of anyone. Thus, there are almost certainly thousands of people in DPS custody with undiagnosed HCV. And, once a prisoner receives an HCV diagnosis, she may go years without follow-up testing.

7. By maintaining these policies and practices, Defendants have shown deliberate indifference to Plaintiffs' serious medical needs in violation of the Eighth Amendment's prohibition of cruel and unusual punishments. Defendants have also violated Plaintiffs' rights under the Americans with Disabilities Act by denying them medical services on the basis of their disability.

8. Plaintiffs seek declaratory and injunctive relief on behalf of themselves and a class of all current and future persons in the custody of the North Carolina Department of Public Safety who have or will have chronic HCV, have at least 12 weeks remaining on their sentences, and have not received DAA treatment. Named Plaintiffs also seek damages for the harm suffered by the denial of medically necessary treatment.

9. Plaintiffs have either exhausted their administrative remedies or the DPS Administrative Remedy Procedure has been unavailable to them.

JURISDICTION AND VENUE

10. Plaintiffs bring this action under 42 U.S.C. § 1983, the Eighth and Fourteenth Amendments to the United States Constitution, and the American with Disabilities Act of 1990, 42 U.S.C. § 12101, *et seq.*

11. Jurisdiction is proper under 28 U.S.C. § 1331 and 28 U.S.C. § 1343(a)(3).

12. Venue is proper under 28 U.S.C. § 1391(b)(2), as substantial events at issue in this litigation occurred in the Middle District of North Carolina.

PARTIES

13. Plaintiff Lloyd Buffkin is an adult man currently incarcerated at Scotland Correctional Institution in Laurinburg, North Carolina. He has been diagnosed with chronic HCV and has not been treated for it.

14. Plaintiff Robert Parham is an adult man currently incarcerated at Polk Correctional Institution in Butner, North Carolina. He has been diagnosed with chronic HCV and has not been treated for it.

15. Plaintiff Kim Caldwell is an adult man currently incarcerated at the Dan River Prison Work Farm in Blanch, North Carolina. He has been diagnosed with HCV and has not been treated for it.

16. Defendant North Carolina Department of Public Safety is a public entity as defined by Title II of the Americans with Disabilities Act. It is sued for declaratory and injunctive relief and money damages on Plaintiffs' ADA claims only.

17. Defendant Erik Hooks is the Secretary of DPS. He is responsible for the overall operation of DPS, including North Carolina's prisons. Defendant Hooks has a legal duty to provide adequate medical care to all persons in DPS custody. He is sued in his official capacity for injunctive and declaratory relief, and in his personal capacity for money damages.

18. Defendant Paula Smith is the former Medical Director for the Division of Adult Correction (DAC) of DPS. She was responsible for the creation and implementation of

DPS medical policy governing treatment of patients incarcerated in DAC. Defendant Smith had a legal duty to provide adequate medical care to all persons in DAC custody. She is sued in her personal capacity for money damages.

19. Defendant Abhay Agarwal is the acting Medical Director for DAC. He is responsible for the creation and implementation of DPS medical policy governing treatment of patients incarcerated in DAC. Defendant Agarwal has a legal duty to provide adequate medical care to all persons in DAC custody. He is sued in his official capacity for injunctive and declaratory relief, and in his personal capacity for money damages.

20. Defendant Kenneth Lassiter is the Director of Prisons for DAC. He is responsible for the overall operation of North Carolina's prisons, including the creation and implementation of DPS policy. Defendant Lassiter has a legal duty to provide adequate medical care to all persons in DAC custody. He is sued in his official capacity for injunctive and declaratory relief, and in his personal capacity for money damages.

21. Defendants may be referred to collectively as DPS.

DR. ANDREW MUIR

22. Plaintiffs' counsel has retained Dr. Andrew Muir, a board-certified gastroenterologist and Chief of the Division of Gastroenterology at Duke Hospital, to consult on Defendants' policies and practices regarding HCV. He has signed an affidavit that discusses background information on HCV, the medical standard of care for screening and treatment of HCV, facts specific to people living with HCV in DPS custody, and DPS's policies on screening and treatment of HCV. His affidavit is attached to the complaint as Exhibit A and informs the following allegations.

FACTS

Background Information on Hepatitis C

23. HCV is a viral infection that causes liver inflammation. The disease spreads by exposure to blood or blood products. Transmission commonly occurs through tattooing, sex, organ transplants, blood transfusion, and intravenous drug use.

24. HCV infection can be acute or chronic. Patients with acute HCV are usually asymptomatic or have mild symptoms such as fatigue. An acute infection may spontaneously clear itself from a patient's blood within six months of exposure. When HCV is still detectable in a patient's blood six months after exposure, the condition is defined as chronic. Approximately 80 percent of infected patients will develop chronic HCV.

25. Untreated, the inflammation caused by HCV will result in scarring of the liver, called fibrosis. Fibrosis significantly impairs the liver's critical functions of digesting nutrients, filtering toxins, and fighting infections.

26. Extensive fibrosis is called cirrhosis. Advanced fibrosis or cirrhosis puts patients at risk of liver cancer and hepatic decompensation. Research has shown that the median time for progression to cirrhosis from infection is 30 years, but ranges from 13 to 42 years. Approximately one third of patients with chronic HCV have an expected median time to cirrhosis of less than 20 years.

27. The development of fibrosis and cirrhosis is clinically silent in the majority of patients. Symptomatic patients often experience swelling, fluid retention, various skin problems, joint and muscle pain, and fatigue.

28. Cirrhosis may progress from a silent condition to hepatic decompensation, which involves the development of painful complications from portal hypertension. These include ascites (fluid buildup in the abdomen), pedal edema (leg and feet swelling), variceal bleeding (bleeding from abnormal blood vessels, usually in the esophagus but possibly anywhere in the gastrointestinal tract), hepatorenal syndrome (kidney failure), and hepatic encephalopathy (confusion due to the accumulation of toxic substances in the blood).
29. All patients with cirrhosis are at risk of portal hypertension and liver cancer (hepatocellular carcinoma, or “HCC”), both of which carry high mortality rates.
30. Treatment of these conditions often requires invasive and painful procedures. Patients who develop these conditions are at high risk of death and should be evaluated for a liver transplant.
31. As the DPS policy governing HCV treatment acknowledges, it is difficult to predict the rate at which the disease will progress.
32. The METAVIR scale measures a patient’s level of fibrosis. It grades the degree of fibrosis on a 5-point scale from 0 to 4. A liver biopsy can measure a patient’s level of fibrosis, but because biopsies are painful and carry risks of hemorrhage and even death, other less invasive tests have been developed and are more commonly used.
33. DPS uses a FibroSure test to determine a patient’s level of fibrosis. A score of F0 means no fibrosis, F1 is mild fibrosis, F2 is moderate or significant fibrosis, F3 is severe fibrosis, and F4 is cirrhosis.

34. Research has shown, however, that the FibroSure's utility in assessing fibrosis is quite limited. FibroSure is best suited to determining whether a patient has cirrhosis or not. The test's accuracy in determining a patient's specific stage of fibrosis, on the other hand, is poor. The test's sensitivity for detecting significant fibrosis has been reported at only 60-75 percent.

35. Therefore, a patient with a FibroSure result showing mild or moderate fibrosis has an alarmingly high chance of actually having far more advanced fibrosis and more urgently requiring treatment.

HCV Screening

36. HCV is typically diagnosed through a blood test that reveals HCV antibodies. Guidelines from the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA)—which constitute the current standard of care for HCV screening—recommend screening certain populations based on demography, prior exposures, behaviors, and medical conditions. This screening increases the likelihood of early detection and reduces the risk of liver cancer, death, and transmission to others.

37. The AASLD/IDSA guidelines recommend screening of all persons who have ever been incarcerated. The Centers for Disease Control and Prevention (CDC) recommend screening of all persons born between 1945 and 1965, and all who have ever injected drugs.

Medical Standard of Care for HCV

38. Before 2013, HCV treatment involved injectable interferon-alpha medications that caused severe side effects including flulike symptoms, psychiatric and autoimmune disorders, and gastrointestinal problems. The treatment regimen lasted between six and twelve months, and ultimately worked in only about half of the patients who could tolerate the medicine.

39. The standard of care for chronic HCV changed after direct-acting antiviral drugs became available in 2013. DAAs are taken orally, involve a regimen of only eight to twelve weeks, cause minimal side effects, and cure HCV in 90-95 percent of patients.

40. These drugs include Sovaldi (sofosbuvir), Olysio (simeprevir), Harvoni (sofosbuvir/ledipasvir), ViekiraPak (ombitasvir/paritaprevir/ritonavir/dasabuvir), Daklinza (daclatasvir), Technivie (ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazprevir), Epclusa (sofosbuvir/velpatasvir), and Mavyret (glecaprevir and pibrentasvir).

41. The AASLD and IDSA provide guidelines setting out the current standard of care for HCV treatment.

42. These guidelines state that *all* patients with chronic HCV should receive treatment with DAAs. The only exception is for patients “with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy.”

43. In ongoing litigation in the Eastern District of North Carolina, Defendant Smith has agreed that DAA treatment for chronic HCV, except for patients with short life expectancies, is the current standard of medical care.

44. Beyond a patient having an allergy to DAAs or some other life-threatening condition, few other medical reasons exist for not treating chronic HCV with DAAs.

45. It is not medically acceptable to recommend treatment based on a patient's level of fibrosis.

46. Successful HCV treatment depends in part on how far the disease has progressed. Patients treated earlier will respond better to treatment and have a greater likelihood of being cured.

HCV as a Public Health Issue

47. Hepatitis C presents immense public health concerns. The disease causes more deaths in the United States every year than 60 other infectious diseases combined, including HIV, pneumococcal disease, and tuberculosis.

48. There is a higher concentration of persons with HCV in prison and jail than in the general population. The National Institute of Health (NIH) has estimated that 17.4 percent of all incarcerated persons have HCV. The CDC place the figure at 33 percent. Defendant Smith recently stated that DPS has identified 1,543 inmates as having chronic HCV, but, based on the CDC and NIH figures, she estimated that the total number of infected inmates was between 6,559 and 12,553.

49. Defendant Smith reported in April 2018 that only 589 DPS inmates had completed DAA treatment, and another 72 were receiving or had been approved for DAA treatment.

50. This heavy concentration of HCV in North Carolina's prison population presents a serious public health problem. Prisoners are at increased risk of infection, and the vast majority of them will be released. This places the general population at greater risk,

especially if a released prisoner doesn't know that he has HCV—an event that seems all too likely given DPS's outdated, scattershot approach to screening.

51. The concentration of HCV in prisons, however, also presents a unique opportunity. Because such a disproportionately large number of HCV-infected persons live in a highly controlled environment, it is less challenging to diagnose them, treat them, and in doing so, eradicate a significant portion of HCV in North Carolina. While DAA treatment is often expensive, North Carolina will likely pay for a prisoner's treatment even after he is released. North Carolina's Medicaid program covers the cost of DAA treatment for qualifying individuals regardless of the patient's fibrosis level.

ALLEGATIONS BY NAMED PLAINTIFFS

Lloyd Buffkin

52. Lloyd Buffkin has been incarcerated in DPS custody since July 2013. He has a projected release date of December 13, 2030.

53. Buffkin was diagnosed with hepatitis C in August 2017 while in DPS custody.

54. As of July 2017, Buffkin had a FibroSure score of F1-F2.

55. Therefore, he has at least suffered moderate to significant liver scarring. Because of the FibroSure test's inaccuracy, however, he may have in fact suffered more advanced fibrosis.

56. Buffkin has also experienced chronic conditions associated with HCV, including fatigue and atopic dermatitis. These conditions cause him significant pain and suffering on a near daily basis.

57. Buffkin's chronic HCV also causes him great stress and worry. It is extremely difficult for him to know that the disease is gradually scarring his liver, but he cannot receive the cure until the disease progresses to where he is at even greater risk of severe injury and suffering.

58. Buffkin will not be considered again for DAA treatment until October of this year, following completion of another FibroSure test.

59. During this time, Buffkin's HCV may progress, further scarring his liver, impairing liver function, and putting him at increasing risk of cirrhosis, liver disease, excruciating pain, and death.

60. No medical reason exists to deny Buffkin treatment with DAAs.

61. Defendants' refusal to treat Buffkin with DAAs constitutes deliberate indifference to his serious medical need.

Robert Parham

62. Robert Parham has been incarcerated in DPS custody since October 2008. He has a life sentence.

63. Parham has lived with chronic HCV for over 20 years.

64. Prior to DAAs becoming the standard of care for chronic HCV, DPS medical staff considered treatment with the old regimen of interferon, but concluded that Parham was not a suitable candidate.

65. Lab records from February 2015 show that his disease had advanced to F2. Lab records from January 2018 show a score of F1-F2. Thus, Parham has already suffered moderate to significant fibrosis. Because of the FibroSure test's inaccuracy, however, he

may have in fact suffered more advanced fibrosis. Indeed, his medical records that he has a history of cirrhosis. Parham has experienced symptoms consistent with advanced fibrosis and cirrhosis including pedal edema, fluid retention, dermatitis, pruritis, and joint pain. These conditions cause Parham significant pain and suffering on a near daily basis.

66. In March 2018, DPS medical providers performed an ultrasound of Parham to assess his liver. Yet, DPS policy states that periodic liver ultrasounds should not be performed unless cirrhosis is already present or there is another definitive indication.

67. Medical providers concluded, after review of Parham's ultrasound, that cirrhosis was not present. However, ultrasound is not appropriately utilized to diagnose cirrhosis.

68. Parham's chronic HCV also causes him great stress and worry. It is extremely difficult for him to know that the disease is gradually scarring his liver, but he cannot receive the cure until the disease progresses to where he is at greater risk of severe injury and suffering.

69. Parham has not received any treatment for his chronic HCV. He will not be considered for DAA treatment until at least January 2019 after completion of another FibroSure test.

70. During this time, Parham's HCV may advance, further scarring his liver, inhibiting liver function, and putting him at even greater risk of cirrhosis, liver disease, excruciating pain, and death.

71. No medical reason exists to deny Parham treatment with DAAs.

72. Defendants' refusal to treat Parham with DAAs constitutes deliberate indifference to his serious medical need.

Kim Caldwell

73. Kim Caldwell has been incarcerated in DPS custody since July 2015. He has a projected release date of April 24, 2021.

74. He was diagnosed with HCV in 2015 while in DPS custody.

75. Since then, he has not undergone any follow-up testing, although medical records from July 2016 indicate that HCV was still a concern at the time. Given this timeframe and that about 80% of acute HCV cases become chronic, it is highly likely that Caldwell has developed chronic HCV.

76. Without appropriate testing, Caldwell has no way of knowing to what extent his disease has progressed.

77. No medical reason exists to forgo HCV testing for Caldwell or to deny him treatment with DAAs if his infection has become chronic.

78. Defendants' refusal to conduct follow-up testing and provide medically necessary treatment constitutes deliberate indifference to his serious medical need.

DPS Screening and Treatment Policy

79. Policy #CP-7 in the DPS Health Services Policy and Procedure Manual governs the detection, evaluation, and treatment of HCV in North Carolina's prisons.

80. This policy does not provide for universal screening of prisoners for HCV.

81. Medical staff may order testing after consideration of certain risk factors, but there are no circumstances under which DPS policy requires that anyone be tested.

82. DPS's total reliance on risk-based assessment falls short of the AASLD/IDSA guidelines, which recommend screening all persons who have ever been incarcerated. As

a result, it is a virtual certainty that thousands of people in DPS custody have HCV, but have not been diagnosed.

83. After a patient is diagnosed with HCV, Step 2 of the policy directs medical staff to perform a physical examination, take a medical history, obtain baseline labs, evaluate for other potential causes of liver disease, begin patient counseling, and take certain preventative health measures.

84. Step 3 then directs medical staff to conduct a pretreatment evaluation, which includes reviewing lab tests, conducting a pregnancy test, and discussing treatment options with the patient.

85. In Step 4a, the policy requires a determination of whether treatment is contraindicated.

86. Most of the contraindications listed appear to be holdovers from the previously used regimen of interferon-based medicines, which DPS no longer uses. As such, they present medically unjustified barriers to treatment that now serve only to spare DPS the cost of treating more patients with DAAs.

87. Medical staff must cease all testing and treatment if a patient will not be incarcerated for long enough to complete treatment. Even though a course of treatment with DAAs typically requires no more than twelve weeks, the policy states that “[u]sually a twelve (12) month period would be required to complete assessment and treatment for Hepatitis C.”

88. As it stands now, the twelve month requirement has no medical justification. It exists only to spare DPS the cost of treating HCV-infected patients with less than a year left on their sentences.

89. Testing and treatment must also stop if the patient “has infractions related to alcohol or drug use in the previous twelve months.”

90. This condition also lacks any medical justification, and may be another holdover from the previous interferon-based regimen. Today, this policy only serves to punish inmates for a disciplinary infraction by denying them necessary medical care, and to spare DPS the costs of DAA treatment for another subset of HCV-infected prisoners.

91. Testing and treatment must also cease if the patient has a life expectancy of less than ten years. This window, however, provides ample time for an HCV-infected patient to develop cirrhosis, liver cancer, portal hypertension, and the painful resulting complications.

92. DPS policy further lists unstable medical or mental health conditions as a contraindication. Under the interferon-based treatment regime, it would have been appropriate to withhold treatment for patients with severe mental illness. With DAAs, however, as long as the patient is willing to receive treatment, these diagnoses are not contraindications.

93. In Step 4b, the policy requires follow-up testing at certain intervals. Every six months, inmates with HCV must have alanine transaminase (ALT), aspartate aminotransferase (AST), bilirubin, albumin, and prothrombin time (INR) tests performed. Every year, a complete blood count (CBC) must be performed.

94. As demonstrated by Plaintiff Caldwell, however, there is no guarantee that DPS will conduct *any* follow-up testing for patients diagnosed with HCV. Caldwell was initially diagnosed in 2015 but has not undergone any further HCV testing since that time.

95. Step 5 sets out who may receive treatment. The policy permits DAA treatment only for patients at stage F2 and higher, with one exception: patients with a lower level of fibrosis but who are also infected with HIV or hepatitis B may also receive treatment. All others must be monitored as set out in Step 4b.

96. There is no medical reason to prohibit DAA treatment for patients with a FibroSure score below F2. Indeed, Dr. Thomas Nuzum, a UNC physician who provides hepatology services for DPS, has admitted in other litigation that when treating non-incarcerated HCV patients, he does not require that they have a score of F2 or higher.

97. Annual FibroSure testing is permitted by DPS policy, but not required. As a result, DPS has created a catch-22 in which HCV-infected prisoners may go indefinitely without a FibroSure test, but they cannot qualify for treatment unless they receive a sufficient FibroSure score.

98. DPS policy expressly forbids the treatment of patients whose HCV is caught early, when they might be spared significant liver scarring, painful symptoms, and unnecessary risk of further injury and death. The only way for patients to qualify for HCV treatment is to wait while their disease advances, and hope that DPS decides to order a timely FibroSure test that provides an accurate result.

99. Plaintiff Parham's lab records from February 2015 show that his disease had advanced to F2, but records from January 2018 show a score of F1-F2. DPS policy renders him ineligible for treatment, despite medical symptoms consistent with advanced fibrosis and cirrhosis including pedal edema, fluid retention, dermatitis, pruritis, and joint pain.

100. Plaintiff Buffkin was diagnosed with HCV in August 2017 and his last lab records show a score of F1-F2. He suffers from chronic conditions associated with HCV, including fatigue and atopic dermatitis, but does not qualify for treatment under DPS guidelines.

101. Similarly, Roger Elks is incarcerated at Greene Correctional Institution in Snow Hill, North Carolina. He was diagnosed with chronic HCV in March 2006 but does not qualify for treatment under DPS guidelines despite suffering from swelling in his legs, abdominal pain, and an enlarged liver.

102. DPS policy may also deny DAA treatment to patients with even the most advanced cases of HCV. These patients are at the highest risk of developing liver cancer, portal hypertension, and the most painful HCV-related complications. They are denied potentially lifesaving treatment only because they fall under one of the policy's medically unjustified contraindications.

103. For example, Jackie Housand is incarcerated at Greene Correctional Institution in Snow Hill, North Carolina. He was diagnosed with HCV in 2009 at Central Prison and remained in DPS custody until 2016. As he neared his release date, he learned he had

advanced HCV but that he would not be treated for the disease because he was within twelve months of his release date.

104. Housand was re-admitted to DPS custody in October 2017. He learned that he has advanced cirrhosis. He has not received any treatment for HCV.

CLASS ACTION ALLEGATIONS

105. Plaintiffs seek to certify a class of all current and future prisoners in DPS custody who have or will have chronic HCV, at least 12 weeks remaining on their sentences, and have not been treated with DAAs (the “Plaintiff Class”).

106. Defendants have the ability to identify all members of the Plaintiff Class.

107. The named Plaintiffs are members of the Plaintiff Class.

108. The requirements of Federal Rule of Civil Procedure 23(a) are satisfied:

- a. *Numerosity.* The Plaintiff Class is so numerous that joinder of all its members is impracticable. Defendant Smith has stated that in April 2018, DPS had identified 1,543 inmates with a diagnosis of chronic HCV. In December 2017, applying estimates from the NIH and CDC, Defendant Smith stated that the total number of prisoners in DPS custody with HCV could be between 6,559 and 12,553.
- b. *Commonality.* Questions of law and fact common to the Plaintiff Class include but are not limited to: (1) whether chronic HCV is a serious medical need; (2) whether Defendants’ policy and practice of not treating chronic HCV with DAAs constitutes deliberate indifference to serious

medical needs; (3) whether Defendants' policies and practices concerning screening and monitoring HCV comply with the standard of medical care and constitute deliberate indifference to serious medical needs; (4) whether chronic HCV is a disability under the ADA; (5) whether prison medical services are a program or service under the ADA; (6) whether Defendants have discriminated against members of the Plaintiff Class on the basis of their disability.

- c. *Typicality*. The claims of the named Plaintiffs are typical of the claims of the Plaintiff Class. The named Plaintiffs have been diagnosed with HCV, are subject to DPS's policy concerning HCV treatment and screening, have been denied HCV treatment, and are at the same kind of risks of substantial harm as members of the Plaintiff Class.
- d. *Adequacy*. The class representatives and class counsel will fairly and adequately protect the interests of the Plaintiff Class. The class representatives are committed to obtaining declaratory and injunctive relief that will benefit themselves and the Plaintiff Class by ending Defendants' unlawful policy and practice of denying medically necessary care. They have a strong personal interest in the case and have no conflicts with class members. Named Plaintiffs are represented by experienced counsel who have specialized expertise in civil rights litigation on behalf of prisoners.

109. The requirements of Rule 23(b)(2) are satisfied. DPS has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding

declaratory relief is appropriate respecting the class as a whole. The injunctive relief sought will end the unlawful policy and practice for all class members, allowing them to receive proper screening and treatment for HCV.

CAUSES OF ACTION

Count I – Eighth Amendment to the U.S. Constitution, via 42 U.S.C. § 1983

110. Defendants know of and enforce the policies and practices described above. They know of Plaintiffs' and the Plaintiff Class's serious medical needs, but intentionally refuse to provide screening and treatment addressing those needs. Defendants know that failure to treat those serious medical needs has harmed Plaintiffs and the Plaintiff Class, and continues to place them at substantial risk of serious harm.

111. Defendants' conscious disregard of the risks facing Plaintiffs and the Plaintiff Class violates all standards of decency and constitutes deliberate indifference to serious medical needs.

Count II – Americans with Disabilities Act, 42 U.S.C. § 12131, et seq.

112. The Americans with Disabilities Act (ADA) prohibits public entities from discriminating against persons with disabilities in their programs, services, and activities. 42 U.S.C. §§ 12131–12134.

113. The ADA defines “public entity” as any state or local government or “any department, agency . . . or other instrumentality” of a state or local government. 42 U.S.C. § 12131(1)(A), (B).

114. Defendant DPS is a “public entity” under the ADA.

115. Plaintiffs and each member of the Plaintiff Class have a disability under the ADA.

116. Plaintiffs and each member of the Plaintiff Class are “a qualified individual with a disability” under the ADA because they meet the essential eligibility requirements for the receipt of services or participation in programs or activities provided by DPS, except that they require reasonable modifications to rules, policies, or practices, the removal of barriers, or the provision of auxiliary aids and services.

117. DPS discriminates against Plaintiffs and the Plaintiff Class in violation of the ADA by withholding medically necessary treatment that will likely cure their disability, while not withholding medically necessary treatment from individuals with different disabilities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court issue the following relief:

- a. A declaratory judgment that Defendants’ policy of withholding DAA treatment from persons in DPS custody diagnosed with chronic HCV violates the Eighth Amendment and the ADA.
- b. A declaratory judgment that Defendants’ failure to offer HCV screening to all persons in DPS custody violates the Eighth Amendment and the ADA.
- c. Preliminary and permanent injunctions ordering Defendants to: (i) formulate and implement an HCV treatment policy that meets the current standard of medical care, including identifying and monitoring persons with HCV; (ii) treat Plaintiffs members of the Plaintiff Class with appropriate DAAs; and (iii) provide Plaintiffs and members of the Plaintiff Class an appropriate and accurate assessment of their level of fibrosis or cirrhosis, counseling on drug interactions, and ongoing medical care for complications

and symptoms of HCV; and (iv) any further appropriate injunctions to prevent future violations of Plaintiffs' and the Plaintiff Class's rights.

- d. Award named Plaintiffs compensatory and punitive damages.
- e. Award Plaintiffs' costs, including reasonable attorneys' fees.
- f. Allow any further relief to which Plaintiffs and the Plaintiff Class may be entitled.

Respectfully submitted, this the 15th day of June, 2018.

/s/ Michele Luecking-Sunman

Michele Luecking-Sunman

N.C. Bar No. 31655

Daniel K. Siegel

N.C. Bar No. 46397

North Carolina Prisoner Legal Services, Inc.

P.O. Box 25397

Raleigh, NC 27611

(919) 856-2220

mlueckingsunman@ncpls.org

dsiegel@ncpls.org

/s/ Christopher A. Brook

Christopher A. Brook

N.C. Bar No. 33838

Emily E. Seawell

N.C. Bar No. 50207

ACLU of North Carolina

P.O. Box 28004

Raleigh, NC 27611

(919) 834-3466

cbrook@acluofnc.org

eseawell@acluofnc.org

Attorneys for Plaintiffs

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individually, and**

**The NORTH CAROLINA
DEPARTMENT OF PUBLIC
SAFETY,**

Defendants.

**AFFIDAVIT OF
DR. ANDREW JOSEPH MUIR**

1. My name is Dr. Andrew Joseph Muir. I am over the age of 18 and am otherwise competent to declare in this matter.
2. I have been retained by counsel for the Plaintiffs to render an opinion in this case on the Defendants' policies and practices regarding hepatitis C virus (HCV) infection.
3. I have not decided whether any exhibits will be used to summarize or support my testimony, but I will supplement this affidavit if that changes.

Qualifications

4. I am a physician and have been licensed to practice medicine in North Carolina since 1995. I am currently Professor of Medicine at Duke University, and I am also the Chief of the Division of Gastroenterology at Duke. I am board certified in Gastroenterology. I have cared for patients with HCV and conducted HCV research since 2000. HCV has been the focus of my clinical practice and research during my career, and I have published over 100 manuscripts in medical journals.
5. I graduated from Trinity University in 1989 and the Duke School of Medicine in 1993. Following graduation, I completed an internal medicine residency at Duke University Medical Center and also served as chief resident. I then completed gastroenterology training at Duke with a particular emphasis in hepatology. During this period of training, I completed coursework for the Duke Clinical Research Training Program and received my master's degree from this program in 2001. I joined the faculty at Duke in 2000 and focused my practice on the care of patients with liver disease. My practice has always included both outpatient and inpatient components. In the outpatient setting, we are focused on HCV treatment to cure the patient and prevent progression to cirrhosis. On the inpatient service, we are managing the complications of cirrhosis and liver cancer. Many of these patients have HCV as the cause of their cirrhosis, and many require liver transplantation due to the complications of their HCV infection. After joining the faculty, I also started to conduct health services research in HCV infection and participated in clinical trials of novel therapies for HCV. I also became a faculty member at the Duke Clinical Research Institute and served as a medical monitor and coordinating center principal investigator for several novel HCV therapies that were in development. I remain active in clinical trials and continue to care for many patients with HCV in my clinic at Duke. My background and qualifications are detailed in my CV, which is attached to this declaration. My CV includes my publications, invited lectures and grant funding. I have not testified in any legal cases as a medical expert. I am not being paid to consult on this matter, and I am available to testify if required.

Materials Reviewed

6. I have reviewed the following materials specific to this case to aid me in formulating my opinions:
- North Carolina Department of Public Safety Health Services Policy and Procedure Manual section on Hepatitis C (effective date: October 2015);
 - North Carolina Prisoner Legal Services letter to the North Carolina Department of Public Safety dated January 29, 2018;
 - North Carolina Department of Public Safety letter response to North Carolina Prisoner Legal Services dated February 26, 2018;
 - Medical records of Robert Parham;
 - Medical records of Lloyd Buffkin;
 - Medical records of Kim Caldwell; and
 - Affidavit of Thomas Nuzum, MD dated December 15, 2016
7. When considering guidelines for the recommendations about HCV infection, screening strategies have been outlined by the Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force.¹ Treatment recommendations are provided by the joint guidance panel formed by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). The AASLD-IDSA guidance recommendations are updated frequently to react to developments in the HCV field, and the recommendations can be viewed online at hcvguidelines.org.²
8. My professional opinions are based on my background, professional experience, education and review of the materials and articles referenced in this document.

Hepatitis C General Information

9. HCV is a viral infection which is spread by exposure to blood or blood products. Common methods of transmission include intravenous drug use (via exposure to blood on shared equipment) and receipt of blood products or organs before universal testing of donors. Sexual transmission is less common with heterosexual sex but is more common among men who have sex with men.
10. When patients are initially exposed to HCV, most will show mild or even no symptoms. Approximately 80% of patients exposed to HCV will develop chronic infection. Chronic infection also generally has no symptoms or perhaps fatigue

¹ Moyer VA, U.S. Preventive Services Task Force Screening for hepatitis C virus infection in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2013; 159:349.

² AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Accessed April 30, 2018.

and other nonspecific mild symptoms. During this chronic infection phase, patients are slowly developing scarring or fibrosis in the liver. This process can lead to severe liver scarring, called cirrhosis, usually 20 to 40 years after infection.

11. Fibrosis can significantly impair liver function and damage the liver's ability to filter toxins and fight infections.
12. Once patients develop cirrhosis, they are at risk for painful and life-threatening complications that often require invasive and painful treatments. These complications include:
 - Bleeding varices (large veins) in the esophagus or stomach. When these varices bleed, the risk of death is approximately 20%.³ All patients with cirrhosis are recommended to have an upper endoscopy to look for varices and then treatment with endoscopic procedures or medications.
 - Ascites (fluid in the abdomen). Patients are treated with a low sodium diet and diuretics. If these steps do not work, patients get a paracentesis, which is a procedure in which a needle is inserted into the abdomen to drain off fluid. If the fluid becomes infected, this is called spontaneous bacterial peritonitis. If this diagnosis coincides with septic shock, the mortality rate has been reported at greater than 80%.⁴
 - Hepatic encephalopathy, which is confusion that develops because the liver cannot clear toxins well. This condition is treated with medications, but patients are at risk for recurring episodes and progression to coma.
 - Hepatorenal syndrome, which is a condition in which patients with cirrhosis develop kidney failure. Patients with hepatorenal syndrome have high mortality risk and require urgent liver transplantation to survive.

Once patients develop complications of portal hypertension, they should undergo transplant evaluation due to the high risk of mortality from these conditions.⁵ HCV infection is the most common reason that Americans receive a liver transplant.

³ D'Amico G, De Franchis R, Cooperative Study Group. Upper digestive bleeding in cirrhosis. Post-therapeutic outcome and prognostic indicators. *Hepatology*. 2003;38(3):599.

⁴ Karvellas CJ, Abalde JG, Arabi YM, Kumar A, Cooperative Antimicrobial Therapy of Septic Shock (CATSS) Database Research Group. Appropriate and timely antimicrobial therapy in cirrhotic patients with spontaneous bacterial peritonitis-associated septic shock: a retrospective cohort study. *Aliment Pharmacol Ther*. 2015 Apr;41(8):747-57. Epub 2015 Feb 20.

⁵ Martin P, DiMartini A, Feng S, Brown R Jr, Fallon M. Evaluation for liver transplantation in adults: 2013 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. *Hepatology*. 2014 Mar;59(3):1144-65.

13. All patients with cirrhosis from HCV are at risk for the development of liver cancer or hepatocellular carcinoma (HCC). Among patients with cirrhosis at the time of HCV treatment, this risk is reduced but not removed for patients cured of HCV. Moreover, if a patient is not treated with DAAs before cirrhosis occurs, the patient's fibrosis may be irreversible. Most patients with HCC present at late stages, and the median survival for hepatocellular carcinoma is approximately 20 months.⁶
14. Chronic HCV is a serious medical need that should be treated regardless of whether it is detected at an early stage. HCV infection can be subtle for many years. Screening for HCV is required to diagnose patients prior to the development of the complications of cirrhosis and liver cancer. Failure to identify patients and cure their HCV infection at early stages of disease places them at risk for the development of the life-threatening complications of portal hypertension and liver cancer.

HCV Screening

15. An effective HCV treatment program requires screening. The initial test for HCV screening or diagnostic evaluation is a blood test for the HCV antibody. This antibody test is positive in patients with chronic infection, those exposed to HCV who cleared infection spontaneously, and those who were cured of HCV with antiviral therapy. A blood test for HCV RNA confirms the presence of active HCV infection. There are 6 genotypes and multiple subtypes of HCV infection with slightly different genetic makeup, and a blood test determines the genotype.
16. HCV screening was previously recommended for persons with history of risk factors associated with HCV transmission. Due to low rates of screening, the CDC recommended also screening all U.S. persons born between 1945 and 1965. Approximate 75% of HCV infections in the USA were found within this age group, and this cohort strategy therefore was added to the recommendations.⁷ The AASLD/IDSA guidance document provides the most updated recommendations to include:

⁶ A new prognostic system for hepatocellular carcinoma: a retrospective study of 435 patients: the Cancer of the Liver Italian Program (CLIP) investigators. *Hepatology*. 1998;28(3):751.

⁷ Smith BD, Jorgensen C, Zibbell JE, et al. Centers for Disease Control and Prevention initiatives to prevent hepatitis C virus infection: a selective update. *Clin Infect Dis*. 2012 Jul;55 Suppl 1:S49.

- One-time hepatitis C testing is recommended for persons born from 1945 through 1965 without prior ascertainment of risk.
- Other persons should be screened for HCV infection risk factors. One-time testing should be performed for all persons with behaviors, exposures, and conditions or circumstances associated with an increased risk of HCV infection.
 - Risk Behaviors
 - Injection-drug use (current or ever, including those who injected only once)
 - Intranasal illicit drug use
 - Risk Exposures
 - Persons on long-term hemodialysis (ever)
 - Persons with percutaneous/parenteral exposures in an unregulated setting
 - Healthcare, emergency medical, and public safety workers after needle-stick, sharps, or mucosal exposures to HCV-infected blood
 - Children born to HCV-infected women
 - Prior recipients of transfusions or organ transplants, including persons who:
 - Were notified that they received blood from a donor who later tested positive for HCV
 - Received a transfusion of blood or blood components, or underwent an organ transplant before July 1992
 - Received clotting factor concentrates produced before 1987
 - Persons who were ever incarcerated
 - Other Conditions and Circumstances
 - HIV infection
 - Sexually-active persons about to start pre-exposure prophylaxis (PreP) for HIV
 - Unexplained chronic liver disease and/or chronic hepatitis, including elevated alanine aminotransferase (ALT) levels
 - Solid organ donors (deceased and living)

17. Incarcerated populations have higher rates of HCV than the general population. An estimated 16-41% of incarcerated persons in North America are positive for

antibodies against HCV (Spaulding 2012).⁸ These data support the recommendation for screening of persons who were ever incarcerated. Recent modeling data suggests that treatment of incarcerated persons helps the incarcerated population but also has public health benefits by averting infections that would have occurred after the individuals are released in prison.⁹ HCV screening in prisons would diagnose between 42,000 – 91,000 new HCV cases in the next 30 years in prisons in this model. HCV screening followed by antiviral treatment in prisons could prevent 4,200–11,700 liver-related deaths. Compared with no screening, HCV screening could prevent 5,500–12,700 new HCV infections spread by these individuals, and 90% of these averted infections would have occurred outside of prisons. By focusing on this population with high prevalence of HCV infection and curing them prior to release, there is less opportunity for them to spread HCV infection to others in the society.

18. For the case in question, the current NC DPS policy recommends only risk-based HCV screening. This policy is not consistent with the CDC recommendation to screen the baby boomer cohort born between 1945 and 1965. This policy is also not consistent with the AASLD/IDSA recommendation to screen all persons ever incarcerated. Screening policies based upon risk factors alone were abandoned due to their failure to identify many individuals. An effective strategy to HCV begins with effective screening, and the current strategy is destined to fail. The NC DPS should alter their approach and screen all persons for HCV given the high rates of HCV among incarcerated persons.

HCV Natural History

19. Once a patient has been exposed to HCV, approximately 15-20% of people will clear infection spontaneously. Clearance of infection can occur within 6 months after exposure. If the patient has HCV RNA detected more than 6 months after exposure, the patient has chronic HCV infection.
20. All patients with chronic HCV infection require an assessment of fibrosis. Patients may even have progressed to the level of cirrhosis without obvious physical examination findings, and so reliance on physical examination findings cannot be recommended. Patients with cirrhosis may require longer duration of antiviral treatment. Patients with cirrhosis require monitoring for progression to the complications of cirrhosis and surveillance for liver cancer.

⁸ Spaulding AC, Thomas DL. Screening for HCV infection in jails. JAMA 2012; 307:1259.

⁹ He et al Prevention of HCV by Screening and Treatment in US Prisons. Ann Intern Med. 2016 January 19; 164(2): 84

21. Fibrosis develops slowly over the course of years for patients with HCV infection. The most commonly utilized scoring systems rate fibrosis based upon review of liver biopsies with special stains for fibrous tissue and use a scale of 0 to 4:

- 0: no fibrosis
- 1: fibrosis confined to the portal areas (mild fibrosis)
- 2: periportal fibrosis (moderate or significant fibrosis)
- 3: bridging fibrosis (advanced fibrosis)
- 4: cirrhosis

More recently developed biomarkers have followed this same scoring system. When thinking about the progression of fibrosis, research has shown that the rate varies among patients and is impacted by a number of factors. We know that fibrosis develops faster among men and those patients who are older at the time of HCV infection, drink excessive alcohol, have HIV infection, and have had a liver transplant. A classic study of 2235 patients estimated that the median rate of fibrosis progression per year was 0.133 fibrosis units.¹⁰ The median estimated duration of infection for progression to cirrhosis was 30 years but ranged from 13 years to 42. Without treatment, 33% had an expected median time to cirrhosis of less than 20 years. Another 31% would not progress to cirrhosis for at least 50 years and so expected to die of other causes. Many patients are therefore at risk for progression to cirrhosis and the life-threatening complications of portal hypertension and liver cancer.

22. Strategies to prevent cirrhosis are critical to impact the course of HCV infection. Cirrhosis can be divided into compensated and decompensated cirrhosis. Compensated cirrhosis is present when a liver biopsy might reveal cirrhosis, but the patients have not had complications of cirrhosis. Patients generally appear well at this phase, and their main symptom is fatigue. Decompensated cirrhosis is present once the patient has developed one of the complications of portal hypertension. This transition from compensated cirrhosis to decompensated cirrhosis can be quite sudden. Patients with decompensated are obviously ill appearing and now at risk for mortality. A landmark study of 384 patients with compensated cirrhosis due to HCV found that the risk of developing hepatic decompensation was 3.9 percent per year. In this study, the 5-year survival was 96% for compensated cirrhosis but 50% once decompensated cirrhosis developed.¹¹

¹⁰ Poynard T, Bedossa P, Opolon P. Natural history of liver fibrosis progression in patients with chronic hepatitis C. The OBSVIRC, METAVIR, CLINIVIR, and DOSVIRC groups. *Lancet*. 1997;349(9055):825.

¹¹ Fattovich G, Giustina G, Degos F, et al. Morbidity and mortality in compensated cirrhosis type C: a retrospective follow-up study of 384 patients. *Gastroenterology* 1997; 112:463.

23. The other major risk to patients with cirrhosis is the development of Hepatocellular carcinoma (HCC). All patients with cirrhosis from HCV are at risk for the development of liver cancer. Among patients with cirrhosis at the time of HCV treatment, this risk is reduced but not removed for patients cured of HCV. All patients with cirrhosis, including those cured of HCV and those with persistent HCV, are recommended to have an ultrasound and a blood test called alphafetoprotein (cancer marker) every 6 months. If the cancer is detected at an early stage, curative options including surgical resection or liver transplantation might be offered. Patients with more advanced cancer might be offered embolization or ablation procedures performed by interventional radiologists or systemic chemotherapy prescribed by oncologists. Due to the advanced stage at diagnosis for most patients, the median survival for hepatocellular carcinoma is approximately 20 months.
24. Once HCV infection becomes chronic, it is unlikely that the infection will spontaneously go into remission. When a patient develops chronic HCV, the disease will almost certainly progress—scarring the liver, decreasing liver function, and increasing the risks of further harm—until the infection is cleared or the patient dies.
25. HCV carries risk of early mortality particularly in patients with cirrhosis. HCV mortality rates in the United States surpassed deaths from HIV infection starting in 2007 with more than 15,000 deaths per year.¹² A critical component of a strategy to reduce this risk of early mortality would be early treatment prior to the development of cirrhosis.

Diagnostic Evaluation

26. The initial HCV test for HCV screening or diagnostic purposes is the HCV antibody. A positive HCV does not confirm infection. The HCV antibody test will remain positive even in patients who cleared HCV spontaneously. HCV RNA is the confirmatory blood test. If the HCV RNA is detected, the patient has active infection. If the exposure to HCV is known to be within 6 months, HCV RNA should be tested again at 6 months from exposure to see if HCV RNA clearance has occurred. If the patient has HCV RNA detected more than 6 months after exposure, the patient has chronic HCV infection. HCV genotype testing should

¹² Ly KN, Xing J, Kleven RM, et al. The increasing burden of mortality from viral hepatitis in the United States between 1999 and 2007. *Ann Intern Med* 2012; 156:271

then be performed. There are 6 strains of HCV with slightly different genetic make-up, and antiviral treatment recommendations require knowledge of the genotype.

27. The initial evaluation of HCV is focused on ruling out advanced disease or decompensated cirrhosis. The relevant history contains the complications of portal hypertension, including variceal hemorrhage, ascites in the abdomen, and confusion from hepatic encephalopathy. The physical examination is focused on signs of decompensated cirrhosis, including fluid in the abdomen or legs, an enlarged spleen, muscle wasting and alterations in mental status.
28. If the patient does not have obvious features of decompensated cirrhosis, an assessment of fibrosis should be performed. The main clinical question is to determine if cirrhosis is present. For many years, liver biopsies were performed to evaluate for fibrosis. Liver biopsies are performed when patients are awake and therefore painful, and they also carry risk of hemorrhage plus mortality of 1/10,000. As a result, many patients declined liver biopsy, and the lack of a fibrosis assessment became a barrier to HCV treatment. A number of non-invasive tests have been developed to assess fibrosis in patients with HCV. Vibration controlled transient elastography was developed with a device called Fibroscan that measure liver stiffness. A liver with more fibrosis has greater stiffness. A number of serum markers have been developed, including the commercially available Fibrosure, which measures alpha-2-macroglobulin, alpha-2-globulin (haptoglobin), gamma globulin, apolipoprotein A1, GGT, and total bilirubin. With image-based and serum markers, there are some general themes. Although these tests report specific stages from 0 to 4, assessments of test characteristics reveal that they cannot do so with consistent accuracy. When a result is given for a value such as stage 1, the clinician cannot feel confident that this is the actual value. This weakness in these tests has made it difficult to assess fibrosis progression over time with confidence in an individual patient. These tests perform best in their assessments of advanced fibrosis or cirrhosis, and it is generally recommended they be used only for that capacity. In the case of Fibrosure, the test has been studied for its ability to identify patients with significant fibrosis or stages 2 to 4. The test characteristics are modest with sensitivity for detecting significant fibrosis reported at 60-75% with specificity 80-90%.¹³

¹³ Halfon P, Bourliere M, Deydier R, Botta-Fridlund D, Renou C, Tran A, Portal I, Allemand I, Bertrand JJ, Rosenthal-Allieri A, Rotily M, Sattonet C, Benderitter T, Saint Paul MC, Bonnot HP, Penaranda G, Degott C, Masseur MF, Ouzan D. Independent prospective multicenter validation of biochemical markers (fibrotest-actitest) for the prediction of liver fibrosis and activity in patients with chronic hepatitis C: the fibropaca study. *Am J Gastroenterol.* 2006;101(3):547.

29. For patients who have developed cirrhosis, surveillance is recommended for HCC and for varices. Patients are recommended to have an upper endoscopy to rule out varices and ultrasound with serum alphafetoprotein every 6 months.

Treatment of HCV Infection

30. For more than two decades, antiviral treatment for HCV involved regimens that included interferon-alpha. This medication was injected by the patient and given three times weekly initially and then weekly with pegylation. Interferon-alpha has numerous side effects including severe flu-like symptoms and bone marrow suppression. Interferon-alpha also was associated with anxiety and depressive symptoms including successful suicides. As a result of these side effects, many patients discontinued treatment or were not eligible for treatment. Even among those who could tolerate the medicine, cure was achieved in only approximately 50%.
31. In 2013, combinations of direct acting antiviral medications became available for HCV. These medications were dramatic steps forward with improved efficacy with minimal side effects. Several highly effective regimens are now available. Harvoni and Zepatier cover some but not all genotypes. Epclusa, Mavyret and Vosevi can be used in patients with all genotypes. There are some nuances to the treatment recommendations, but an important message is that all patients can be safely treated with one of the currently available regimens. Cure rates were over 90% in clinical trials, and these high efficacy rates have been seen in registries of real world patients. As a result, interferon-based regimens are no longer recommended for HCV treatment by the AASLD/IDSA guidance panel.¹⁴

NC DPS Policy Review

32. The current NC DPS policy includes a section to determine if HCV treatment is contraindicated. The policy includes the following contraindications:
- (1) Inmate will be incarcerated for an insufficient period of time to complete treatment. Usually a twelve (12) month period would be required to complete assessment and treatment for Hepatitis C.
 - (2) Inmate has an unstable medical or mental health condition which precludes antiviral therapy.
 - (3) Inmate refuses treatment.

¹⁴ AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Accessed April 30, 2018.

- (4) Inmate life expectancy estimated to be less than 10 years due to co-morbid conditions.
- (5) Inmate has infractions related to use of alcohol or drugs in the last twelve (12) months.
33. There are two major contraindications to antiviral treatment with DAA regimens. The main contraindication is if a patient is unwilling to be adherent. The other contraindication is if a patient has short life expectancy. The AASLD/IDSA guidance document states, "Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy." Most clinicians would apply this recommendation to patients with decompensated cirrhosis that cannot be easily managed or patients with advanced cancers or cardiopulmonary disease.
34. A course of DAA treatment typically requires only 8-12 weeks. Therefore, requiring that a patient have at least 12 *months* left on a sentence is not a medically based contraindication.
35. NC DPS's requirement of a 10 year life expectancy is not the standard for treatment of HCV. Within that period of time, a patient could progress from compensated liver disease to decompensated cirrhosis and die from the awful complications of portal hypertension or liver cancer.
36. The NC DPS policy also lists unstable mental health conditions as a contraindication. This would appear to be a holdover from the days of treatment with interferon-based regimens. Under the interferon-based treatment regime, it would have been appropriate to withhold treatment for patients with severe depression or severe mental illness. With DAA treatment, as long as the patient is willing to be adherent, these diagnoses are not contraindications.
37. The NC DPS policy also lists patient refusal as a contraindication. The current NC DPS strategy may inappropriately lead to patient refusals. The informed consent for HCV treatment within the NC DPS policy includes interferon-based treatment options. These are associated with severe side effects and those side effects are listed in the informed consent. These regimens are no longer recommended by AASLD/IDSA. By including these regimens in the informed consent and reviewing the severe side effects, patients may be more likely to decline antiviral treatment. The NC DPS policy and the informed consent needs to be updated to reflect the current recommended regimens and the accurate side effect profile so that patients can make a better informed decision.

38. The NC DPS policy also lists use of alcohol or drugs within the previous 12 months as a contraindication. There is no medical justification for this requirement.
39. NC DPS's requirement to have achieved F2 fibrosis by Fibrosure before a patient is considered for treatment is not the standard of care for chronic HCV and is not consistent with the current AASLD/IDSA guidance panel recommendations. The AASLD/IDSA guidance panel recommends treatment regardless of fibrosis level except those with short life expectancies. NC DPS currently uses at least an F2 by Fibrosure as the threshold to recommend antiviral treatment. As outlined earlier, serum non-invasive markers have modest test characteristics when predicting patients with significant fibrosis (F2-F4). The use of this imperfect test means that many patients may have HCV treatment withheld inappropriately due to an inaccurate test. There is a significant likelihood that a patient with a Fibrosure score of F1 may in fact have fibrosis in the range of F2 to F3. Even if the test was accurate, the policy to delay treatment until significant fibrosis has developed cannot be recommended. This strategy places patients at medically unjustified risk of developing advanced fibrosis with the risk of complications of portal hypertension and liver cancer. The risk of liver cancer is decreased but remains if the patient is cured of HCV once they have developed cirrhosis. An effective strategy would involve treating patients well before the development of cirrhosis. Studies have also demonstrated benefit from earlier treatment. One study examined 820 patients with stage 0 or 1 fibrosis and then followed patients for up to 20 years. The 15-year survival in cured patients was 93% compared with 82% for those who failed treatment.¹⁵ Other studies have demonstrated improvements in patient reported outcomes and quality of life scores with HCV cure.¹⁶
40. Review of the patient charts associated with this case highlights the impact of living with HCV. The anxiety described by these patients is very similar to the emotions of patients in my own clinic. In the last two years, several commercial payers and NC Medicaid switched from requiring F2 fibrosis to treating all patients. I therefore cared for many patients who were told they were "too well" to receive HCV treatment. There is great stress living with a virus that can cause cirrhosis and liver cancer, and there is great relief with cure. Being aware that

¹⁵ Jezequel C, Bardou-Jacquet E, Desille Y, Renard I, Laine F, Lelan C, et al. Survival of patients infected by chronic hepatitis C and F0F1 fibrosis at baseline after a 15 year follow-up. 50th Annual Meeting of the European Association for the Study of the Liver. J Hepatology 2015;:S589.

¹⁶ Younossi ZM, Stepanova M, Henry L, Gane EJ, Jacobson IM, Lawitz EJ, et al. Effects of sofosbuvir-based treatment, with and without interferon, on outcome and productivity of patients with chronic hepatitis C. Clin Gastroenterol Hepatol. 2014 Aug;12(8):1349-59

curative treatment was available and realizing that it would not be offered was especially distressing to my patients. We were therefore grateful to see the changes in policy from the commercial payers and NC Medicaid. It should also be noted that Medicare and the Veterans Affairs medical centers do not restrict DAA therapy according to fibrosis.

Review of Records for Robert Parham

41. My review of Mr. Parham's records show that he has chronic HCV. His Fibrosure test in February 2015 indicated an F2 value. In January 2018 his Fibrosure score indicated an F1-F2 value. If the test is accurate then these scores would indicate that he has already experienced moderate to significant liver scarring.
42. Although his records do not indicate a Fibrosure score higher than F2, Mr. Parham's records state that he has a history of cirrhosis.
43. Mr. Parham suffers from dermatitis. This is a symptom commonly associated with HCV.
44. Mr. Parham has also experienced pedal edema. This is commonly associated with cirrhosis of the liver. Given the unreliable nature of the Fibrosure test, it is possible that Mr. Parham's HCV has advanced beyond the F1-F2 level. NC DPS medical providers performed an ultrasound of Mr. Parham to assess his liver. However, ultrasound is not appropriately utilized to diagnose cirrhosis.
45. Based on my review of Mr. Parham's records, I have concluded that no medical reason exists to deny him treatment for HCV. He should be treated with DAAs.

Review of Records for Kim Caldwell

46. My review of Mr. Caldwell's records show that he was diagnosed with HCV in 2015 while he was in DPS custody. Because he has received no follow-up screening or testing since that time, I do not know to what extent his disease has progressed.
47. Mr. Caldwell needs immediate follow-up testing to determine the status of his HCV infection.
48. Based on my review of Mr. Caldwell's records, I have concluded that no medical reason exists to deny him treatment for HCV assuming that the infection has

become chronic. Following a confirmation of his HCV status, he should be treated with DAAs.

Review of Records for Lloyd Buffkin

49. My review of Mr. Buffkin's records shows that he has chronic HCV. His Fibrosure test in September, 2017 indicated an F1-F2 value. If the test is accurate then this score would indicate that he has already experienced moderate to significant liver scarring.
50. Mr. Buffkin suffers from atopic dermatitis. This is a symptom commonly associated with HCV.
51. Based on my review of Mr. Buffkin's records, I have concluded that no medical reason exists to deny him treatment for HCV. He should be treated with DAAs.

Conclusion

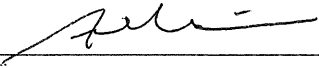
52. It is my opinion, based on my education, training, and experience, that NC DPS is not meeting the accepted standard of care for the management of HCV in several ways:
 - a. NC DPS policy uses risk-factor based screening for HCV. This strategy is well known to be ineffective, and routine screening should be recommended for all incarcerated persons.
 - b. NC DPS policy is out of date and is based in part on interferon-based regimens. The criteria for HCV treatment are outdated and include restrictions based upon interferon side effects. The informed consent includes language of the severe side effects of interferon, and this language may lead to patient decisions to reject treatment. The policy would deny treatment if a patient might die within ten years, but this time frame would allow the progression to portal hypertension, liver cancer, and their miserable complications. The policy would also deny treatment to a patient with less than a year left on a sentence or who committed a drug or alcohol infraction in the previous twelve months. These restrictions have no medical justification and risk denying treatment even to patients who may have advanced fibrosis and cirrhosis and who have even more urgent need for treatment.
 - c. NC DPS policy restricts treatment until patients have developed F2 fibrosis. Current technologies have limitations in assessing F2 fibrosis. Delaying treatment until patients have significant fibrosis places them at risk for the complications of advanced liver disease. Denying treatment to patients is associated with adverse patient reported outcomes and quality of life. NC DPS is not consistent with other entities with HCV treatment programs. HCV treatment is currently offered regardless of fibrosis to patients with NC Medicaid, Medicare, Veterans Affairs

- benefits, and commercial payers. The NC DPS policy should be revised to offer HCV treatment regardless of the level of fibrosis. This is the standard of care.
- d. The failure to provide appropriate HCV screening and antiviral treatment will lead to greater spread of HCV in North Carolina and increased suffering and death.

This opinion is based on the materials I have reviewed thus far. I reserve the right to supplement this Affidavit should new material become available to me.

I understand that a false statement in this Affidavit will subject me to penalties for perjury. I declare under penalty of perjury that the foregoing is true and correct.

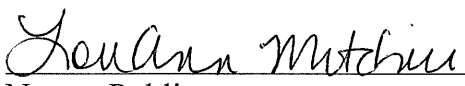
This the 11th day of June, 2018



Andrew J. Muir, MD

Sworn to and subscribed before me,

This the 11 day of June, 2018



Notary Public

My Commission expires: Sept. 09, 2022

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Lawsuit Claims North Carolina Prisons Refuse Inmates' Hepatitis C Treatments](#)
