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.

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.

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[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, Abraldes 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:

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[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.

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[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]

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[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, Klevens 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]

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[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, Masseyeff 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.

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[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

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[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