



State of Louisiana
Louisiana Department of Health
Office of the Secretary

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Joshua M. Sharfstein, M.D.
Department of Health Policy and Management
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street
Baltimore, MD 21205

Dear Dr. Sharfstein,

Hepatitis C is a pressing public health challenge in Louisiana, affecting 73,000 people in our state. Unfortunately, the astronomical costs for curative therapy have limited our ability to provide care to those in need and reduce the risk of transmission to others across the state.

Recently, The Drug Pricing Lab at Memorial Sloan Kettering Cancer Center posted an interactive program that asks the public to find the funding needed treat patients with Hepatitis C in Louisiana through statewide discretionary budget cuts. Participants must weigh the benefits of treating Hepatitis C against the cost of providing other needed, valuable services to our state's residents. This program illustrates that funding appropriate Hepatitis C treatment would come at an extreme cost to Louisiana including cuts for treatment of mental illness and the blind, educational opportunities for both children and adults, and many essential State functions.

As you know, a committee of the National Academy of Medicine recommended that the federal government consider purchasing the rights to a direct-acting antiviral medication to use for parts of the market that are neglected. There is also a federal law known as 28 U.S.C. § 1498 which permits the government to directly purchase drugs without regard to their patent status. In the 1960s, the federal government used this provision to purchase medications for the Department of Defense at far lower costs than otherwise would be possible.

I am aware of your research on this topic and am writing to ask for your expert advice on whether, as Secretary of Health for Louisiana, I should ask the U.S. Department of Health and Human Services for assistance in purchasing Hepatitis C treatments as recommended by the committee of the National Academy of Medicine or under 28 U.S.C. § 1498.

I provide background on my request in the following pages.

Hepatitis C in Louisiana is increasing and an important health equity issue

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). For the majority of patients who become infected with the virus, the infection becomes a chronic illness.¹ Patients can have symptoms of fatigue, nausea, muscle and joint aches, weakness, and weight loss. Patients with HCV can develop problems in organs besides the liver, such as their kidneys and immune system. They also have a higher risk of developing depression, nerve pain, and lymphoma. Up to 30% of patients with chronic hepatitis will develop liver scarring, known as cirrhosis, which can lead to liver failure or liver cancer. Patients with end-stage liver failure suffer debilitating symptoms such as vomiting blood, delirium, turning yellow, and severe bloating. As one nurse who cares for many patients with HCV describes it, “At the end you die not knowing who you are, your belly looks 12 months pregnant, you’re malnourished, and you’re bleeding to death.”²

At least 73,000 Louisianans are currently infected with the Hepatitis C Virus,³ and an estimated 250 to 500 people are newly infected each year. The majority of new infections are asymptomatic and therefore remain undiagnosed and unreported. Annually, we estimate that 120 Louisianans die from the complications of HCV each year.⁴ A large share of Louisiana’s state prison inmates are also infected with HCV.⁵

The burden of Hepatitis C infection falls on state and federal taxpayers. Hepatitis C disproportionately affects low income populations and individuals with tax payer funded insurance such as Medicaid.⁶ The 45-64 age group has the highest Hepatitis C prevalence and the 65+ age group has the second highest number of Hepatitis C patients. Taken together, these demographics indicate that Medicare’s share of Hepatitis C patients will increase in coming years.⁷

Finally, Hepatitis C poses a substantial risk to public health. It is the most common blood-borne illness in the United States, the most common cause of chronic liver disease, and the most frequent indication for liver transplant.^{8,9} The virus is spread by contact with blood or body fluids. Most infections occur in relation to injectable drug use, but hepatitis C virus can also be spread by sexual contact, from mother to newborn, within households, after tattooing and body piercing, and in healthcare environments.⁵ Previously, blood transfusions facilitated virus transmission. Modern safety precautions have prevented this, but many older adults were infected prior to these precautions being implemented.⁸ Recent research has shown that the Hepatitis C virus can survive outside the human body, and is still infectious after weeks in bottled water or dried on a surface.^{10,11}

In sum, in Louisiana, Hepatitis C impacts individual health and the wellbeing of our citizens more broadly. We must take action to reduce the burden of hepatitis C.

Chronic Hepatitis C treatments’ high cost is the major barrier to access

The good news is that those who contract Hepatitis C live longer due to new treatments. The introduction of the new antiviral treatments Sovaldi, Harvoni, Viekira Pak, and Zepatier has

substantially improved cure rates of Hepatitis C. As high as 99% of patients treated with these new regimen experience elimination of blood viral loads.^{10,12} These direct-acting anti-retroviral treatments can be effective after only 12 weeks of use.

The bad news is that the high prices of these Hepatitis C treatment regimens prevent most people from getting them.

Even with modest declines in these prices, treating all patients with Hepatitis C would cost nearly as much as the US currently spends on all prescription drugs.¹³ The high prices of new hepatitis C treatments has already been linked to the growth of US health expenditures; in 2015, retail prescription drug spending grew 9% due, in part, to the introduction of expensive, brand-name drugs.¹⁴ As a result, nationally only about 10% of patients with hepatitis C receive new treatments like Sovaldi and Harvoni.¹⁵

Furthermore, Hepatitis C's increased prevalence among low income populations leads public payers to assume a larger proportion of Hepatitis C treatment cost.⁸ Up to half of patients with Hepatitis C eligible for these new treatments are estimated to have government-sponsored insurance, and an estimated 20 to 30% of all patients with Hepatitis C are covered under Medicaid, representing a specific burden to state budgets.^{16,17} Louisiana is in a particularly difficult situation compared to the rest of the nation, as our state has some of the highest levels of individuals living in poverty in our nation.^{3,4}

In Louisiana, treating all patients with Hepatitis C eligible for care with these new drugs would add several billion dollars to the budget and be a ruinous burden. Louisiana's state government is currently confronting a budget deficit; part of the solution is decreasing and delaying payments to Medicaid health plans.¹⁸ Medicaid payments were also delayed in 2015 and, in this budget year, we are having to cancel several programs.¹⁹ These cuts impact a large part of our state as the Medicaid program covers over 1.6 million enrollees, or 32% of residents overall.^{20,21} Additional costs from Hepatitis C treatment would be financially unsustainable and could further harm Medicaid enrollees' access to care.

As a result, Louisiana has been forced to restrict who has access to Sovaldi and other hepatitis C treatments. Louisiana's Medicaid program lists Sovaldi and its formulations as a "nonpreferred" drug, and requires that patients submit for drug and alcohol testing before prescription approval as well as abstain from alcohol and drug use during treatment.²² In order to qualify for treatment, patients have to undergo a liver biopsy to prove they have cirrhosis.²³ Further regulations have been released that limit the quantity of treatment disbursed, duration of treatments, specialists allowed to prescribe treatment, and establish preauthorization.^{24,25,26,27,28}

The Louisiana Department of Health, in collaboration with Dr. Peter Bach, the director of the Center for Health Policy and Outcomes at Memorial Sloan-Kettering Cancer Center, has developed a decision-making program which asks participants to find funding in the state budget to pay for more hepatitis C treatment. This program demonstrates the impossible choices Louisiana would have to make in order to afford hepatitis C treatments.

Potential Innovations in Drug Pricing to Improve Public Health

Recently, a committee of the National Academy of Medicine released *A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report*.²⁹ This report recommends, "The federal government, on behalf of the Department of Health and Human Services, should purchase the rights to a direct-acting antiviral for use in neglected market segments, such as Medicaid, the Indian Health Service, and prisons. This could be done through the licensing or assigning of a patent in a voluntary transaction with an innovator pharmaceutical company."

I have also read several commentaries on Section §1498 in Title 28 of the U.S. Code. Under §1498, the federal government can obtain the generic version of a patented drug for government use and reward the patent holder a reasonable price.³⁰ Various articles and commentaries have suggested that the government begin to use this authority again for pharmaceuticals.^{31,32,33,34} However, some articles note potential harms from invoking §1498 authority.³⁵

Louisiana's Department of Health is interested in further exploring the recommendations of the committee of the National Academy of Medicine and §1498 for their potential for addressing the public health crisis of hepatitis C. I am interested in understanding:

1. The history of use of §1498
2. Appropriate principles for use of voluntary licensing and of §1498 to address public health challenges
3. Key considerations for potential implementation of voluntary licensing and of §1498
4. Application of those principles and considerations to Hepatitis C in Louisiana
5. Analysis and recommendations

Your input would help us decide whether to ask Secretary Price of the U.S. Department of Health and Human Services to invoke one or both of these mechanisms to reduce hepatitis C treatment costs and expand access to these life-saving medications for the people of the State of Louisiana.

Thank you for considering this request.

Sincerely,



Rebekah E. Gee, MD, MPH
Secretary
State of Louisiana Department of Health

Notes

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