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Secretary of Health  
State of Louisiana

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Subject: Hepatitis C in Louisiana: Recommendations on Drug Availability

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## Executive Summary

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Hepatitis C is a blood-borne infectious disease that can cause pain, liver failure, and death. An estimated 73,000 people in Louisiana suffer from this infection. Unfortunately, highly effective treatment costs more than \$20,000 per patient, so that the cost of therapy for all of those in need will exceed \$1 billion dollars -- far too expensive for the state to afford.

As part of a strategy to tackle the hepatitis C crisis, we recommend that the Louisiana Department of Health ask the U.S. Department of Health and Human Services (HHS) to take urgent steps action to lower the price of medication for low-income populations.

Specifically, we recommend you, as Secretary of Health, write the HHS Secretary, with the following request:

1. HHS should pursue the recommendation made by a committee of the National Academy of Sciences, Education, and Medicine in *A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report* to obtain a license for a highly effective therapy and then make deeply discounted medications available to Louisiana; and
2. Simultaneously, HHS should invoke 28 U.S.C. §1498, which provides for government use of patented products including pharmaceuticals, and authorize a company to make available a highly effective treatment at a fraction of current market cost.

If the first step is successful in the short term, then the second step does not need to be pursued further. You may wish to take public comment in Louisiana to determine support for these actions before proceeding.

## **Background**

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In April 2017, Dr. Peter Bach and the Drug Pricing lab at Memorial Sloan Kettering, in partnership with the State of Louisiana Department of Health, released the Louisiana Budget Allocator.<sup>1</sup> This online tool gives the public the opportunity to attempt to find necessary funding in the Louisiana budget to pay for hepatitis C medications in the Medicaid program. The online tool shows that at current prices, providing treatment for even a fraction of patients in need would lead to unacceptable tradeoffs with other education, economic, and health priorities.

In this context, and at your request,<sup>2</sup> a group of experts in law, economics, and public health policy<sup>3</sup> met at Johns Hopkins University on April 17, 2017 to consider alternatives for low-income and uninsured populations to help Louisiana address the hepatitis C crisis.

## **Unconventional Options to Obtain Lower Prices for Hepatitis C Treatment**

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We considered two options for making the price of medications that cure hepatitis C affordable to Louisiana.

The first option, voluntary licensing, was proposed recently by a Committee of the National Academy of Sciences, Education, and Medicine as part of a report outlining a national strategy to eliminate hepatitis C. The committee recognized that the high prices of hepatitis C drugs are a primary obstacle in treating people with the disease, and found that this delay in treatment leads to the spread of infection, significant suffering, and thousands of preventable deaths. The Committee recommended a “voluntary transaction between the federal government and a patent holder, wherein the companies [...] compete to license their patent to the federal government for use in neglected patients.”<sup>4</sup> The Committee’s hope and expectation is that this

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<sup>1</sup> Drug Pricing Lab. Louisiana Budget Allocator. 2017. Accessed May 1, 2017 at <http://drugpricinglab.org/tools/louisiana-budget-allocator/>. The Louisiana Budget Allocator calculates the cost of treatment for only the Medicaid and uninsured populations, which comprise about half of all hepatitis C patients in Louisiana.

<sup>2</sup> Letter from Rebekah Gee, Secretary of Health, State of Louisiana. 12 April 2017.

<sup>3</sup> The following individuals participated: Gerard Anderson, Jeromie Ballreich, Jeremy Greene, Aditi Sen, Joshua Sharfstein, Antonio Trujillo from Johns Hopkins University; Peter Bach from Memorial Sloan Kettering Cancer Center; Hannah Brennan from Hagens Berman Sobol Shapiro LLP; Rena Conti from The University of Chicago; Amy Kapczynski, from Yale Law School; Aaron Kesselheim from Brigham and Women’s Hospital/Harvard Medical School; and Rachel Sachs from the Washington University School of Law.

<sup>4</sup> Committee on a National Strategy for the Elimination of Hepatitis B and C; Gillian J. Buckley and Brian L. Strom, ed. A National Strategy for the Elimination of Hepatitis B and C:

voluntary transaction would provide access at far lower and more affordable cost for defined populations of low-income individuals.<sup>5</sup>

The second option is to invoke 28 U.S.C. §1498, which provides for government use of patented inventions.<sup>6</sup> This provision of federal law has a history that dates back more than a century. Until 1910, the federal government freely used the inventions of patent holders and often did not compensate them for such uses. In 1910, Congress passed a bill that allowed patent holders to gain “reasonable” compensation for such uses. However, this bill was carefully crafted to preserve the Government’s long-standing right to use the patents it granted whenever it saw fit and to do so at a reasonable price. In short, the bill allowed the government to continue circumventing price gouging behavior on the part of patent holders.<sup>7,8</sup>

In the late 1950s and 1960s, the federal government routinely used 28 U.S.C. §1498 to obtain medications at reasonable prices. Over one three-year period in the 1960s, the federal government used 28 U.S.C. §1498 to obtain 50 drugs for a total savings of \$21 million. In one case, the Department of Defense awarded the patent holder for diazepam a 2% royalty for use of the patent. The use of this authority for pharmaceuticals stopped by the early 1970s, but it was nearly invoked in 2002 by then HHS-Secretary Tommy Thompson following the anthrax attacks in an effort to reduce the price of ciprofloxacin.<sup>9</sup>

In recent times, this provision has been used by the Department of Defense and more than 10 other government departments, including the National Institutes of Health, to lower prices that the government pays for patented inventions.

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Phase Two Report. Washington, DC: National Academies of Sciences, Education, and Medicine, 2017.

<sup>5</sup> If companies are interested in participating in such an initiative, there may be alternate ways to structure the financial arrangement to accomplish the same goal.

<sup>6</sup> Kapczynski A, Kesselheim AS. 'Government Patent Use': A Legal Approach ToReducing Drug Spending. *Health Aff (Millwood)*. 2016 May 1;35(5):791-7.

<sup>7</sup> Brennan H, Kapczynski A, Monahan CH, Rizvi Z. A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health. *Yale J.L. & Tech* 2016; 275(18): 275-354.

<sup>8</sup> The statute reads: “Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . . For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.”

<sup>9</sup> Judgement Fund Payment Search. 2017. U.S. Department of Treasury. Accessed at: <https://jfund.fms.treas.gov/jfradSearchWeb/JFPymtSearchAction.do>.

Under this existing provision, HHS could authorize a drug manufacturer to make an effective hepatitis C medication at low cost for government use.<sup>10</sup> HHS would then provide reasonable compensation to the patent holders, either through agreement or through litigation in the United States Court of Federal Claims.

## Principles for Using Unconventional Approaches to Drug Prices

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It is our view that the rationale for these approaches to obtain affordable drugs for low-income populations covered by government insurance programs is strongest when several key criteria are met. These include:

- *The state is facing a major public health challenge.* This is unquestionably the case for hepatitis C infection in Louisiana, a prevalent and communicable disease.
- *The challenge can be addressed by providing effective therapy to those in need, and there are no viable alternative treatments.* This is true for highly effective treatments against hepatitis C.
- *Conventional pricing does not permit access to care for all those who need therapy.* In the case of hepatitis C treatment, the companies<sup>11</sup> and the market<sup>12</sup> do not anticipate that there will be access to hepatitis C treatments for most patients at current prices. As the Louisiana Budget Allocator indicates, the price, even with deep discounts provided to the Medicaid program under current law, is simply not affordable.

In addition, we discussed two other important considerations. These include:

- *Reasonable compensation.* In the case of voluntary licensing, manufacturers can choose whether to offer a license to HHS. By contrast, 28 U.S.C. §1498 does not provide manufacturers with the opportunity to walk away; the law permits the government to use the patent, while paying the patent holder reasonable compensation. This creates a

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<sup>10</sup> The periods of protection for the various patents that are part of hepatitis C treatments are as follows:

Treatment	Expiration Year
Sovaldi	2028-2030
Harvoni	2028-2032
Viekira Pak	2019-2035
Epclusa	2028-2032
Zepatier	2029-2031
Technivie	2019-2031

<sup>11</sup> The Senate Committee on Finance found that in pricing Sovaldi, Gilead chose higher prices knowing that the volume of patients treated would be far lower than the national need. Full Report: United States Senate Committee on Finance. The Price of Sovaldi and Its Impact on the U.S. Health Care System. Washington, DC: U.S. Government Publishing Office, 2015.

<sup>12</sup> Bach, Peter B. and Trusheim, Mark. (January 17, 2017). The U.S. Government Should Buy Gilead For \$156 Billion To Save Money On Hepatitis C. Forbes. Accessed at <https://www.forbes.com/sites/sciencebiz/2017/01/17/the-u-s-government-should-buy-gilead-for-156-billion-to-save-money-on-hepatitis-c/>.

responsibility on HHS to assure that the reasonable compensation does not undermine incentives for innovation. One way to do so is to provide compensation to the patent holder that exceeds, in aggregate, what it was likely to receive for a largely untreated patient population.

- *Overall strategy.* Drug pricing strategies should be part of an overall screening and treatment effort to make care accessible to all those who are in need.

### **Key Logistical Considerations for Unconventional Drug Pricing Strategies on Hepatitis C**

For voluntary licensing, a central question is whether companies will voluntarily offer licenses at a reasonable cost to the government. As there is little precedent in this area, it is difficult to assess the likelihood of success. Therefore, while a voluntary license may be pursued by HHS, it should not be relied upon as the only option.

For 28 U.S.C. §1498, we reviewed four logistical considerations.

1. *Which populations would qualify for discounted medications.* With respect to hepatitis C treatment, our view is that Louisiana should seek discounted medication for the following populations: individuals in the Medicaid program, on the grounds that the state is responsible for providing coverage; individuals without insurance, on the grounds that the state historically is a provider of last resort; and individuals who are incarcerated, based on civil rights guaranteed to institutionalized persons under the 8th Amendment of the Constitution.
2. *How government patent use would interact with data exclusivity.* After HHS contracts for production of a hepatitis C treatment under 28 U.S.C. §1498, the next step is for the medication to be reviewed and approved by FDA.

In the case of generic medications, FDA does not approve products until two distinct types of market protection have expired: patent protection (which is expressly addressed by 28 U.S.C. §1498), and data exclusivity.<sup>13</sup> Whether data exclusivity would block government use of patented inventions is not a question that has been addressed to date by the courts. Fortunately, data exclusivity expires for one highly effective hepatitis treatment in 2018 and for another in 2019. As a result, if HHS contracts for a generic hepatitis C treatment, FDA could review generic applications and approve them at the expiration of data exclusivity, and HHS could have medications ready for use by the end of 2018.<sup>14</sup>

3. *How much HHS should pay in compensation to patent holders.* We reviewed different approaches to this question, considering such factors as the cost of development, the recoupment of development costs, the cost of production, and industry rates of return. Because most of the people who would be receiving this drug do not have access at

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<sup>13</sup> Data exclusivity refers to the ability of generic companies to reference data in the original drug's application about the safety and effectiveness of treatment. During the period of exclusivity, generic companies are not permitted to reference this data, and so FDA is unable to approve the generic product.

<sup>14</sup> There may be other viable approaches to FDA approval besides the generic drug pathway.

current prices, a compensation that is as low as \$1,000 per patient, for example, would more than cover the marginal costs of producing the medications and leave both the people of Louisiana and the company better off.

4. *Whether other states might seek a similar arrangement for unconventional pricing.* Such requests are quite possible, given the national challenge in treating hepatitis C. Our view is that other states should go through a similar assessment using the principles discussed above, and if those principles are met, should be able to access similar pricing arrangements.

## **Recommendations for Louisiana**

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Given the public health imperative of hepatitis C in Louisiana, and the impossibility of addressing this challenge through conventional approaches to drug pricing, we recommend that Louisiana pursue two complementary approaches to obtain necessary medications at far lower cost than is possible today.

These alternatives are feasible and legal. It is our view they may also be necessary to prevent suffering and save lives in Louisiana. Accordingly, we recommend you, as Secretary of Health for the State of Louisiana write the Secretary of HHS with two requests.

First, as recommended by the committee of the National Academy of Sciences, Education and Medicine, HHS should seek to voluntarily license a highly effective hepatitis C treatment for use in the Medicaid population, the incarcerated, and the uninsured.

Simultaneously, HHS should start the contracting process under 28 U.S.C. §1498 with a company that can make a generic version of a highly effective hepatitis C treatment. Should a voluntary licensing approach yield a satisfactory outcome, it would not be necessary to pursue government patent use further.

While these steps can make treatment far more affordable for Louisiana, there will still be some additional expense to develop systems to deliver broader and more affordable treatment for hepatitis C than is possible today. As HHS is moving forward on the two steps above, Louisiana should begin discussing with private and public funding partners opportunities to support this effort.

Because of the unprecedented nature of this request, you may wish to seek public comment on this course of action before proceeding.