From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Tuesday, May 09, 2017 8:39 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	David Rangaviz
Comment	I work within the prison population and have seen the impact that Hep-C can have. I believe that Louisiana should use section 1498 to reduce the cost of Hepatitis C medications. It is a truly innovative approach to reducing drug prices, and would make Louisiana a leader in the nation in this area. If this is done in Louisiana, I would hope that other states would follow your lead. This is an incredibly important step in reducing the price of life-saving medications for those who need it. Please do not let the pharmaceutical industry intimidate you out of taking this important step for your most vulnerable citizens. I urge Louisiana to use section 1498 to make Hep-C drugs more affordable.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Tuesday, May 09, 2017 9:16 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Emily Fish
Comment	To the state of Louisiana, Thank you so much for taking steps to cure all people on Medicaid and in the Louisiana prison system of Hep C. I work with young men coming out of prison and also teach behind the wall in a County Jail in Massachusetts. I think it is a great idea to provide this service to these populations as it will dramatically increase their quality of life. In my experience, young men who are healthy are more able to focus on education, employment, and family, which no only benefits their own lives but also benefits the greater community. Thank you, if you do this you will be setting an example for the rest of the country.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Tuesday, May 09, 2017 9:18 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Ivy Wang
Comment	My uncle died of hepatitis, leaving behind his wife and young son. My father and aunt have had to shoulder the responsibility of caring for them now that he is gone. Hepatitis is a devastating disease and its impact is felt by more than just the people who suffer and die from it. The most vulnerable people in our state should be able to access a cure at a price that is affordable to healthcare providers. Please use 48 USC 1498 to create affordable access to a cure for Hepatitis C. Thank you.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Tuesday, May 09, 2017 10:22 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Kiersten Taylor
Comment	I support this idea

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Tuesday, May 09, 2017 11:03 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Zain Rizvi
Comment	I applaud the recent efforts of Louisiana state officials to explore new ways to increase access to hepatitis C treatments. As an activist, I think it's unconscionable that hundreds of thousands of people have been denied access to a lifesaving treatment due to exorbitant costs. As a scholar, I think 1498 represents an important tool for the government to improve its leverage in negotiations, to correct market failures, and to bring some rationality into the drug pricing landscape. For too long, the government has been held hostage to claims about innovation, and failed to take any meaningful action on drug pricing. We cannot let speculative dangers override our material public interest in protecting public health. The government must use 1498 to fulfill its obligations. Louisiana can, and must, take the first step.

From: DHHINFO Sent: Tuesday, May 09, 2017 11:03 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Zain Rizvi
Comment	I applaud the recent efforts of Louisiana state officials to explore new ways to increase access to hepatitis C treatments. As an activist, I think it's unconscionable that hundreds of thousands of people have been denied access to a lifesaving treatment due to exorbitant costs. As a scholar, I think 1498 represents an important tool for the government to improve its leverage in negotiations, to correct market failures, and to bring some rationality into the drug pricing landscape. For too long, the government has been held hostage to claims about innovation, and failed to take any meaningful action on drug pricing. We cannot let speculative dangers override our material public interest in protecting public health. The government must use 1498 to fulfill its obligations. Louisiana can, and must, take the first step.

From: Idhinfo@la.gov [mailto:Idhinfo@la.gov] Sent: Tuesday, May 09, 2017 12:48 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Tanya Khan
Comment	As a physician in training, I have witnessed first hand the complications of Hepatitis C from liver cirrhosis to its many decompensations like bleeding, ascites, encephalopathy, cancer and finally death. The fact that there is a cure for available for this infection that could prevent these terrible outcomes, costly hospital stays and the need for transplantation is a feat of modern science. From a population health perspective, it is the responsibility of our governing bodies and health institutions to help make such a medication available to patients with Hepatitis C especially when the cost of the medication is exorbitant by any relative measure. This medication will not only save individual lives and prevent further disease transmission but also reduce the burden on our health system and save public and private dollars. Please help reduce the barrier for patients to access the important treatment.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Tuesday, May 09, 2017 5:34 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Eric Parrie
Comment	I am writing in strong support of the Hepatitis C treatment plan. Louisiana should set an example for all states and treat all people with Hepatitis C. As a pubic school teacher in New Orleans who works with students and families at high risk of contracting this disease, I have a deep interest in seeing this plan succeed. I also donated an organ to a fellow Louisianan in 2011 - I have a keen interest in seeing our health care system have the policies in place so that our doctors and hospitals have the ability to help everyone.

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Tuesday, May 09, 2017 11:51 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Joseph Schottenfeld
Comment	Dear Secretary Gee, I strongly believe that you should take action and use Section 1498 to provide affordable Hepatitis C treatments to your ill constituents. Doing so would not only allow you to provide treatments to the grievously ill now; it would also set a powerful example for all states moving forward: Where lawful action with enormous benefits for the sick and impoverished is possible, states should act.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov]

Sent: Tuesday, May 09, 2017 6:27 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Riley Lipschitz
Comment	I am a primary care physician and I have seen how the treatments for hepatitis C have changed my patients lives. Having access to affordable medication will make huge strides to improve the health of Louisianans! Louisiana is leading the way to make sure these medications are available to everyone who needs them. In doing so, it will save millions of dollars and countless lives down the road.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, May 10, 2017 9:59 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Anna VanCleave
Comment	I worked for nearly ten years as a lawyer for poor and incarcerated individuals in Louisiana and have seen first hand the tragedy that happens when the Hep C cure is available in theory but out of reach as a practical matter. I support this initiative.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov]

Sent: Tuesday, May 09, 2017 8:15 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Sebastian Brady
Comment	This is a great initiative. I suffer from two chronic conditions with no known curesthose whose diseases are curable should not be denied treatment just because they can't afford it. I'm proud my state is considering taking these steps on behalf of its citizens.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, May 10, 2017 3:11 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Catherine Pearson
Comment	I am a resident physician at the University of Pennsylvania in Primary Care Internal Medicine. I regularly see the consequences of untreated Hepatitis C in the hospital, as I take care of people dying of liver cirrhosis or kidney failure as a consequence of Hepatitis C. I also work in a primary care clinic, where I unfortunately must tell patients all too often that while their Hepatitis C now has a cure, their insurance company will not cover treatment for their disease due to the price of the drugs. I commend Dr. Rebekah Gee for this initiative. Making Hepatitis C treatments more affordable and accessible is critical to keep not only individuals but whole communities healthy. With the rise of the injection drug use epidemic, hepatitis c rates will undoubtedly rise as well, and the urgency of this need will only be greater.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, May 10, 2017 10:26 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Richard Zacharias
Comment	I support permitting the government to make the cure for Hepatitis C available widely. This has the potential to greatly help many people throughout Louisiana, and it would exemplify the state leading the nation in caring for sick citizens.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov]

Sent: Wednesday, May 10, 2017 11:22 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Leah Ward
Comment	Louisiana should set an example for all states and treat all people with Hep C. I work with the prison population and it would be very beneficial to provide inmates and individuals with lower incomes with an opportunity for more affordable drugs.

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Wednesday, May 10, 2017 1:01 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Korak Sarkar
Comment	I have seen the impact of Hep C through my patients, friends, and family. I have also seen the remarkable efficacy of these new generation of medications. I strongly support this initiative and have encouraged my peers to do so as well.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, May 10, 2017 2:41 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Christopher Lapinig
Comment	I write to voice my support for the Recommendations on Drug Availability publicly posted on your website and to encourage the Louisiana Department of Health to avail itself of the options outlined in that letter. Specifically, I believe that the Louisiana Secretary of Health should write to the U.S. Department of Health and Human Services (HHS) to request that HHS Secretary Tom Price negotiate a voluntary license or else invoke 42 U.S.C. § 1498 to affordably obtain and make available the highly effective hepatitis C medications. Such actions would enable the State of Louisiana to treat, and likely cure, all individuals living with Hepatitis C who are in the state's Medicaid program, without insurance, or currently incarcerated. The State of Louisiana cannot afford the \$1-billion-dollar-plus price tag attached to treatment of all 73,000 people in Louisiana who currently suffer from Hepatitis C. Therefore, the state must look to other options. First, the State of Louisiana could attempt to negotiate a voluntary license, as per the recommendation of the National Academy of Science, Education, and Medicine. If such negotiations fail, I strongly support use of § 1498 to obtain affordable hepatitis C medications. This provision is nearly a century old and has been routinely used § 1498 to obtain medications at reasonable prices. Nowhere is the government's interest more strong than with respect to the health and welfare of its citizen. The Recommendations on Drug Availability outline the legality of this strategy and its potential for drastically lowering the cost of hepatitis C treatment. I ask the Louisiana Department of Health strategy and its potential for drastically lowering the cost of hepatitis C treatment. I ask the Louisiana bepartment of Health to avail itself of this option to protect the health and welfare of its citizens.

From: Idhinfo@la.gov [mailto:Idhinfo@la.gov] Sent: Wednesday, May 10, 2017 3:38 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Danielle Levine
Comment	Please make the Hep C cure available to all who need it. As an MPH working in Louisiana I know how devastating Hep C is, particularly in our poorest communities. We have the capacity to CURE THIS, it is definitely in the best interest of the government to do so.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, May 10, 2017 6:45 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	James Babst
Comment	This is absolutely the right decision for the public health of all Louisianians and is supported by all medical professionals with sense and compassion.

From: Idhinfo@la.gov [mailto:Idhinfo@la.gov] Sent: Wednesday, May 10, 2017 7:51 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Hayley Goldbach
Comment	As a physician I think that this is the just, moral course of action. We must not put the profits of pharmaceutical corporations above the interests of our citizens.

From: <u>Idhinfo@la.gov</u> [mailto:Idhinfo@la.gov] Sent: Thursday, May 11, 2017 9:21 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Andrew Cox
Comment	I am a Louisiana resident and think this is a phenomenal proposal. Curing a devastating illness in so many people is an absolute good. If there is a way to do that legally and affordably, we have a moral duty as a state to purse it. The fact that Louisiana would be at the forefront of public health innovation is lagniappe.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Thursday, May 11, 2017 9:53 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Will Bercik
Comment	I live in Louisiana and I think this is a good idea

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Thursday, May 11, 2017 2:11 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Rebecca Kiley
Comment	As a public defender, I work with a lot of prisoners and unfortunately many of them have Hepatitis C. This sounds like a great way to help people in that situation.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Thursday, May 11, 2017 9:54 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Shaun Yockelson
Comment	I am a critical care physician and anesthesiologist beginning practice in New Orleans, Louisiana. My practice is critical, but so is this endeavor to clear hepatitis C from the prison population. I hope you will strongly consider reinforcing this policy.

From: ldhinfo@la.gov] Sent: Saturday, May 13, 2017 2:03 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Dr. Iyabiye Healing home
Comment	Are you a HEPATITIS or HIV AIDS patient? Worry no more the cure is available, contact Dr. lyabiye for treatment and total cure through email: <u>iyabiyehealinghome@gmail.com</u> or Tel: +2348072229413

From: <u>ldhinfo@la.gov</u>]

Sent: Saturday, May 13, 2017 8:18 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Shawn Mckee
Comment	Do it! This is a no brainer. No Louisianian would oppose this.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Sunday, May 14, 2017 8:29 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Alexandra Eynon
Comment	I strongly support the Louisiana Secretary of Health taking action to prevent the spread of a completely curable disease by using 48 USC 1498 provision to purchase generic drugs. This is a huge opportunity to eliminate a public health and human rights crisis at a low cost. In doing so, Louisiana would be a leader among the states by choosing the health and safety of its citizens over big pharmaceutical interest, and not only Louisiana but the entire country would be better for it.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Sunday, May 14, 2017 4:06 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Nora Fuller
Comment	As a community health outreach worker, who has built rapport with people who inject drugs, I'm writing to support these recommendations regarding hepatitis C treatments for the State of Louisiana. Treatment of infected individuals is an important step in reducing the incidence of Hepatitis C among communities of drug users, their friends, and their families. It is heartbreaking to walk people through the process of accessing treatments, such as Sovaldi and Harvoni, only for them to be denied access because of the high costs.

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Monday, May 15, 2017 3:00 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Enrique Moresco
Comment	I Enrique Moresco, a health care access advocate, agree and support that Louisiana Department ask the U.S. Department of Health and Human Services (HHS) to take urgent steps action to lower the price of medication to cure HBV infection for low-income populations. 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.

From: <u>ldhinfo@la.gov</u>]

Sent: Monday, May 15, 2017 4:10 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Joseph Buffaloe
Comment	I strongly support the proposed mechanism to obtain life-saving drugs at an affordable price for Louisiana. This is a public health crisis that can't be ignoredhepatitis C killed more Americans last year than every other infectious disease reportable to the CDC combined. The proposed idea both compensates the pharmaceutical companies in a reasonable manner, and is the responsible thing to do to address a serious public health crisis.

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Monday, May 15, 2017 4:48 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Logan Kinamore
Comment	As Executive Director of the grassroots, harm reduction organization No Overdose Baton Rouge, I come into contact with individuals at high-risk for contracting HCV almost daily. Many of our participants are already living with HCV and express a desire to receive treatment, but are barred from accessing drug therapy by the enormous cost. This outrageous barrier-to- care is a nation-wide problem. If the Louisiana DHH is successful in this endeavor, it would provide a landmark precedent for other states, expanding access to HCV treatment and saving countless lives.

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Monday, May 15, 2017 11:54 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	B. Edlin
Comment	My personal opinion, as a physician who has been treating and researching hepatitis C for 20 years, and a passionate advocate for public health and human rights, is that Louisiana should do everything in its power to obtain an unlimited supply of hepatitis C medication. Tens of thousands of Americans are dying of hepatitis C every year one every 15 minutes or less despite the fact that a safe, quick, nontoxic, easy treatment is readily available. To withhold these drugs from people who desperately need them because of our heartless system for paying for drugs is unconscionable, especially since the systems that are blocking access to the drugs are awash in money and could easily afford to pay for them. What it would cost our society to make and distribute enough medication to treat every person who needs it is a drop in the bucket, compared to the massive wealth that exists in our society, and, in particular, in the entities who could open the doors to those who are suffering and need treatment if they wished. But large, wealthy interests are standing in the way so they can line their pockets with even more untold riches. When private interests have blocked the US healthcare system form attending to the needs of the US public, it is time for the government to step in. That is the purpose of government to promote the general welfare of the people. Our government grants monopoly rights to pharmaceutical companies to incentivize them to develop drugs that meet the needs of the public. When they use that power to price the drugs out of reach of the public, the rationale for monopoly pricing rights falters, and government must step in to protect the health, well-being, and lives of its citizens. We cannot unconscionably stand by and watch as our fellow citizens suffer and die needless, preventable deaths because of the greed of rich, powerful corporations. You will be a hero if you are able to break this logjam and bring relief to your citizens.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Tuesday, May 16, 2017 11:59 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Cynthia Lehigh
Comment	The government needs to regulate the price of life-saving prescription drugs. They are not a luxury. Companies should not profit from the misfortune of others. Both my children have Type 1 diabetes and rely on insulin to stay alive. Insulin was developed in 1921, 96 years ago, by two Canadian scientists, who, wanting to save lives not fill their pockets, sold the patent to the University of Toronto for \$1. But, to keep up with demand, the University soon signed a nonexclusive license with Eli Lilly, opening the door to for-profit marketing. Insulin prices have skyrocketed, despite the fact that companies recouped development costs long ago. In the past 5 years, some prices have increased by more than 160%, according to a 2015 Bloomberg Health report. My kids use Humalog, at a retail cost of \$300, or \$10,800 per year without insurance. Why does the United States, unlike other countries, not regulate the price of live-saving prescription drugs? Not doing so is costing the lives people with diabetes, Hep C, cancer, and other chronic conditions. It's time to put people before profits. Our constitution states that "We the people, in order to form a more perfect union, promote the general welfare, do ordain and establish this constitution." Please consider the Louisiana Secretary of Health's recommendation to lower the cost of Hepatitis C medications by invoking 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." Do it for "the general welfare" of real people, who will die without it. Do it because it is your fiduciary responsibility to keep prices down, particularly for low-income patients with government assistance. Do it because it is right.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Monday, May 15, 2017 9:15 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Diana Lee
Comment	I am writing in support of the Hepatitis C initiative. It is important that the Louisiana government take action on behalf of Hepatitis C patients and their families, and set an example for other states considering similar measures.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Thursday, May 18, 2017 12:02 PM To: DHHINFO Subject: Hepatitis C Initiative

Name	Julianne Haydel
Comment	It is refreshing to see DHH dancing around the restraints that make hep C treatment unavailable to all who need it. There are still questions, however. How much would the cost of caring for individuals with hepatitis C, in the populations described, cost over time? Who determines the reasonable cost to the patent holder for government use of the patent? The drug companies may agree that \$1,000.00 per patient is reasonable. But, if the drug companies anticipated that their exclusive data would be used by a government entity and they had no recourse, would they be willing to cut the prices if the state limited the use of discounted meds to Medicaid, the uninsured and prisoners? Solead and Gilead have deliberately priced their product in such a manner that they know people will die due to cost considerations. The people in the demographic groups who can afford Solead and Gilead medications are also those with access to transplants. Thus, they can extol the financial virtues of their meds by including the cost of caring for a liver transplant patient and justify the cost. Could someone with math skills extrapolate the cost of these products over the entire population in need and determine the actual savings considering all those who are not eligible for transplants and the availability of organs for donation? Have other alternatives been explored? Even Medical Tourism could be less expensive although highly impractical for prisoners. Could Louisiana, along with other heavily burdened states combine resources to produce a generic equivalent to a highly effective Hep C medication? Is there any way to legally purchase medications directly from India where several of the meds are actually manufactured? The people of Louisiana deserve high quality Medical Care. Laying out the costs of paying for meds with nothing changed compared to the cost of alternatives would garner a lot of support. I understand that people are entitled to make money. I like money. But I object to a profit margin predicated on people dying. Maybe a

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, May 24, 2017 2:01 PM To: DHHINFO <<u>ldhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Rob Restuccia
Comment	May 22, 2017 Rebekak E. Gee, MD, MPH Secretary of the Louisiana Department of Health 628 N. 4th Street Baton Rouge, LA 70802 RE: Louisiana's Use of 28 U.S.C. § 1498 to treat Hepatitis C in the Louisiana Medicaid, uninsured, and state prison populations - Support Dear Secretary Gee, I am the Executive Director of Community Catalyst's first priority is quality affordable health care for all. Since 1998, we have provided leadership and support to state and local consumer organizations, as well as policymakers, provider organizations and foundations working to change the health care system so it serves everyone – especially vulnerable members of society. Today we collaborate with organizations in over 45 states, including Louisiana. Access to quality and affordable prescription drugs has been a key issue of concern for our constituencies. The sharp rise in specialty drug prices has heightened this concern by reducing consumer access to essential medications leading Medicaid programs to severely restrict coverage for lifesaving treatments, and increasing the burden of out-of-pocket costs and premiums on low- and middle-income families. On behalf of Community Catalyst, I write to voice our support for the Recommendations on Drug Availability publicly posted on your website and to encourage the Louisiana Department of Health to avail itself of the options outlined in that letter. Specifically, we believe that the Louisiana Secretary of Health should write to the U.S. Department of Health and Human Services (HHS) to request that HHS Secretary Tom Price negotiate a voluntary license or else invoke 42 U.S.C. § 1498 to affordably obtain and make available the highly effective hepatitis C medications. Such actions would enable the State of Louisiana to treat, and likely cure, all individuals living with Hepatitis C who are in the state's Medicaid program, without insurance, or currently incarcerated. It would be very challenging for the State of Louisiana to afford the \$1-billion-dollar-plus price tag attached to treatment

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Monday, May 22, 2017 1:50 PM To: DHHINFO <<u>ldhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Jabe Curley
Comment	To whom it may concern: The discussion to invoke provision 48 USC 1498 in order to expand access to affordable Hepatitis C therapies for us in the Medicaid program and prison populations addresses a critical need. The burden on individuals with few resources is crippling, and the healthcare system is forced to absorb the costs associated with the ongoing disease progression. Louisiana has a chance to set the precedence and lead the nation in a progressive approach to public health. I work in drug development and have seen the time and costs associated with developing new therapies. If possible, we need to do everything we can to expand access to critical drugs. Thank you, Lowry

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Thursday, May 18, 2017 11:00 AM To: DHHINFO Subject: Hepatitis C Initiative

Name	Molly Green
Comment	I was born and raised in Louisiana but now I live in California. When I hear about Louisiana in the news, it's often not positive coverage. However, I was really happy to hear about the Hepatitis C Initiative. I would be so proud to see Louisiana making positive strides in healthcare and become an example for the U.S. I hope the initiative is implemented and we can show the rest of the U.S. that Louisiana is an innovative state that cares about the health of its citizens!

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Thursday, May 25, 2017 3:05 PM To: DHHINFO <<u>ldhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Brian Highsmith
Comment	Louisiana should set an example for all states and treat all people with Hepatitis C. I worked in public health in DC before law school and will be working with the prison population as a public interest lawyer starting next year, and I fully support this policy. Thank you!

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Friday, May 26, 2017 12:01 PM To: DHHINFO <<u>ldhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Jonathan Petkun
Comment	I am writing in support of the proposal to us 42 U.S.C. Sec. 1498 in order to procure life-saving medicine for Louisianians suffering from Hepatitis C. I am a JD/PhD candidate in economics, and part of my dissertation research focuses on military procurement. From the defense sector, we know that, when necessary, the government can exercise Sec. 1498 without inhibiting long-term research and development. As long as patent holders are compensated with a reasonable royalty which Sec. 1498 guarantees industry will continue to innovate. In the meantime, this plan could make vital Hepatitis C medicine available to thousands of Louisianians.

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Monday, May 29, 2017 10:46 AM To: DHHINFO <<u>Idhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Marguerite Green
Comment	As a citizen of Louisiana I am proud of the idea of us doing this. It's so great and would set an example. HIGHLY IN FAVOR!

From: <u>Idhinfo@la.gov</u> [<u>mailto:Idhinfo@la.gov</u>] Sent: Thursday, May 25, 2017 3:57 PM To: DHHINFO <<u>Idhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Sean Colenso-Semple
Comment	I am writing to applaud Louisiana for its innovative Hepatitis C Initiative. By aggressively fighting Hepatitis C, Louisiana has the potential not only to do great good for its own citizens, but also to be a national leader and model for other states to follow. I look forward to monitoring the progress of this valuable initiative.

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Sunday, June 04, 2017 2:22 PM To: DHHINFO <<u>ldhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Kaitlin Marone
Comment	This seems like the only humane response to having a cure for a deadly disease that many people have. Why would we, as humans, force people to suffer when we could relieve it?

From: Idhinfo@la.gov [mailto:Idhinfo@la.gov] Sent: Tuesday, June 06, 2017 3:09 AM To: DHHINFO <Idhinfo@la.gov> Subject: Hepatitis C Initiative

Name	Rae Belanger
Comment	I am one of the unfortunate statistics in Louisiana, I am 35 yrs. old and have tried my best to get treatment, I have had an advocate worker try to give a go, but as always to no avail we are unable to even get an appointment with a doctor anytime soon, I think other primary care doctors should be able to administer the treatments like Harvoni to people because the infectious disease doctors just are not able to handle the case load imposed on them. I hope we can collaboratively come up with a streamlined solution to help in this issue. Thanks, Rae

From: Idhinfo@la.gov [mailto:Idhinfo@la.gov] Sent: Tuesday, June 06, 2017 8:28 PM To: DHHINFO <Idhinfo@la.gov Subject: Hepatitis C Initiative

Name	Joanne Chan
Comment	Comments of the Pharmaceutical Research and Manufacturers of America Responding to the Louisiana Department of Health Request for Public Comment on Hepatitis C Drug Pricing Dear Secretary Gee: The Pharmaceutical Research and Manufacturers of America ("PhRMA") submits these comments in response to the notice issued by Secretary Rebekah Gee of the Louisiana Department of Health dated May 4, 2017, seeking public comment on matters relating to "Hepatitis C in Louisiana: Recommendations on Drug Availability" ("Notice"). PhRMA appreciates Secretary Gee's outreach to stakeholders and offers the following comments on matters discussed in the Notice. The issues raised in the Notice would have a significant impact on PhRMA members. Inventions

made by PhRMA members provide patients with life-saving medicines. The U.S. biopharmaceutical sector accounts for approximately 17% of dollars spent on all research and development ("R&D") by U.S. businesses, with biopharmaceutical companies operating in the U.S. investing more than \$70 billion in R&D in 2015. The U.S. biopharmaceutical sector invests twelve times more in research and development per employee than the average of all other manufacturing industries. Only 12 percent of investigational medicines entering clinical trials are ultimately approved by the FDA, reflecting the high level of uncertainty associated with drug development. Only two of every ten marketed drugs return revenues that exceed or match the substantial R&D investments made. Bringing new treatments and cures to patients is time-consuming, risky, and expensive. The Notice proposes that Louisiana ask the U.S. Department of Health and Human Services ("HHS") to obtain a license for obtaining deeply discounted hepatitis C medications for Louisiana and, if HHS is unsuccessful in doing so, to invoke 28 U.S.C. § 1498 ("section 1498") to authorize a company to make a generic version of the patent-protected medications. PhRMA submits that it would be a mistake for the state of Louisiana to rely on section 1498 in an effort to reduce the cost of hepatitis C drugs. Section 1498 does not permit the federal government to disregard patents. Rather, it creates a remedy for the patent holder in the event of governmental infringement by providing for "reasonable and entire compensation" for patent holders whose invention "is used or manufactured by or for the United States." Recent situations that led to discussions about section 1498 in the context of pharmaceutical patents involved government stockpiles for national security purposes. There, government officials acknowledged that governmental action was contemplated only because of the exigent circumstances of a shortage of the one drug available to address the condition at issue, which is not the case here. In 2001 during government negotiations to obtain discounted Cipro® to build a national stockpile in response to the threat of anthrax, Secretary of Health and Human Services Tommy Thompson stated that it would be illegal to break the patent on the drug after the manufacturer made the decision to increase its production. In 2006 when Senator Chuck Schumer proposed to seek an alternative supply of Tamiflu® in response to the threat of an H5N1 avian flu pandemic, he noted that it was "not the expense of the drug, but rather the shortage of supply" that motivated his proposal. Section 1498 does not apply to the production of discounted medications for the general public. Section 1498 provides "reasonable and entire compensation" for patent holders whose invention "is used or manufactured by or for the United States." An arrangement between HHS and a pharmaceutical manufacturer to produce generic medications for the general public in order to reduce drug prices (let alone on behalf of a state for particular segments of the state's population), would not amount to activity by or for the United States as required by section 1498. The Notice cites several instances where the federal government purportedly either used or was prepared to use section 1498 to obtain discounted medications, but glosses over details relevant to the applicability of section 1498, such as procurement by the Military Medical Supply Agency. Section 1498 has never been used affirmatively by the government to permit a pharmaceutical company to manufacture generic versions of patent-protected drugs and thereby lower drug prices for public consumption. Even if section 1498 were to apply, reasonable and entire compensation must be provided. This measure of damages requires at least payment of a reasonable royalty arising from the government's use of the patented invention. Reasonable royalty calculations typically include consideration of the marketplace and are not insignificant. The court may consider additional factors that could increase damages, such as the value of a ground-breaking drug product or the fact that the patent owner would not ordinarily license its patent rights to third parties. And because drug products are usually covered by multiple patents, damages assessments would be conducted considering all of the patents. This process would result in the federal government's facing the uncertainty of relying upon section 1498 without any clear sense of what damages might be assessed. These damages would be assessed on top of the cost already borne by the federal government for its contract with the generic manufacturer, further

decreasing any potential government savings from the proposal in the Notice. Other possible methods for calculating damages in this context, e.g., lost profits or a portion of governmental cost savings, could result in even higher amounts of damages. It is worth noting that if section 1498 were found not to apply, the patent owner could seek lost profit damages and injunctive relief. Implementation of a section 1498 strategy would be complicated and time consuming. Any drug introduced under this program would need to be approved by the U.S. Food and Drug Administration ("FDA"), which would need to make the determination that the drug is safe and effective before it could be available for human consumption. In addition, the statutory FDA approval process for generic drugs under the Hatch-Waxman Act expressly contemplates patent litigation, which routinely occurs during the generic drug approval process and may affect the timing of generic drug approval. It is unclear how approval could occur under this framework governing approval of generic drugs, which specifically respects intellectual property rights. Even if FDA approval were somehow granted, HHS in conjunction with the generic company and the state of Louisiana would need to establish a complex distribution and reimbursement scheme that aligns with the requirements of section 1498 and other applicable state and federal laws. Hepatitis C drugs can significantly reduce healthcare costs over time. Before pursuing a section 1498 strategy, PhRMA urges the State of Louisiana to reconsider its cost assessment of hepatitis C drugs. The cost of such drugs must be evaluated in light of broader health care costs and savings. Without such drugs that can cure hepatitis C in as little as 12 weeks, hepatitis C patients would continue to require hospitalization and other costly health services over the course of decades, resulting in an estimated \$21.5 billion in medical costs nationwide over the ten-year period from 2015-2025 if untreated. (Milliman, Inc., An Actuarial Approach to the Incremental Cost of Hepatitis C in the Absence of Curative Treatments. September 2015.) In addition, hepatitis C patients in the work force who are cured of the disease are able to continue working and contributing to the economic development and vibrancy of the state of Louisiana. These factors need to be taken into account when evaluating the cost of hepatitis C drugs. Disregard for patent rights will discourage innovation. Like innovators across the spectrum of American industries, biopharmaceutical companies make the substantial R&D investments that vield new and improved medicines in reliance on a legal regime that provides protection for any resulting intellectual property. In particular, PhRMA's members rely on patents to protect their inventions and provide an opportunity to recover their R&D costs and fund new research. Given the high failure rates, time, and costs of drug development, increasing regulatory requirements, and the need to make up for the many failures and earn a return to foster continued R&D, patents are critical for biopharmaceutical innovation. Failure to safeguard the patent system will decrease the incentives for biopharmaceutical companies to invest in future biomedical innovation. PhRMA urges the State of Louisiana to reject the proposal of invoking 28 U.S.C. § 1498 as a way of increasing access to hepatitis C treatments. PhRMA looks forward to continued dialogue with the Department on this issue. Sincerely, Joanne Chan Assistant General Counsel Law Department

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, June 07, 2017 7:46 AM To: DHHINFO <<u>ldhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Ed Martin
Name	June 6, 2017 Secretary Rebekah Gee Louisiana Department of Health 628 N. 4th St. Baton Rouge, LA 70802 RE: Hepatitis C Drug Pricing Dear Secretary Gee: Eagle Forum Education & Legal Defense Fund, a national conservative public policy organization with state leaders and members across the nation including in Louisiana, is pleased to comment on the State of Louisiana's consideration of "unconventional options" for obtaining Hepatitis C medication at prices extremely below market rates. Eagle Forum Education has long engaged in issues relating to our patent system and inventors. This includes the Bayh-Dole Act, which provides for the transfer of technology arising from federally funded basic research into commercial application and the resulting public benefits, due to this law's providing certainty and exclusivity to private entities willing to shoulder the risk and burden of attempting to commercialize these patented inventions. We acknowledge that Hepatitis C affects many Americans and can place strains on public health care resources for those patients with low incomes. Eagle Forum Education also empathizes with the individuals suffering from this disease. Further, we wish medicines did not cost so much (but that is the price of having access to new drugs and therapies much sooner in the United States than do patients in countries with government-run health systems that impose price controls, ration care, and expropriate medical resources). Yet, Louisiana's proposals of (1) licensing of 'a highly effective therapy" with "deeply discounted" availability to the state through the U.S. Department of Health and Human Services and (2) using 28 U.S.C. Sec. 1498 to obtain "a highly effective treatment at a fraction of current market cost" run tremendous risks that augur against Louisiana's taking such extraordinary steps. First, the measures under consideration would directly infringe private companies' patents. The nature of these medicines is that they come from a lengthy, complex process in which trial and error re
	encroachment of private property and/or property rights, which is what both of Louisiana's proposals regarding Hepatitis C medicines amount to, short- sightedly jeopardizes broader access to such Hepatitis C medicines as Sovaldi and Harvoni (both of which are cures for the disease, not merely treatments). There is no free lunch. The companies that own the patents on Hepatitis C cures have invested years and billions of dollars in their products, and those costs must be made up somewhere. While Louisiana
	would benefit in the short term from encroachment of patented property, other payors, including private insurers, other states' public health programs, and federal payors such as Medicare and CHIP, would face higher costs for the special treatment Louisiana arrogated for itself. Third, Section 1498 creates a remedy for patent owners whose inventions the federal government infringes. It does not create a right to infringe by federal

or by state governments. The law's requirement of the government to pay "reasonable and entire compensation" helps safeguard the exclusive property right of the inventing company. The "reasonable and entire compensation" rightly due the patent owner, under Louisiana's proposed "unconventional options," would saddle taxpayers with significant additional costs. Fourth, the use of such "unconventional options" by Louisiana places at tremendous risk the prospect of future medical innovation and patient clinical outcomes. The area of biologics, which are scientifically more complex than pharmaceuticals using chemical compounds, provides therapeutic benefits but are significantly more expensive to develop and to manufacture. Yet, biopharmaceuticals hold the key to precision medicine, which President Obama championed in his 2015 State of the Union speech. Further, the proposed approaches fail to consider that multiple therapies for Hepatitis C are now on the market, and the eradication of this disease is now in sight. These proposals invade the market because Louisiana only looks at the high cost of treating Hepatitis C, while instead you should encourage people to develop more treatments by respecting patent rights. The precedent Louisiana would set would risk causing innovator pharmaceutical companies to curb R&D into therapies for some of the greatest medical challenges. Should other efforts by state or federal governments infringe on exclusive patent property rights and values, a snowball effect would likely result in measurable slowdown in biopharmaceutical progress. In other words, Louisiana's actions would jeopardize confidence in the R&D, risk-and-reward model that relies upon secure patent rights and exclusivity, as the U.S. Constitution guarantees. That would cause, not cure patients' suffering, hamper medical progress, and deprive Americans of access to newer, better, higher-value medical innovations over time. Therefore, Eagle Forum Education & Legal Defense Fund urges you to reject the "unconventional options" for cutting-edge Hepatitis C — or any other — medicines. Respectfully, Ed Martin President Eagle Forum Education & Legal Defense Fund 7800 Bonhomme Avenue St. Louis, MO 63105

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, June 07, 2017 9:08 AM To: DHHINFO <<u>ldhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	James Love
Comment	In addition to asking the federal government to invoke 28 USC 1498(a), a path we support, Louisiana should consider its options under the doctrine of state sovereign immunity, and also asking a country to set a running royalty on infringing products. For a discussion of all three options, see: 2014:1 KEI Policy Brief: Nonvoluntary use of patents for drugs to treat the Hepatitis C Virus in the United States: Mechanisms available to the Federal Government, State Governments and Private Actors. July 18, 2014.http://keionline.org/node/2058 Also informative are these 3 videos: 1. Feb 2017 panel on use of 28 USC 1498 for the Department of Veterans Affairs, https://www.youtube.com/watch?v=Za9RbL0jtds, 2.a 2015 video about a proposal to modify 28 USC 1498 for the Department of Veterans Affairs, https://www.youtube.com/watch?v=XAY4Ua7B2mQ and 3. a 2015 video on the risks to state sovereign immunity in the TPP trade negotiations. https://www.youtube.com/watch?v=RbVQZa85xVQ

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, June 07, 2017 1:44 PM To: DHHINFO <<u>ldhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Tom Rippolon
Comment	I am writing to express support for the proposal to reduce hepatitis C treatment prices in the state of Louisiana. Gilead Sciences and others have priced curative hepatitis C treatments out of reach of many of my fellow Louisianians, and the price is making it impossible for the state to continue to treat people suffering from hepatitis C. I support efforts to license the monopoly rights to hepatitis C treatments and save millions of our tax dollars while also providing care to those who need it. SINGLE PAYER INSURANCEDO IT NOW!!!!

From: Idhinfo@la.gov [mailto:Idhinfo@la.gov] Sent: Wednesday, June 07, 2017 1:23 PM To: DHHINFO <Idhinfo@la.gov> Subject: Hepatitis C Initiative

Name	Carl Schmid
Comment	The AIDS Institute is encouraged that Louisiana is taking strides to treat its uninsured population living with hepatitis C (HCV), particularly its Medicaid beneficiaries, and is pleased to offer comments on Hepatitis C in Louisiana: Recommendations on Drug Availability. HCV is a serious deadly infectious disease with treatment available that leads to a cure. Access to these curative medications is necessary to avoid future related health problems such as liver disease, cirrhosis, liver cancer, and to decrease future infections. Given that treatment is so necessary and in almost all instances leads to a cure, we believe Louisiana's current Medicaid policy, which restricts treatment until patients have severe liver damage, is unacceptable and violates current Medicaid law. We are pleased that you are taking steps to change it so that more people in Louisiana will be able to take advantage of the curative medications. We realize that Louisiana is only in the position to make these changes possible because it has expanded Medicaid, which is a benefit to an estimated 428,000 low-income people in the State. However, we believe that some of the assumptions Louisiana is making that has led you to propose extraordinary actions are flawed. The analysis that Louisiana conducted fails to consider 1) future cost-savings that the state Medicaid program will realize by curing people with HCV; 2) the time frame that Medicaid beneficiaries with HCV will seek treatment; and 3) other payers, such as the Ryan White HIV/AIDS Program, that can assist with uninsured people who are co-infected with HIV. While we realize that purchasing HCV curative medications will impact Louisiana's Medicaid budget, we disagree that it is impossible to address this challenge through conventional approaches to drug pricing. This is due to the fact that the price of the drug has been dramatically discounted and total expenditures will be spread out over several years. Other states are successfully treating their citizens in compliance with current Med

abstained from substance use for 12 months or longer, and have received their prescription from a specialist. These restrictions violate current Medicaid law, which forbids states from restricting access to medical treatment on the basis of the treatment's cost. The restrictions are also contrary to the American Association for the Study of Liver Diseases' (AASLD) treatment guidelines that encourage treatment of nearly all patients diagnosed with HCV--regardless of Fibrosis Score or abstinence length. Additionally, the National Academies of Science, Engineering, and Medicine (NASEM) recently recommended that health plans, including Medicaid, "remove restrictions that are not medically indicated and offer direct-acting antivirals to all chronic hepatitis C patients" in order to make eliminating viral hepatitis as a public health threat in the United States a possibility. Withholding treatment and forcing patients to wait until their liver is severely damaged or until they have reached a certain length of abstinence causes undue harm. This is a policy that must be changed. While headlines often focus on the list price of the HCV curative medications, according to analysis conducted for the Louisiana Department of Health, the average cost to the state's Medicaid program would only be \$8,280 per patient receiving HCV treatment. This reflects the significant rebates and discounts that pharmaceutical manufacturers are offering and the fact that the federal government carries the largest share of the costs in the Medicaid program. According to our calculations, treating the 20,000 Medicaid recipients living with HCV at \$8,280 per treatment would cost the state \$165.6 million. The recommendations focus heavily on the estimated \$765 million cost to treat the Medicaid and uninsured populations living with HCV, but more than half of the target population can be treated for a small portion of that cost. Because treatment results in a cure nearly 100 percent of the time, this would be a one-time cost and unlike so many other Medicaid costs, not reoccurring. We fail to understand why Louisiana is singling out and only restricting HCV treatment. In 2015, Louisiana spent \$8.3 billion on its entire Medicaid program and of that amount, only 4.8 percent, or \$398 million, on prescription medications. Therefore, when considering the State's overall Medicaid expenditures. HCV treatment would not be a significant cost. We believe it is unfair to present to policy makers that Louisiana must make a choice between funding schools, public services and infrastructure programs or HCV curative medications. While The AIDS Institute would never suggest a reduction in Louisiana Medicaid spending for HIV medications, we note that the state Medicaid program spent \$48 million on HIV treatments in 2015. Unlike HCV, HIV is an incurable chronic condition, so the costs are incurred year after year. With HCV, all the costs would be over a short duration until a patient is cured. Louisiana Medicaid also spends billions of dollars treating other chronic conditions and other Medicaid services that bear a much greater share of the Medicaid budget. Instead, Louisiana continues to focus on HCV treatment. We also take issue with the assumption that all HCV treatment costs will be borne in a single year. It is highly unlikely that all of the estimated 20,000 Medicaid recipients living with HCV will receive treatment in the first year of increased access. More than 50 percent of people living with HCV do not know they are infected, so they do not know they even need to seek treatment. Treatment rates will be spread across multiple years as individuals gradually learn they have the disease. States that currently have no or few treatment restrictions in Medicaid have not had their entire treatment-eligible population come in for treatment in a single year. In fact, the Department of Veterans Affairs (VA) has opened access to HCV treatment and actively pursued connecting veterans living with HCV to treatment. They have not been able to treat all of their HCV patients in one year. The VA currently estimates it will take four years to treat 80 percent of their HCV population. The \$165.6 million estimated to treat the 20,000 Louisiana Medicaid recipients living with HCV would be spread across multiple years, which means the expenditures per year will only be a fraction of the assumed total. We believe that future cost-savings to the Medicaid program by treating and curing people with HCV should also be considered as part of Louisiana's cost calculations. Numerous studies have found that it is cost-effective to treat HCV early because untreated HCV can lead to liver disease, cirrhosis, liver cancer, and liver transplants. All of

these require long-term care at high costs. Louisiana's Medicaid program would save money in the long-term by treating HCV early and robustly. Additionally, the fact that approximately five percent of people living with HCV are also co-infected with HIV is also not considered. Some of these individuals who are co-infected can be treated through the Ryan White HIV/AIDS Program. lowering the state's overall treatment costs. The AIDS Institute recommends that the Louisiana Department of Health follow current Medicaid law, AASLD guidelines, and NASEM recommendations and remove access restrictions to HCV treatment to allow all Medicaid recipients diagnosed with HCV to receive treatment. Opening up treatment access will result in cost savings in the long-run. Short-term costs would be spread out over multiple years, keeping them manageable without drastic adjustments to the existing budget. We also recommend the state work to connect individuals co-infected with HCV and HIV to the Ryan White HIV/AIDS Program to receive treatment. By increasing access and actively working to connect individuals living with HCV to one-time curative treatment, it is possible to treat a large portion of Louisiana's Medicaid population living with HCV through the existing mechanisms of accessing medications. The price of the medications has dropped precipitously, Louisiana's share would only be slightly over \$8,000 per cured patient, and it would be spent over several years. We urge the Louisiana Department of Health to reject the proposed recommendations in Hepatitis C in Louisiana: Recommendations on Drug Availability and look to conventional, proven solutions to combatting this serious public health threat. Thank you. Sincerely, Carl Schmid Deputy Executive Director Program and Administrative Office 17 Davis Blvd., Suite 403, Tampa, FL 33606 | Ph: 813-258-5929 | Fax: 888-714-7243 National Policy Office 1705 DeSales St NW, Suite 700 Washington, DC 20036 | Ph: 202-835-8373www.theaidsinstitute.org

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, June 07, 2017 3:54 PM To: DHHINFO <ldhinfo@la.gov> Subject: Hepatitis C Initiative

Name	Frank Cullen
Comment	

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, June 07, 2017 4:21 PM To: DHHINFO <<u>ldhinfo@la.gov</u>> Subject: Hepatitis C Initiative

Name	Alex Niculescu
Comment	This absolutely needs to happen. Gilead purchased the company that did the R&D for the medication, and that R&D I believe was taxpayer funded, so keeping the prices where they are is essentially forcing taxpayers to pay twice for a medication/product that has already recouped its investment
	costs on Gilead's end. Anything close to the market price at this rate is pure price gouging. HCV is currently the leader in infectious diseases causing mortality in the United States, more than every other infectious disease in the US combined (according to a paper in CID and a press release by CDC). If pricing is reduced and access is expanded, there's a real hope to eradicate the virus, or (without a vaccine), at least make it as minimal and manageable as other occasional infections. Furthermore, with the increase in injection drug use among younger people, there is a possibility of a second burden of HCV infection, which could possibly be nipped in the bud
	if we used fairly priced HCV medication in the vein of Treatment as Prevention model used successfully with HIV medication. >1% of this country has been exposed to HCV, so it's unfathomable to me that as a society we would find it morally appropriate to not make every effort possible to provide a functional cure to as many people as we can and we can only do that if prices are lowered through this patent law and access is expanded by allowing primary care clinicians and midlevel providers to prescribe HCV treatment and manage the HCV treatment course. Thank you kindly, Alex Niculescu

From: ldhinfo@la.gov [mailto:ldhinfo@la.gov] Sent: Wednesday, June 07, 2017 5:01 PM To: DHHINFO <ldhinfo@la.gov> Subject: Hepatitis C Initiative

Name	Victor Roy
Comment	1. We commend the state of Louisiana's efforts to address the challenge of hepatitis C drug pricing and meet patient and public health needs. Our research has demonstrated, along with the recent National Academy of Sciences report, that hepatitis C can be eliminated as a public health problem – but that current prices in the U.S. are a significant barrier (1). 2. To overcome this barrier, we support the two strategies proposed by the panel assembled by the LA Department of Health: either voluntary licensing or 28 U.S.C. §1498. Furthermore, with no assurances of a voluntary negotiation and given the significant public health challenges faced by the state, the 28 U.S.C. §1498 pathway should be fully pursued. 3. These approaches to drug pricing cannot be viewed in isolation, however, to the development of an elimination-oriented public health strategy. Such a strategy would not only define the goal of elimination within a given time-bounded period (such as by 2030), but set specific targets in the near-term – among them targets for treatment scale-up (1). Several jurisdictions within the US have begun planning for such efforts – including the city of San Francisco and the state of New York (2). Similar planning in Louisiana, possibly already underway, can buttress efforts on drug pricing by mobilizing public stakeholders and making the public health case even more tractable (2. The pricing and funding of hepatitis C medicines would thereby be connected directly to a delivery strategy. 4. Were an opportunity for a voluntary negotiation emerge, an elimination-oriented tartegy can also link to better deals for pricing and reimbursement, such as the one the government of Australia struck with Gilead. Australia's health department and Gilead agreed to a discounted price for a yearly annual rate of patients treated, above which Gilead agreed to offer the drugs at further discounts. Such an approach creates an incentive for the health system to treat more patients while also generating a return for Gilead agreed to of
	<u>1.pdf?amp%3Bqid=1567791</u> (3) "Australia shows alternative to rationing hepatitis C treatment". See: <u>http://www.hepatitisaustralia.com/newsarticles/australia-shows-an-</u>
	alternative-to-rationing-hepatitis-c-treatment/8/6/2016 (4) Roy, V and Lawrence King. 2016. "Betting on Hepatitis C: How Financial Speculation in Drug Development Influences Access to Medicines." BMJ 354:i3718. (5) Gilead SEC 10-K filings, 2015 and 2016.

We are organizations representing more than a million Americans, including public health experts and consumers committed to advancing public health and promoting access to affordable medicines.

42 U.S.C § 1498 presents a unique opportunity to significantly reduce the prices of curative hepatitis C treatments through generic competition [1]. Competition has consistently proven itself as the most effective method of ensuring drug prices continue to fall over time. In countries where generic hepatitis C treatments are available, a full course of treatment is often priced below \$1,000 [2]. Researchers have estimated that production costs of one common hepatitis C treatment to be only \$200 for a 12-week regimen [3].

Without generic competition, current policies continue to restrict access to hepatitis C treatment. Twenty-three state Medicaid programs continue to require individuals to wait until they've suffered severe liver scarring or liver failure to qualify for treatment [4]. And twenty-one states continue to impose alcohol and drug abstinence periods of greater than six months to initiate treatment [5]. Restrictions and financial barriers also continue to limit treatment in commercial insurance plans and Medicare Part D [6]. These restrictions remain contrary to current clinical guidelines, which recommend providing nearly all HCV-infected patients with treatment, and expose these individuals to a life-long elevated risk of liver cancer [7].

Unprecedented public support to lower drug prices

A clear public consensus exists to lower prescription drug prices and increase access to patients in need. Americans across the political spectrum support government action to lower drug prices. A majority of Republicans, Democrats and Independents agree that action on drug prices should be taken [8]. 92 percent of Americans agree that the government should negotiate with drug companies to get a lower price on medications for people on Medicare [9].

State and federal action on drug pricing

The U.S. Department of Health and Human Services estimated that the U.S. spent \$457 billion on prescription drugs in 2015 and projects spending more than \$500 billion this year [10]. In response to prescription drug companies charging high prices that strain budgets, multiple states have initiated legislative responses. These include transparency efforts to establish the public's right to know what drug prices are, with legislation pending in Nevada, California, and Indiana [11]. Legislatures in New York and Maryland have also recently passed laws to combat price gouging by companies [12].

Both major political parties have proposed federal legislation on drug pricing [13]. Elected officials have proposed a comprehensive reform package to lower drug prices, the *Improving Access to Affordable Prescription Drugs Act* (S.771, H.R.1776). Among the Act's eighteen provisions are requirements for increased transparency around drug prices, research & development (R&D) costs and other pertinent information; limitations on unfair price increases; and a host of other reforms [14].

Monopoly power drives high drug prices

Claims that high medicine prices in the U.S. are derived from R&D costs are not borne out by the available evidence [15]; and the American public—including Louisiana residents— often pays twice for medicines, once through funding and subsidizing pharmaceutical R&D and a second time through exorbitant prices for medicines.

Specifically, in the hepatitis C treatment space, companies have already made back their investments and generated substantial profit. In terms of hepatitis C products, Gilead Sciences has made nearly \$50 billion in sales as of March 31, 2017 [16].

The investigation into Gilead's hepatitis C treatment pricing from Sens. Ron Wyden (D-Ore.) and Charles Grassley (R-Iowa) also establishes that the company paid a fraction of those sales for research and development. Specifically, Gilead paid \$11 billion to purchase the company that held the drug's patents, Pharmasset [17]. According to its annual filings, Pharmasset spent an estimated \$62.4 million on research through Phase III clinical trials and benefitted from National Institutes of Health (NIH) grants funded by American taxpayers [18]. Gilead also stated that they spent an additional estimated \$880.3 million on total direct R&D costs [19].

Notably, most of the profit from these sales appears to have remained offshore and has not been reinvested into R&D. By placing ownership of the drug patents in an Irish subsidiary and not remitting profits back to the United States, Gilead Sciences has not paid any U.S. corporate taxes on at least \$10 billion in sales [20].

This trend in R&D costs is not isolated to a single company in the industry. A recent report found that domestic U.S. pharmaceutical companies generated sales revenue equivalent to 176 percent of their global R&D spending; revenue was calculated from the amount by which higher U.S. drug prices exceeded drug prices in other developed countries [21]. Meanwhile, prescription drug corporations spend more money on sales & marketing than on research & development [22]. Globally, the twenty largest companies earned profits of more than \$124 billion, while spending only a fraction of that on research & development costs in 2015 [23].

And it should be noted that while the prescription drug industry reaps enormous profits, it continues to engage in fraudulent and other unlawful behavior, imposing a high cost on consumers. A recent Public Citizen report, examining major financial settlements and court judgments between 1991 and 2015, found that drug companies entered into 373 settlements totaling \$35.7 billion in criminal and civil penalties [24].

Advantages of immediate state treatment of hepatitis C

There are robust legal and public health reasons to treat individuals now rather than waiting for patents to expire around 2030.

In particular, treating every person with hepatitis C now as opposed to delaying treatment until 2030 would lower medical costs [25]. Compare the costs of treatment using low-cost generics in

the paragraph below to the costs Louisiana and other states will continue to pay in lost lives, continued pain and suffering, and liver transplantation [26]. In terms of lost lives, the National Academy of Sciences estimates that the nationwide cost of not eliminating hepatitis C will exceed \$666 billion before 2030 [27].

But the costs to treat a patient with a generic drug licensed at a reasonable royalty rate rather than at current brand name prices would enable payers to significantly expand access to treatment. The estimated cost of manufacturing the latest combination regimens runs at \$96 to \$216 for twelve weeks. [28]. Currently, rather than about \$333 per pill, Indian manufactures—under a sublicense from Gilead Sciences— sell generics for a profit of \$14 per pill [29]. This translates to \$1152 for a full twelve-week course of treatment [30]. Generic treatment—including a reasonable royalty based off historical precedent at 10 percent—would save an estimated \$737.4 million in treatment costs for uninsured and Medicaid patients in Louisiana. But even a royalty of 100 percent would lower the cost of treating *every* uninsured or Medicaid-covered Louisiana resident from \$764 million to \$48.4 million [31].

These high medical costs for brand-name HCV treatments also do not include the costs of litigation. Some states, including the state Medicaid program in Washington and the prison system in Kentucky, have incurred legal costs while defending against successful lawsuits against restricted access to treatment. Ultimately, they have been required to expand treatment [32]. The Louisiana Medicaid program and Medicaid managed care programs are legally obligated to not unreasonably restrict coverage of hepatitis C drugs [33]. The Louisiana prison system is also constitutionally obligated to treat the estimated 12-35 percent of individuals with hepatitis C in the prison system [34]. Reducing treatment costs through generic competition could help Louisiana avoid such legal challenges.

Finally, at the current of rate of 324 Louisiana residents receiving treatment annually, little progress will be made towards eradicating the disease [35]; every year 250-500 people are newly infected in Louisiana [36]. It's also possible that the rate of new infections will go up with the national rate of new hepatitis C infections tripling between 2010 and 2015 [37].

High prices charged by prescription drug corporations present a public health challenge to all states. But 42 U.S.C. § 1498 presents a serious policy opportunity to increase generic competition, reduce unfair drug prices, and to expand treatment. We encourage Louisiana to explore the use of this valuable policy tool to expand access to medicines to all of its residents.

Signed:

Public Citizen Health Global Access Project Social Security Works Treatment Action Group

[1] Written Testimony of Robert Weissman, President Public Citizen before the Committee n Veterans' Affairs U.S. Senate on "Hepatitis C in Veterans" Public Citizen Dec. 3 2014 <u>https://www.citizen.org/sites/default/files/weissman-veterans-affairs-hepatitis-c-</u> <u>testimony.pdf</u>

[2] Isabelle Andrieux-Meyer, et. al., Disparity in market prices for hepatitis C virus direct-acting drugs. The Lancet Global Health. 3(11) Nov 2015 DOI: <u>http://dx.doi.org/10.1016/S2214-109X(15)00156-4</u>

[3] Andrew Hill, et. al., Rapid reductions in prices for generic sofosbuvir and daclatasvir to treat hepatitis C. J. Virus Erad. 2(1) Jan 2016 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4946692/

[4] National Viral Hepatitis Roundtable and Center for Health Law & Policy Innovation. Hepatitis C: The State of Medicaid Access, Preliminary Findings. Harvard Law School. Nov 14 2016 http://www.chlpi.org/wp-content/uploads/2013/12/HCV-Report-Card-National-Summary_FINAL.pdf

[5] *Id.*

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I am writing to express support for the proposal to reduce hepatitis C treatment prices in the state of Louisiana. Gilead Sciences and others have priced curative hepatitis C treatments out of reach of many of my fellow Louisianians, and the price is making it impossible for the state to continue to treat people suffering from heptatitis C. I support efforts to license the monopoly rights to hepatitis C treatments and save millions of our tax dollars while also providing care to those who need it. SINGLE PAYER INSURANCE...DO IT NOW!!!!

MR tom rippolon

I am writing to express support for the proposal to reduce hepatitis C treatment prices in the state of Louisiana. Gilead Sciences and others have priced curative hepatitis C treatments out of reach of many of my fellow Louisianians, and the price is making it impossible for the state to continue to treat people suffering from heptatitis C. I support efforts to license the monopoly rights to hepatitis C treatments and save millions of our tax dollars while also providing care to those who need it.

Mr. D P

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Mr. George Bond

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We understand that developing this treatment was costly, but expect businesses to pay themselves back over an extended period of time, not all at once.

Avis Ogilvy

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Lynn O'Shea

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Mr. Adam Kay

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David Finkelstein

Treatable health problems are not going to go away. Health care is not meant to be a prize given to those who are wealthy enough to afford the treatments they need. Those of us who rely on medical care in order to live our lives cannot be dismissed because their medical treatment is too expensive. There are good reasons to lower the price of treatments to a modest amount. Saving lives is a high priority.

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Ms. Carol Burk

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Mr. Stephen Villano

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Ms. Sandy Rhein

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Angelita Espino

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Elizabeth Widerquist

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Louisiana is last for children health care in America. We are even on of the poorest states of America. To take away what health care we in Louisiana have will be another death sentence for many. Louisiana needs to expand in what we have for Healthcare. I know that Givernor Bel Edwards is fighting for Louisiana health. It is the Republicans that are in Louisian's

Cacuss that hinders the governors effort to help the people of Louisiana. Just as the Republicans in Louisiana government that hinders the balance budget approach that governor Edwards has proposed.

The Republicans need to remember that it is the tax paying people of Louisiana that pays the salaries of our government. Steve

Scalise should know this. With his participation in Washington D.C.

With the gang of EIGHT to undermine the people of America. Playing theat guessing game of who Russia's Putin pays for their cooperation in to American affairs. This is high treason Steve Scalise. Louisiana

Is watching.

Ms. SharonAnn Irving

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marc isaac

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Keith Horn

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Mr. gw derieg

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The government's power to negotiate drug prices is strong in single payer systems which is why we need one in the US. Health, education, and welfare should not be for big profits.

Penelope Lawrence Gilles

I am writing to express support for the proposal to reduce hepatitis C treatment prices in the state of Louisiana. Gilead Sciences and others have priced curative hepatitis C treatments out of reach of many of my fellow Louisianians, and the price is making it impossible for the state to continue to treat people suffering from heptatitis C. I support efforts to license the monopoly rights to hepatitis C treatments and save millions of our tax dollars while also providing care to those who need it.

Mr. Jordan Burton

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Ms. Jeanne Stulb

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Ms. Brieaux Poche

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Lang Baker

Dear LA Health Dept.:

I am writing to express support for the proposal to reduce Hepatitis C treatment prices in the state of Louisiana. Gilead Sciences and others have priced curative Hepatitis C treatments out of reach of many of my fellow Louisianians, and the price is making it impossible for the state to continue to treat people suffering from Hepatitis C. I support efforts to license the monopoly rights to Hepatitis C treatments and save millions of our tax dollars while also providing care to those who need it.

Thank you,

Kristen Langley

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Robert Glaze

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Mr. Paul Barry

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Ms. Kim Turner

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Janet Dales

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Ms. Karen Ardoin

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Dr. Howard Mielke

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Making so much money off of sick people is despicable and greedy beyond comprehension.

With so many people living in Louisiana with so many quality of life issues, why would you permit the increase in the misery index of the desperate?

Nancy Sanders

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Dr. Polly Stone

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Yuana Blanke

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Mr. GERARD F. GAUDIN

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Mr. Wayne Gossett

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Scott Jennings

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Mr. Robert Starnes

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Pam Freshney
I am writing to express support for the proposal to reduce hepatitis C treatment prices in the state of Louisiana. Gilead Sciences and others have priced curative hepatitis C treatments out of reach of many of my fellow Louisianians, and the price is making it impossible for the state to continue to treat people suffering from heptatitis C. I support efforts to license the monopoly rights to hepatitis C treatments and save millions of our tax dollars while also providing care to those who need it.

Mrs. Christie Ruppel

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Mr. Robert Frank

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Roslynn Seibold

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Mr. benjamin miles

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MRS Eileen HAKENJOS Sacks

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Jason Mayeaux

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Ms. Tymekia Scott

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Jacqueline Campbell

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Ms. Evelyn Wilson

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I. Klaver

http://www.theadvocate.com/baton_rouge/opinion/letters/article_788b9890-4b99-11e7-af63-d71d428ad4f2.html

Letters: Law could help La. fight hepatitis

Jeanie Donovan JUN 7, 2017 - 6:00 PM

More than 73,000 Louisianans carry the hepatitis C virus, a highly contagious blood-borne infection that can cause acute illness along with long-term, chronic damage to the liver that can include cirrhosis, cancer and death.

While hepatitis C has been around for a long time, it's become a more serious problem in recent years with the rise in opioid addiction. An estimated 500 new cases are diagnosed each year in the Pelican State. And because nearly half of those living with the disease are either on Medicaid or uninsured, this comes at a potential high cost to the state.

The good news is most cases of hepatitis C are curable, given recent treatment advancements. The bad news is those new treatments cost \$85,000 per patient because the drugs are still under patent, which prohibits competition from generic drug manufacturers The exorbitant cost, coupled with the state's dire budget situation, means it's simply not possible to treat everyone who needs it. As a result, Louisiana has been forced to ration care, treating only those who have the most advanced symptoms and leaving the rest to suffer while potentially spreading the disease it to others.

Story Continued Below

Louisiana's Secretary of Health, Dr. Rebekah Gee, has proposed to lower the cost of these treatment by invoking a little-known federal patent law that lets the federal government authorize the production of generic versions of patented inventions if it determines that it's in the public interest. The law has been used several times, including by the Department of Defense in the 1960s to secure antibiotics at a quarter of the price charged by the drug's patent-holder, Pfizer.

A team of medical experts, including Dr. Joshua Sharfstein at Johns Hopkins University's Bloomberg School of Public Health, has determined that the hepatitis C situation in Louisiana meets the three key criteria required for this unconventional approach. First, the state is facing a major public health challenge. Second, the challenge could be addressed by providing the patented treatment and there are no viable alternative treatments. And finally, the high price of the patented treatment effectively blocks the state from providing treatment for all those who need it.

At a time when politics in our country, especially on health care, are badly divided, this represents an opportunity for the state to work hand-inhand with the federal government to address a public health epidemic and help people who otherwise would needlessly suffer. It could ease pressure on the state budget, and set a blueprint that other states could then follow. As such, we all should applaud Gee's ingenuity and urge her to move forward with requesting the necessary action by the U.S. Secretary of Health.

Jeanie Donovan

senior policy analyst, Louisiana Budget Project

Baton Rouge



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