UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

DORENA COLEMAN, CURTIS JACKSON, FEDERICO PEREZ and WILLIAM WILLIAMS, on behalf of themselves and all others similarly situated, Plaintiffs, v. PHIL WILSON, Acting Executive Commissioner, VICTORIA FORD, Chief Policy and Regulatory Officer, and MICHELLE ALLETTO, Chief Program and Services Officer, in their official capacities with the Texas Health and Human Services Commission (HHSC), Defendant.	)	No.

DECLARATION OF DR. BENJAMIN P. LINAS

1. ***Background Expertise.*** I am a medical doctor and scientist dedicated to improving the health of individuals living with human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infections. I am board certified in Infectious Diseases. I have over sixteen years of experience as a medical researcher and clinician in the treatment of infectious disease and have authored over 85 peer-reviewed publications. My research generally focuses on the comparative- and cost-effectiveness of interventions to identify and treat HIV and HCV, employing methods of computational biology, clinical epidemiology, and clinical economics. I am an Associate Professor of Medicine at Boston University School of Medicine and an Associate Professor at Boston University School of Public Health. I am the director of the Population Data and Modeling core of the Center for Health Economics of Treatment Intervention for Substance Use Disorders, HCV, and HIV, funded by the National Institute on Drug Abuse (NIDA); and a

current member of the American Association for the Study of Liver Diseases (AASLD)-Infectious Diseases Society of America (IDSA) Hepatitis C Virus Guidance Panel, the leading U.S. HCV guidance body. I work closely with the U.S. Centers for Disease Control and Prevention (CDC) Division of Viral Hepatitis, and consult with the World Health Organization (WHO) Viral Hepatitis Program. I also am an HIV and HCV care provider in Boston Medical Center's Department of Infectious Diseases, where I provide primary care and sub-specialty management to patients with HIV, HCV, AND HIV/HCV co-infection. A copy of my curriculum vitae is attached as Exhibit 1 to this declaration.

2. ***Importance of Cost-Effectiveness Analysis.*** Cost-effectiveness research focuses on determining the value of healthcare technologies. It is not medically appropriate to make treatment decisions solely based on cost. Cost-effectiveness analysis helps healthcare providers and payers better value a treatment by considering both its costs and benefits. The ultimate goal of cost-effectiveness research is to maximize individual well-being and public health given the resources available for healthcare spending.

As its name suggests, cost-effectiveness analysis compares two metrics of value: cost and effectiveness. Effectiveness can be measured in terms of increased life expectancy or the number of quality-adjusted-life-years (QALYs) that are gained. The QALY unit of measurement accounts for the fact that it is not only duration of life, but also quality of life, that is important to treatment decisions. Measures of cost and effectiveness are used to calculate the incremental cost-effectiveness ratio (ICER) of cost per QALY gained. By comparing the ICER of a new medication or intervention, such as HCV treatments, to that of other interventions employed routinely in the U.S. healthcare system, it is possible to establish the relative value of the new intervention. Interventions with ICERs similar to or lower than that of other commonly

employed interventions provide good value and should be implemented, while those with ICERs that are much higher than other interventions likely are not cost-effective and resources would be better employed elsewhere. There is no formal ICER threshold that defines what is "cost-effective," but data suggest that in the United States, value should be approximately $100,000 per QALY gained. Thus, in the United States, if a treatment has an ICER of less than $100,000 per QALY gained, that treatment is considered to be "cost-effective."

3. In general, DAA Treatment Is Cost-Effective. There is a consensus among scientists and physicians that the treatment of hepatitis C with direct-acting antiviral drugs (DAAs) is cost-effective. DAAs are curative therapy. They transform what was once a chronic infectious disease into a curable condition with a treatment course of only 8-12 weeks of once-per-day medicine. Curative treatment remains quite rare in modern medicine. We cannot cure HIV, we cannot cure rheumatic diseases like rheumatory arthritis, we cannot cure diabetes or heart disease, and yet we can now cure HCV easily. When DAAs were approved, they fundamentally changed the nature of my medical practice.

DAA treatment is cost-effective. Untreated chronic hepatitis C is a morbid and expensive disease. At all stages of HCV's progression—even at the earliest stages—a person infected with HCV generates higher healthcare costs and experiences a lower quality of life than a person who is not infected. Risk of HCV-attributable mortality increases as a patient reaches cirrhosis and as the likelihood of advanced liver disease increases. However, when a patient is treated with DAAs and achieves sustained virologic response (SVR), the patient's signs and symptoms of liver disease regress and liver-related mortality risks are decreased by 94%. Since 2012, many independent groups have investigated the cost-effectiveness of DAA treatment, and have determined that treatment with DAAs has an ICER of less than $100,000 per QALY gained with

few exceptions. One of my early papers demonstrated that with first generation DAA regimens, which were only marginally effective against HCV genotype 3 virus and which had very high cost, DAA treatment was not cost-effective for patients with early stage HCV genotype 3 infection.[1] Since that time, however, the regimens have improved and are now truly "pan-genotypic"—meaning that they are 95-98% effective for all HCV genotypes—and also they have become far more affordable. At this time, HCV treatment is cost-effective, for all genotypes, all fibrosis stages, and in all settings—Even when patients are at-risk for a relapse to substance use and HCV reinfection.

DAA treatments cost far less than other treatments employed routinely, such as HIV anti-retroviral therapy and monoclonal antibodies to treat cancer and autoimmune conditions. DAAs have grown still more cost-effective as the newest DAAs have been developed and competition in the HCV-treatment market has driven prices down. Further, unlike other new therapies for certain other chronic illnesses, such as inflammatory conditions or cancer treatment, DAAs have demonstrated real-world effectiveness, their use is limited to short treatment courses, they are likely to prevent future spending on treatment of sicker patients, and their prices can be decreased by negotiation because of available competitor products.[2]

4. It Is Not Cost-Effective to Restrict DAA Treatment. In recent years, the wholesale cost of DAA treatment has significantly decreased, which has drastically changed the cost-effectiveness calculus.[3] Costs are even lower for the Texas Medicaid program, which is entitled

[1] *See* Linas BP, Nolen S., *A Guide to the Economics of Hepatitis C Virus Cure in 2017*, 32 Infect. Dis. Clin. North Am. 447 (June 2018).
[2] Lu, Christine Y. et al, *State Medicaid Reimbursement for Medications for Chronic Hepatitis C Infection from 2012 through 2015*, 21 Value in Health 692 (2017).
[3] Available reported costs of certain DAA medications are, for example, $13,200 per month for an 8-week course of Glecaprevir/pibrentasvir (Mavyret) and $22,920 per month for a 12-week course of sofosbuvir/velpatasvir (Epclusa).

to a rebate of at least 23.1% of the average manufacturer price of DAAs.[4] This pricing trend underscores the point that it makes no economic sense to prioritize some patients and withhold treatment from others. Studies that have compared "treatment-for-all" HCV regimes with regimes that restrict treatment in various ways routinely have determined that "treatment-for-all" is a cost-effective approach. Further, treating all patients provides better population-level outcomes than restricting therapy, and it provides those better outcomes at a lower cost per QALY gained. In other words, with any available budget, treating all patients provides better public health than restricting treatment to those with advanced disease. Thus, in economic terms, treating all patients for HCV is cost-saving compared to restricting therapy.[5] That is because HCV infection lowers quality of life and significantly increases healthcare utilization and cost for all persons infected—even those with early-stage HCV, without advanced fibrosis, who may be unaware that they are infected. Treating all patients regardless of fibrosis stage is cost-effective because it prevents accumulation of morbidity and cost while patients wait for cure and increases QALYs with an ICER of less than $100,000 per QALY gained.

5. It is Cost-Effective and Likely Even Cost Saving for Texas Medicaid to Cover All Stages of HCV Infection Rather Than Use its Available Budget to Provide Restricted Access.

HCV Infection is prevalent in Texas, where over 580,000 Texans live with chronic HCV.[6] Patients with advanced liver fibrosis have higher healthcare costs than those with early stage disease. Those costs are not entirely mitigated by HCV cure administered at a later stage of liver fibrosis progression. Once a person becomes cirrhotic, (s)he accrues higher cost over a lifetime

[4] Lu, Christine Y. et al., *supra* n. 2.
[5] Linas BP et al., *Cost Effectiveness and Cost Containment in the Era of Interferon-Free Therapies to Treat Hepatitis C Virus Genotype 1*, 27 Open Forum Infect Dis. 4 (Dec. 2016).
[6] Estimate taken from Texas DSHS presentation, https://www.dshs.state.tx.us/IDCU/health/zoonosis/ELC-Workshop/2019/Presentations/Hepatitis-C-Surveillance-in-Texas.pdf, which itself based its figures on NHANES prevalence rates, *see* https://aasldpubs.onlinelibrary.wiley.com/doi/full/10.1002/hep.30297.

than a person who was never cirrhotic, even if their HCV is cured. Further, a high prevalence of HCV leads to increased cases of end-stage liver disease (ESLD). ESLD is a very expensive and irreversible condition. Once ELSD develops, liver transplantation often becomes the only means of survival. Liver transplantation is expensive, primarily because living with a liver transplant requires life-long therapy with very expensive immune-suppressive agents.

Unrestricted access to HCV treatment regardless of fibrosis score is the optimal strategy for cost-effectiveness from an economic perspective.[7] Indeed, treating all stages of HCV with DAA treatments is not only cost-effective but cost-***saving*** compared to the option of restricting access. That is, they are both more medically effective and *less costly* than the previously recommended course of treatment.[8] A Medicaid policy that treated all patients rather than treating only those with advanced liver disease would lead to savings of upwards of $3.5 billion to the national health care system.[9]

All individuals with HCV—regardless of fibrosis score—accumulate morbidity and costs until they receive DAA treatment, with a resulting lower quality of life. HCV is known as a "silent" disease, which implies that there are no symptoms until a person develops ESLD. While it is true that many people do not know of the infection, that does not mean that they do not have symptoms, which can include fatigue, depression, and chronic pain, among other things. It only means that they do not realize how they could be feeling if they did not have HCV. When researchers employ state of the art methods to evaluate quality of life in patients with even early stage HCV, they find that quality of life is HCV-infected individuals is lower than that in similar

[7] Chhatwal et al., *Direct-Acting Antiviral Agents for Patients With Hepatitis C Virus Genotype 1 Infection Are Cost-Saving,* 15 Clin. Gastroenterol. Hepatol. 827 (2017) (analyzing 24 cost-effectiveness studies, 10 within the U.S., and determining that nearly all were evidence that oral DAAs can result in substantial economic savings).
[8] *Id.*
[9] Younossi et al., *Treating Medicaid Patients With Hepatitis C: Clinical and Economic Impact*, 23 Am. J. Manag. Care 107 (2017); Chidi et al., *Economic and Public Health Impacts of Policies Restricting Access to Hepatitis C Treatment for Medicaid Patients,* 19 Value Health 326 (2016).

individuals who do not have HCV. Similarly, econometric analyses indicate that even early stage HCV is associated with higher healthcare utilization and is not entirely "silent." Until patients attain HCV cure, they accrue this morbidity and cost and their fibrosis progression continues. It is better to spend money now to prevent the accumulation of harm and health-care costs in the long run.[10]

6. Not Treating All Enrollees in Texas Medicaid with Chronic Hepatitis C Denies Those Individuals the Prevailing Standard of Care. The AASLD-IDSA Guidance panel, of which I am a member, has developed guidelines ("the Guidelines") for the treatment of patients infected with HCV in accordance with the current prevailing medical standard of care, which is a consensus national standard of care. These guidelines are publicly available on the panel's website: https://www.hcvguidelines.org. The CDC, with which I also work closely, directs health care professionals to follow the Guidelines, which recommend DAA treatment for ***every person*** with a chronic HCV infection, regardless of fibrosis score, except those with limited life expectancy that cannot be remediated by DAA treatment or liver transplantation.

Texas's Medicaid Program does not comply with the Guidelines or, accordingly, the prevailing standard of care. The Guidelines require DAA treatment for all patients infected with HCV regardless of fibrosis score, but Texas restricts treatment only to patients with advanced stages of liver fibrosis. The AASLD-IDSA recommends against waiting for people to develop advanced liver disease before providing curative treatment that would have prevented further liver damage in the first place. Texas receives a grade of "D+" from the National Viral Hepatitis Roundtable because it deliberately disregards the prevailing standard of care.[11]

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[10] Linas and Nolen, *A Guide to the Economics of Hepatitis C Virus Cure in 2017*, 32 Infectious Disease Clinics of North America 2 (2018).

[11] National Viral Hepatitis Roundtable, Hepatitis C: State of Medicaid Access Report Card (2017) *available at* https://stateofhepc.org/wp-content/themes/infinite-child/reports/HCV_Report_Texas.pdf.

7. There Are Less Restrictive Means of Controlling Costs for Texas Medicaid. In circumstances where a payer is concerned about the up-front costs that it is responsible for, limiting access to HCV treatment until patients experience severe liver scarring is the bluntest, most restrictive, and least thoughtful means of controlling cost. More reasonable alternatives to controlling cost exist, especially as less expensive competitor DAAs continue to lower the cost of HCV treatment.

Faced with a need to control costs, payers should negotiate lower prices, not restrict curative DAA treatment.[12] It is always easier to push costs out to the future, but payers have better options to invest in health care now and reduce overall costs over time. In modeling studies, cost control efforts that use treatment restrictions to control cost always provide worse outcomes than those strategies that instead work to lower drug costs and negotiate price. The time over which costs are spread can be as short as four years before "treatment for all" investments break even, and Medicaid plans can expect to see clear economic benefits within a ten-year window.[13] Removing all access restrictions would result in the greatest reduction in total expenditures when compared to the current policy or a mere shifting in the earliness of treatment.[14]

One example of an innovative financing model is the "Netflix model," which provides payers with an unlimited supply of DAAs in exchange for a set monthly fee. Last year, the state of Louisiana—where HCV infection is highly prevalent but under-treated—became the first state to adopt this alternative payment arrangement with a goal of treating 10,000 people by 2020, and

[12] Linas BP et al., *Cost Effectiveness and Cost Containment in the Era of Interferon-Free Therapies to Treat Hepatitis C Virus Genotype 1*, Open Forum Infect Dis. (Dec. 2016).
[13] Chou et al., *Short-term budget affordability of hepatitis C treatments for state Medicaid programs*, 19 BMC Health Services Research 140 (2019).
[14] *Id.*

31,000 people in the next five years. Under the five-year contract the state signed with Gilead subsidiary Asegua Therapeutics, gross expenditures are capped at a fixed amount but the state retains unlimited access to DAAs for both Medicaid managed-care beneficiaries and those covered under fee-for-service. Similarly, Washington state has announced its intention to eliminate HCV by 2030, and it has secured a five-year unlimited license with AbbVie. Washington invited pharmaceutical companies to bid on a price, and the winning contract with AbbVie provides that the state will pay full price for DAAs up to a certain cap, after which the drugs will be provided at a drastic discount. If price is the primary barrier to providing treatment up to the standard of care, Texas should be seriously exploring these options.

8. Not Treating Medicaid Recipients With HCV Effectively Shifts the Cost to Other Programs and Ultimately Costs Taxpayers More. In many cases, delaying HCV treatment until release will result in the progression of liver fibrosis and even development of cirrhosis. Costs accrue over time as more expensive treatments may be required to treat complications from more progressed infection, both affecting the liver and elsewhere in the body. Disproportionate share hospitals, emergency rooms and other safety-net providers are the most likely bearers of the increased costs of untreated chronic HCV.

9. Not Treating HCV Increases Risk in the Texas Community and Is Contrary to Texas's State Health Plan. Treating HCV at all stages of liver disease progression plays an important role in reducing the incidence of HCV in Texas generally. When individuals are no longer HCV-infected, they cannot transmit the disease to others. The Texas Department of State Health Services recognizes that addressing the incidence of HCV among Texans requires "a coordinated approach to expand prevention, testing and treatment."[15] Texas's State Plan expressly admits

[15] Texas Department of State Health Services, *2018 State Plan for Hepatitis C* (Nov 2018), https://www.dshs.state.tx.us/legislative/2018-Reports/2018-State-Plan-for-Hepatitis-C.pdf.

that lack of treatment contributes to prevalent transmission and that "effective treatment of hepatitis C requires timely diagnosis."[16]

10. I regularly keep myself apprised of current medical and health economics literature on the topics discussed in this declaration. By way of example, I have reviewed the following materials in the preparation of this declaration:

(1) Buti M et al., *Cost-effectiveness analysis of ledipasvir/sofosbuvir in patients with chronic hepatitis C: treatment of patients with absence or mild fibrosis compared to patients with advanced fibrosis*, 24 J. Viral Hepatitis 750 (2017);

(2) Castro, R. et al., *Cost-effectiveness of diagnostic and therapeutic interventions for chronic hepatitis C: a systematic review of model-based analyses*, 18 BMC Med. Res. Methodol. 53 (2018);

(3) Chahal HS et al., *Cost-effectiveness of Early Treatment of Hepatitis C Virus Genotype 1 by Stage of Liver Fibrosis in a US Treatment-Naive Population*, 176 J. Amer. Med. Assoc. Intern. Med. 65 (2016);

(4) Chong, et al., *Health-state Utilities and Quality of Life in Hepatitis C Patients*, 98 Am. J. Gastroenterol. 630 (2003);

(5) Curry MP et al., *Effectiveness of 8- or 12-weeks of ledipasvir and sofosbuvir in real-world treatment-naïve, genotype 1 hepatitis C infected patients*, 46 Aliment. Pharmacol. Ther. 540 (2017);

(6) Davis KL et al., *Direct economic burden of chronic hepatitis C virus in a United States managed care population*. 45 J. Clin. Gastroenterol. 17 (2011);

(7) Gordon, S., Lee, J., Smith, N., & Dieterich, D., *Cost-effectiveness of pan-genotypic direct-acting antiviral regimens for treatment of chronic Hepatitis C in the United States*, 16 Expert Rev. of Pharmacoeconomics & Outcomes Research 1 (2019);

(8) He T et al., *Systematic review: cost-effectiveness of direct-acting antivirals for treatment of hepatitis C genotypes 2-6*, 46 Aliment. Pharmacol. Ther. 711 (2017);

(9) Lynch, S. M., & Wu, G. Y., *Hepatitis C virus: a review of treatment guidelines, cost-effectiveness, and access to therapy*. 4 J. Clin. & Translational Hepatology, 310 (2016);

[16] *Id.*

(10) van der Meer AJ et al., *Association between sustained virological response and all-cause mortality among patients with chronic hepatitis C and advanced hepatic fibrosis*, 308 J. Amer. Med. Assoc. 2584 (2012).

Dated: July 24, 2020 at Boston, Massachusetts.

Benjamin P. Linas, M.D., M.P.H.