3. COVENTRY is a wholly-owned subsidiary of Florida Health Plans Administrator, LLC, which is, in turn, a wholly-owned subsidiary of Coventry Healthcare, Inc. Coventry Healthcare, Inc. is wholly-owned by AETNA, making AETNA the ultimate parent company of COVENTRY.

4. Pursuant to Florida Statute Section 624.26, the OFFICE has jurisdiction to examine health maintenance organizations for compliance with the federal Patient Protection and Affordable Care Act when examining companies for compliance with state law.

5. On May 29, 2014, an administrative complaint was filed by The AIDS Institute and The National Health Law Program. The complaint was filed with the federal Office of Civil Rights, U.S. Department of Health and Human Services ("HHS") and a copy was provided to the OFFICE by HHS and by advocates for people living with HIV/AIDS.

6. The complaint alleged that COVENTRY's two Qualified Health Plans (QHPs) placed all HIV drugs on a specialty drug tier, including generic versions of widely prescribed anti-retrovirals. The complaint further stated that coinsurance for this tier was forty percent (40%), making the access to these medications financially prohibitive for many of COVENTRY's enrollees or potential enrollees. The complaint concluded that this benefit design discriminated against people living with HIV and AIDS, and deterred people who are living with HIV or AIDS from enrolling in the health plans, in violation of federal law.[1]

[1] *See* 45 USC §18116; 45 CFR §156.125, 45 CFR §156.225(b).

7. Subsequently, the OFFICE confirmed that COVENTRY's QHP plans included all HIV drugs on the specialty tier of its formulary for plan year 2014. AETNA, on behalf of COVENTRY, asserts that because of required testing and treatment, the drugs are categorized as specialty medications, and that the categorization is not based on any intent to discriminate.

8. Pursuant to section 641.3007, Florida Statutes, an HMO subscriber contract may not limit coverage for exposure to the HIV infection or a specific sickness or medical condition derived from such infection. AETNA contends that COVENTRY has fully complied with the provisions of section 641.3007, Florida Statutes.

9. The OFFICE makes no finding with respect to whether or not COVENTRY's 2014 QHPs violate the Florida Insurance Code, Federal statutes, or the Code of Federal Regulations. AETNA on behalf of COVENTRY denies any allegation that its classification of drugs unfairly discriminates or that its plan violates the Florida Insurance Code, Federal statutes, or the Code of Federal Regulations, and further denies all of the allegations in the administrative complaint filed with the Office of Civil Rights. However, to avoid litigation, and maintain its commitment to all customers and facilitate access to medication in compliance with Florida law, COVENTRY will use a formulary in 2015, which will include the features described below, so that generic and lower-cost drugs are available at the specified cost sharing levels for subscribers. All generic drugs referred to in the complaint which are currently included in the Specialty Tier will be transferred to

the Non-Preferred Generic Tier. Generic HIV drugs, regardless of the medical condition being treated, will be categorized in the appropriate "Generic" tier.

10. Within 30 days of the date of this Order, AETNA shall request a meeting with representatives of The AIDS Institute, The AIDS Healthcare Foundation, and The National Health Law Program to address access to and the affordability of HIV/AIDS medications for all formulary drugs, as well as a discussion of prescription drug assistance programs.

11. COVENTRY will not require prior authorization for refills of HIV/AIDS drugs referred to in the complaint. Drug quantities shall be made available to subscribers as prescribed by the treating physician and shall never be limited to less than a thirty (30) day supply. Additionally, step therapy shall not be required for the administration of any of these drugs.

12. AETNA shall ensure that COVENTRY complies with all federal and Florida laws and HHS prescription drug guidelines applicable to QHPS in formulary designs, and will update its formulary in accordance with changes to the HHS prescription drug guidelines applicable to QHPs.

13. AETNA shall work with the OFFICE in good faith to address the issue of subscriber prescription medication access in a more comprehensive manner for plan years beginning

January 1, 2016. Beginning on the effective date of this Order through calendar year 2016, COVENTRY will notify the OFFICE in advance of any changes in its formulary for drugs used in the treatment of HIV/AIDS.

14. As an interim measure, during plan year 2015, COVENTRY will cap each subscriber's cost-sharing responsibility for each of the following widely prescribed drugs to $200 per month per drug: Atripla, Complera, Stribild, and Fuzeon. AETNA and COVENTRY makes no representations of the placement of these drugs in the formulary in plan years after 2015, beyond the agreement in paragraph 13 to work in good faith to address drug costs for HIV/AIDS patients.

15. AETNA and COVENTRY hereby knowingly and voluntarily waive all rights to challenge or to contest this Consent Order, the making of Findings of Fact and Conclusions of Law by the OFFICE and all further and other proceedings herein to which they may be entitled by law or rules of the OFFICE, including the right to any administrative proceeding, circuit or federal court action, or any appeal.

16. The parties agree that this Consent Order will be deemed to be executed when the OFFICE has executed a copy of this Consent Order bearing the signature of AETNA and/or its authorized representative, notwithstanding the fact that the copy was transmitted to the OFFICE electronically or via facsimile machine. Further, AETNA agrees that its signature as affixed to this Consent Order shall be under the seal of a Notary Public.

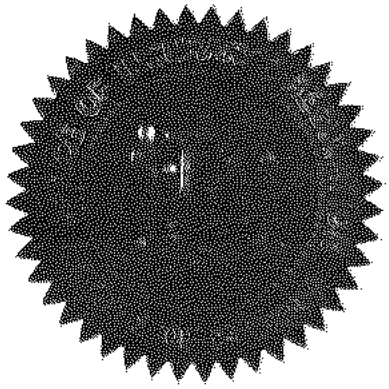
17. The requirements of this Order apply to individual products offered both on and off the federal exchange, and will be implemented in time for open enrollment on the exchange beginning November, 2014 and for all subscriber contracts effective January 1, 2015.

18. Except as noted above, each party to this action shall bear its own costs and attorney's fees.

WHEREFORE, the agreement between AETNA, COVENTRY and the OFFICE, subject to the terms and conditions set forth above, is APPROVED.

FURTHER, all terms and conditions contained herein are hereby ORDERED.

DONE AND ORDERED this 19th day of November, 2014.



Kevin M. McCarty, Commissioner
Office of Insurance Regulation

By execution hereof, COVENTRY HEALTH CARE OF FLORIDA, INC., and AETNA INC. consent to entry of this Consent Order, agrees without reservation to all of the above terms and conditions, and shall be bound by all provisions herein. The undersigned represents he/she has the authority to bind COVENTRY HEALTH CARE OF FLORIDA, INC. and AETNA INC. to the terms and conditions of this Consent Order.

AETNA, INC

By: Christopher A. Ciano

Corporate Seal

Print Name: Christopher Ciano

Title: President

Date: 11/14/14

STATE OF Florida
COUNTY OF Broward

The foregoing instrument was acknowledged before me this 14 day of Nov. 2014,

by Christopher A. Ciano as President
(name of person) (type of authority ..... e.g. officer, trustee attorney in fact)

for Coventry Health Care of Florida + Aetna
(company name)

CORAL N. SUTHERLAND
Notary Public - State of Florida
My Comm. Expires Mar 17, 2015
Commission # EE 45042
Bonded Through National Notary Assn.

Coral N. Sutherland
(Signature of the Notary)

CORAL N. SUTHERLAND
(Print, Type or Stamp Commissioned Name of Notary)

Personally Known ✓ OR Produced Identification _____

Type of Identification Produced _____

COPIES FURNISHED TO:

Shannon Doheny
Assistant General Counsel
Office of Insurance Regulation
200 East Gaines Street
Tallahassee, Florida 32399-4206
Phone: 850-413-4281
Email: shannon.doheny@floir.com

Obamacare: California exchange caps specialty drug costs for patients

By CHAD TERHUNE

MAY 22, 2015, 8:00 AM

Tackling the high price of specialty drugs, California's Obamacare exchange capped what consumers will have to pay for expensive medications each month.

The new limits, set to go into effect in January, mark a first for state exchanges nationwide, according to Covered California. The exchange's four-member board approved the changes unanimously Thursday.

Most consumers will have their specialty drug costs capped at $250 per month, per prescription. But the exchange resisted pleas from patient advocates to extend that same limit to Bronze health plans, the cheapest coverage available on the state-run marketplace.

The monthly cap on Bronze plans will be $500 a month -- after a $500 pharmacy deductible is met.

Consumer groups generally applauded the state's move, but they said it didn't go far enough at protecting consumers from big medical bills.

“As it stands now the Bronze plan will not meet the needs of Californians with chronic conditions," said Liz Helms, chief executive of the California Chronic Care Coalition.

The exchange had lowered its proposed caps after hearing numerous complaints at last month's board meeting. California Insurance Commissioner Dave Jones had been one of the most vocal critics, and he had called for a $300 monthly limit on Bronze plans.

The exchange's decision "makes prescription drug coverage unaffordable to Californians who buy Bronze plans, one of the most popular health insurance levels of coverage," Jones said Thursday.

Under the current rules, some patients can face enormous out-of-pocket costs in the first few months of taking a specialty drug. They can be forced to spend up to

the annual limit of $6,250 for an individual policyholder right away.

Peter Lee, executive director of Covered California, said the exchange was being mindful of not making changes in benefits that drive up premiums too much. Officials estimated that the new spending caps would increase rates by less than 1%.

“These new policies strike a balance between ensuring Covered California consumers can afford the medication they need to treat chronic and life-threatening conditions while keeping premiums affordable for all," Lee said.

"This is the first time that an exchange has ensured that all of its consumers have access to the medications they need," he added.

The huge price tags for some specialty drugs, such as hepatitis C drug Sovaldi, have attracted scrutiny nationwide. These expensive medications often treat chronic conditions such as cancer, multiple sclerosis and rheumatoid arthritis.

A drug industry report issued last week found that 139,000 Americans had medication costs in excess of $100,000 in 2014, nearly triple the number who reached that mark a year earlier.

Covered California board members expressed alarm at the soaring prices and acknowledged that monthly caps won't do much to address the larger problem of reining in medical costs.

"You can fault the drug companies," said exchange board member Marty Morgenstern. "There is no basis for these charges.... They are charging irrational prices."

A representative of the drug industry responded at the board meeting that health insurers do plenty of negotiating over prescription drug prices.

Twitter: @chadterhune

February 23, 2015

Kaiser Permanente reverses decision to move HIV meds to specialty tier in California, reduces out-of-pocket cost for patients

SAN FRANCISCO, February 23, 2015. Project Inform and San Francisco AIDS Foundation applaud Kaiser Permanente's decision last week to revise its 2015 drug categorization which put all HIV medications in the highest specialty tier in the California marketplace. Pricing HIV medications in this tier would have required consumers to pay up to 30% of the price of their prescriptions out of pocket, an increase of several hundred dollars per month in some cases. Kaiser will also reimburse those who paid the higher cost sharing prior to this decision.

Pricing HIV medications in this way would have resulted in decreased access to HIV medications, including the medication used for pre-exposure prophylaxis (PrEP), which could interrupt treatment for those living with HIV and those using PrEP to prevent acquisition of the virus. Consistent access to medication is critical to preserving individual health and to maintaining a non-detectable viral load, which prevents transmission of the virus to others. In the case of PrEP, medications should be taken on a daily basis to ensure protection.

"Historically, Kaiser has been a great partner to the HIV community and has been a leader in California in the prevention and care of HIV," said Neil Giuliano, San Francisco AIDS Foundation CEO. "This move signifies their ongoing commitment to working collaboratively to better the health of this community."

Last week's decision impacts pricing for HIV medications only for patients covered under Kaiser Permanente health plans in California. Medications for other chronic conditions, like hepatitis C, are still priced in the highest specialty tier.

"We are deeply appreciative of Kaiser making this move in California. It is imperative, too, that this example be used by all of Kaiser plans around the country so that Kaiser patients have equal access to HIV medications regardless of where they live," said Dana Van Gorder, executive director at Project Inform. "We also urge Kaiser to look at their tiering practices for other drugs, such as curative treatments for hepatitis C, which are currently in the highest specialty tier in all Covered California plans."

Kaiser Permanente, Project Inform, and other groups have also been engaged in the Covered California specialty drug workgroup, which aims to assure that Covered California's contracted health plan formularies meet consumer needs with regards to their approach, transparency, access and cost sharing.

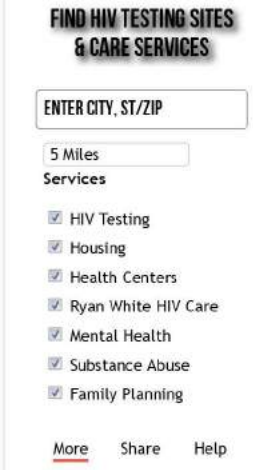
"We are hopeful that the recommendations for effective standards and regulations being developed by this group will be implemented in all marketplace plans in California and that this process will be a model for other states to follow," said Anne Donnelly, director of health care policy at Project Inform. "We want California to set an example for the other states in how to create a more equitable benefits design."

These conversations are the critical first steps to ensuring equal access. Other plans in Covered California and in other marketplaces continue to place all or most of the HIV drugs on the highest cost sharing tiers. Additionally many other classes of drugs are also unaffordable for the average consumer. Finally, the missing players in these conversations, however, are the pharmaceutical companies," said Courtney Mulhern-Pearson, director of state and local affairs at the San Francisco AIDS Foundation. "Efforts to ensure appropriate patient access and reasonable patient cost sharing are not likely to be fully successful without the companies considering their choices on drug pricing and price increases."

###

About Project Inform

Project Inform is a nonprofit education and advocacy organization that believes it is possible to create the first generation free of HIV and hepatitis C within the next decade. To achieve that dream, we focus our work in four areas: drug development, bio-medical prevention, education, and health care access.



Project Inform encourages the development of better treatments and cures for both HIV and hepatitis C. We advocate for innovative, medically based prevention strategies. We provide up-to-date, life-saving information to help people living with HIV and hepatitis C make the best choices regarding their treatment and care. And we press governments to set policies and assure unlimited access to affordable health care that will one day end the HIV and hepatitis C epidemics.

For more information, visit www.projectinform.org.

About San Francisco AIDS Foundation

No city experienced epidemic levels of HIV faster than San Francisco. At San Francisco AIDS Foundation, we work to end the epidemic where it first took hold, and eventually everywhere. Established in 1982, our mission is the radical reduction of new infections in San Francisco. Through education, advocacy, and direct services for prevention and care, we are confronting HIV in communities most vulnerable to the disease. We refuse to accept that HIV transmission is inevitable. More information about the foundation is available at sfaf.org.

Template for Complaint to State Department of Insurance

Prepared by Harvard Center for Health Law and Policy Innovation

Month Date, Year
DOI Address Line 1
DOI Address Line 2

Dear (**Name of DOI Director**):

I am writing to inform you of discriminatory practices by [name the insurer or the insurers] against people living with HIV. In particular, this insurance plan [or plans] [choose as many as may apply]:

1. Does not include all of the approved HIV medications in its formulary.
    a. For example [insert specific example for each plan]
2. Places [most/all] HIV medications on non-preferred and/or specialty tiers and charges extremely high cost-sharing amounts for HIV medications.
    a. For example [insert specific example for each plan]
3. Requires excessive prior authorization or other kinds of medical management for HIV medications.
    a. For example [insert specific example for each plan]
4. Requires use of a mail-order pharmacy for HIV medications.
    a. For example [insert specific example for each plan]

These Actions Constitute Illegal Discrimination Against Individuals Living with HIV

The Patient Protection and Affordable Care Act (ACA) prohibits health insurance issuers with qualified health plans (QHPs) from discriminating against individuals on the basis of disability.[1] All QHPs must provide coverage of Essential Health Benefits (EHB), and a plan does not provide coverage of EHB "if its benefit design, or the implementation of its benefit design, discriminates based on . . . present or predicted disability . . . or other health conditions."[2] Disability includes HIV, even when a person is in the asymptomatic phase of the illness.[3]

The concerns I have listed above have the effect of both discouraging people with HIV from enrolling in the particular plan(s) and from accessing the care they need to stay engaged in care and health. These actions are inconsistent with the current standard of care for HIV as outlined by the Department of Health and Human Services (HHS) and are discriminatory against individuals living with HIV.

The Current Standard of HIV Care

A combination of multiple antiretroviral medications is necessary to suppress the human immunodeficiency virus (HIV), and the most effective combination depends on factors unique to

---

[1] ACA § 1557, codified at 42 U.S.C. § 18116 (2012).
[2] ACA § 1311(c)(1)(A)(i); 45 CFR § 156.125, 45 CFR § 156.200(e), 45 CFR § 156.225, and 45 CFR § 147.104(e); *see also* ACA § 1557(a).
[3] *See, e.g., Bragdon v. Abbot*, 524 U.S. 624, 630–647 (1998) (ADA); *Doe v. County of Centre, Pa.*, 242 F.3d 437, 447 (3d Cir. 2001) (Rehabilitation Act); *Chalk v. United States Dist. Ct.*, 840 F.2d 701, 704–709 (9th Cir. 1988) (Rehabilitation Act).

the individual. Left untreated, HIV can replicate by the billions every day, and as it does so, it mutates rapidly. Indeed, HIV has the highest mutation rate of any virus due to its uniquely error-prone process of transforming RNA into DNA. Because it mutates so rapidly, HIV quickly adapts and becomes immune to drugs when treated with only one type of drug at a time or when treatment is interrupted, even briefly.

A. Medical Guidelines for the Treatment of HIV

The great breakthrough in HIV treatment came in the mid-90s when researchers discovered that effectively fighting the virus requires using multiple types of HIV drugs at the same time.[4] Combination treatments box the virus into a corner, decreasing the amount of the virus in the body to undetectable levels and allowing the immune system to function more normally.[5] Based on this insight, clinicians now combat the virus by prescribing a combination of the following types of antiretroviral drugs:[6] Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTIs), Protease Inhibitors (PIs), Non-nucleoside Reverse Transcriptase Inhibitor (NNRTIs), Entry Inhibitors (EIs),Fusion Inhibitors (FIs), and Integrase Inhibitors (IIs).

HHS guidelines describe the current "state of knowledge" and establish the medical standard of care for the "optimal use" of antiretroviral (ARV) agents for the treatment of HIV infection in adults and adolescents in the United States.[7] The guidelines are a living document that is updated as new treatments become available or new research studies are published. The guidelines include "recommended" regimens and "alternative" regimens[8] and are available online at: http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0.[9]

The multi-drug treatment, known as highly active antiretroviral therapy (HAART), has proven remarkably successful in improving immune function and overall health, delaying the onset of AIDS, and extending life expectancy to near-normal for people with HIV.[10] Proper use of medications has reduced deaths from 50,874 in 1995[11] to 13,712 in 2012.[12] The significant

---

[4] *History of HIV & AIDS in the U.S.*, AVERT, http://www.avert.org/history-hiv-aids-us.htm (last accessed October 17, 2014) ("[After being introduced], it soon became obvious that HAART was going to be revolutionary in HIV treatment."); *see also* HHS Guidelines at D-1 ("Achieving viral suppression requires the use of ARV [i.e., HAART] regimens with at least two, and preferably three, active drugs from two or more drug classes.").

[5] US DEP'T OF HEALTH AND HUMAN SERVS., GUIDELINES FOR THE USE OF ANTIRETROVIRAL AGENTS IN HIV-1-INFECTED ADULTS AND ADOLESCENTS (last updated May 30, 2014), at E-1, *available at* http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf (hereinafter "HHS Guidelines") ("The primary goal of antiretroviral therapy (ART) [i.e., HAART] is to prevent HIV-associated morbidity and mortality. This goal is best accomplished by using effective ART to maximally inhibit HIV replication so that plasma HIV RNA levels (viral load) remain below that detectable by commercially available assays. Durable viral suppression improves immune function and quality of life, lowers the risk of both AIDS-defining and non-AIDS-defining complications, and prolongs life.").

[6] U.S. Institute of Health, *Types of HIV Antiretroviral Drugs* (last updated Sept. 23, 2013); AIDS.gov, *Overview of HIV Treatments* (last revised Aug. 7, 2009).

[7] *See* HHS Guidelines at A-1 to A-2.

[8] For some individuals, the recommended regimens may not be effective. Therefore an alternative regimen may be the preferred regiment for some patients. HHS Guidelines at F-4.

[9] HHS Guidelines at F-4.

[10] *See* HHS Guidelines at D-1.

[11] *See* Denis H. Osmond, *Epidemiology of HIV in the United States*, at Table 3 (2003), *available at* http://hivinsite.ucsf.edu/InSite-KB-ref.jsp?page=kb-01-03&ref=kb-01-03-tb-03&no=3.

reduction in deaths is evidence that HIV medications save the lives of people with HIV. Effective treatment of people with HIV, also greatly benefits other members of the general public. By reducing the amount of virus in an individual with HIV's bodily fluids, HAART reduces the risk of transmission from infected individuals to their sexual partners by at least 96%[13] and perhaps 100%.[14] HAART also prevents women with HIV from transmitting the virus to their newborn children.[15] Therefore, HAART not only saves the lives of people with HIV, but protects the public health as well.[16]

To obtain all of these benefits, HAART should be initiated early and be taken daily without interruption.[17] Delaying treatment causes long-term damage to vital organs[18] and allows HIV to mutate extensively as it replicates throughout the body, risking the possibility that one of those mutations will make the virus drug resistant.[19] Furthermore, due to HIV's high mutation rate, even minor interruptions in the medication regimen can lead to drug resistance, which results in

---

[12] *See* Centers for Disease Control and Prevention, *HIV in the United States: At a Glance* (last updated March 12, 2014), *available at* http://www.cdc.gov/hiv/statistics/basics/ataglance.html.

[13] A 2011 study, the HPTN 052 study, found that HAART reduced the risk of transmission by 96%. *See HPTN 052, Fact Sheet: Initiation of Antiretroviral Therapy (ART) Prevents the Sexual Transmission of HIV in Serodiscordant Couples*, HIV PREVENTION TRIALS NETWORK (July 2011), http://www.hptn.org/web%20documents/HPTN052/HPTN%20Factsheet_InitiationART4Prevention.pdf.

[14] A study, known as the PARTNER study, is currently ongoing in Europe. The study is funded by the National Institute for Health Research in the UK. As of March 2014, interim results show a transmission rate of zero, as no incident of transmission has been reported. The study is still ongoing and final results are not yet available. *See* Allison Rodger, et. al., *HIV transmission risk through condomless sex if the HIV positive partner is on suppressive ART: PARTNER study*, Presentation at CROI, Boston (Mar. 3-6, 2014), http://www.chip.dk/portals/0/files/CROI_2014_PARTNER_slides.pdf.
D. Donnell, et al., *Heterosexual HIV-1 Transmission After Initiation of Antiretroviral Therapy: A Prospective Cohort Analysis*, 375 Lancet 2092, 2095 (Jun. 2010) ("ART use by HIV-1 infected participants was associated with a 92% reduction in risk of transmission"); *see also* HHS Guidelines at A-1 ("[E]ffective treatment of HIV-infected individuals with ART is highly effective at preventing transmission to sexual partners."); *id.* at E-1 ("[H]igh plasma HIV RNA is a major risk factor for HIV transmission and use of effective ART can reduce viremia and transmission of HIV to sexual partners.").

[15] HHS Guidelines at I-20 ("In pregnant women, an additional goal of therapy is prevention of perinatal transmission of HIV with a goal of maximal viral suppression to reduce the risk of transmission of HIV to the fetus and newborn. . . .").

[16] HHS Guidelines at E-4 ("The expanded use of ART to treat individuals with CD4 counts >500 cells/mm^3 has also demonstrated public health benefits . . . because the risk of HIV transmission is associated with level of viremia, from a public health standpoint, this reduction in community viral load can potentially reduce new HIV infections at the community level.").

[17] HHS Guidelines at i-ii ("Antiretroviral therapy (ART) is recommended for all HIV-infected individuals to reduce the risk of disease progression . . . ," including patients with a CD4 cell count >500/mm^3. "The recommendation for initiation of ART in patients with early infection . . . should be offered . . . .").

[18] HHS Guidelines at E-1 ("[Delaying treatment causes] cardiovascular disease (CVD), kidney disease, liver disease, neurologic complications, and malignancies.").

[19] HHS Guidelines at H-4 ("Persistent HIV RNA levels >200 copies/mL often are associated with evidence of viral evolution and drug resistance mutation accumulation; this is particularly common when HIV RNA levels are >500 copies/mL.") (footnotes omitted); *id.* at D-1 ("Maximal and durable suppression of plasma viremia delays or prevents the selection of drug-resistance mutations, preserves CD4 T-cell numbers, and confers substantial clinical benefits, all of which are important treatment goals."); *id.* at C-10 ("Transmission of drug-resistant HIV strains is well documented and associated with suboptimal virologic response to initial antiretroviral therapy (ART).").

increased viral replication, fewer treatment options, higher infection rates, and reduced functioning of the immune system.[20]

Effective HAART treatment requires that patients and their clinicians have the flexibility to identify the regimen that works best for each individual as quickly as possible.[21] Even once a regimen has been found to work for an individual, treatment may stop working due to viral mutations or the development of toxic side effects from long-term treatment.[22] In such instances, the patient must be allowed to switch their drug regimen quickly.[23]

Based on the aforementioned information, there is a general medical consensus that:

(1) HAART should begin as soon as possible after diagnosis, using recommended HIV regimens.[2425]
(2) To promote adherence, patients should be prescribed the most convenient regimen, which is usually a one-a-day pill that combines more than one class of HIV drugs.[26]
(3) Interruptions in treatment must be avoided.[27]
(4) Clinicians must be able to switch or alter drug regimens quickly when the patient's HIV becomes resistant to a drug or the patient develops problematic side effects.[28]

To not discriminate, health plans must allow clinicians to follow widely accepted care and treatment recommendations to provide the standard of care for patients with HIV in the U.S. At a minimum, all recommended drug regimens—including those described as the "alternative" regimens to first-line regimens—should be available and affordable to HIV patients without requiring the use of mail-order pharmacies, prior authorizations or other utilization management techniques that may delay access to treatment.

---

[20] HHS Guidelines at H-1 ("Discontinuing or briefly interruption therapy in a patient with viremia may lead to a rapid incase in HIV RNA and a decrease I nCD4 cell could and increase the risk of clinical progression"); *id.* at D-2 ("Suboptimal adherence may result in reduced treatment response"); *id.* at I-5 ("A large randomized controlled trial of patient with chronic HIV infection found that treatment interruption was harmful in terms of increased risk of AIDS and non-AIDS events").

[21] HHS Guidelines at D-2 ("Regimens should be tailored for the individual patient to enhance adherence and thus improve long term treatment success. Individual regimen choice is based on such considerations as expected side effects, convenience, comorbidities, interactions with concomitant medications, and results of pretreatment genotypic drug-resistance testing.").

[22] HHS Guidelines at H-2 (listing potential causes of virologic failure).

[23] HHS Guidelines at H-4 ("Once virologic failure is confirmed, generally the regimen should be changed as soon as possible to avoid progressive accumulation of resistance mutations."); *id.* at D-1 ("When initial suppression is not achieved or is lost, rapidly changing to a new regimen with at least two active drugs is required.").

[24] HHS Guidelines at I ("Antiretroviral therapy (ART) is recommended for *all* HIV-infected individuals to reduce the risk of disease progression . . . .") (emphasis added).

[25] Günthard HF, Aberg JA, Eron JJ, Hoy JF, Telenti A, Benson CA, Burger DM, Cahn P, Gallant JE, Glesby MJ, Reiss P, Saag MS, Thomas DL, Jacobsen DM, Volberding PA. *Antiretroviral Treatment of Adult HIV Infection: 2014 Recommendations of the International Antiviral Society–USA Panel*. JAMA. 2014.

[26] HHS Guidelines at D-2 ("Regimens should be tailored for the individual patient to enhance adherence and thus improve long term treatment success.").

[27] HHS Guidelines at H-1 ("Discontinuing or briefly interrupting therapy in a patient with viremia may lead to a rapid increase in HIV RNA and a decrease in CD4 cell count and increases the risk of clinical progression. Therefore, this strategy is not recommended . . . .").

[28] HHS Guidelines at D-1 ("When initial suppression is not achieved or is lost, rapidly changing to a new regimen with at least two active drugs is required.").

The DOI Must Take Action to Enforce Non-Discrimination Mandates

The DOI must ensure that none of the plans offered through the state health insurance exchange is employing a discriminatory benefit design or engaging in discriminatory marketing practices. In fact, a state should not approve for sale on its exchange any health plans that do not provide essential health benefits (EHB).[29] An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, *present or predicted disability*, degree of medical dependency, quality of life, *or other health conditions*.[30] The HHS Notice of Benefit and Payment Parameters for 2016 prohibits plans that discourage individuals with chronic health issues from enrolling. Pursuant to the notice, plans that place drugs for certain conditions on the highest cost tiers discriminate in their plan design: "…if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, we believe that such plan designs effectively discriminate against, or discourage enrollment by, individuals who have those chronic conditions."[31] The regulations also state, "[w]e also caution issuers to avoid discouraging enrollment of individuals with chronic health needs. For example, if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, we believe that, absent an appropriate reason for such refusal, such a plan design effectively discriminates against, or discourages enrollment by, individuals who would benefit from such innovative therapeutic options."[32] This proscription on discriminatory benefit designs—or implementation of benefit designs—applies to the design or implementation of a drug formulary[33], selection of pharmacy networks[34], and the use of medical management techniques.[35] In addition to this very specific prohibition on discriminatory benefit designs, the ACA and its implementing regulations impose more general prohibitions against discrimination based on disability,[36] and HIV is a qualifying disability even in its asymptomatic stage.[37]

---

[29] 45 C.F.R. § 156.125.
[30] 45 C.F.R. § 156.125(a).
[31] 79 Fed. Reg. 70674, 70723 (Nov. 26, 2014).
[32] *Id.*
[33] *See* Letter from Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, 2015 Letter to Issuers in the Federally-facilitated Marketplaces 29 (Mar. 14, 2014), *available at* http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf ("We are concerned that some enrollees, particularly those with certain complex medical conditions, are having trouble accessing in a timely fashion clinically appropriate prescription drugs, such as prescription drugs that are combination drugs not covered by their plans' formularies").
[34] *See* 79 Fed. Reg. 70674, 70722 (Nov. 26, 2014) (proposing that a health plan can only restrict access to a particular drug when: "(1) The FDA has restricted distribution of the drug to certain facilities or practitioners (including physicians); or (2) appropriate dispensing of the drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a retail pharmacy."
[35] *See* Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, *supra* note 30, at 29 ("Discriminatory cost-sharing language would typically involve reduction in the generosity of a benefit in some manner for subsets of individuals other than based on clinically indicated common medical management practices").
[36] *See* ACA § 1557, codified at 42 U.S.C. § 18116 (2012). Though 45 C.F.R. § 156.200 specifically allows "appropriately utilizing reasonable medical management techniques," the failure to provide doctors with the ability to follow the standard of care and expeditiously place their patients on necessary treatments for which time is of the essence is, by definition, neither an "appropriate" nor "reasonable" use of medical management techniques.
[37] 29 C.F.R. § 1630.2(j)(3)(iii) (HIV is a recognized disability under the ADA Amendments Act of 2008).

The non-discrimination provisions described above were incorporated into the Public Health Service Act (PHS Act) by the Patient Protection and Affordable Care Act (ACA). "Each State enforces PHS Act requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State."[38] Accordingly, the DOI has an obligation to ensure health insurers who participate in the marketplace and the QHPs offered therein do not discriminate against individuals living with HIV.[39]

Conclusion

The actions of [insert the name of the insurance companies], including [refer back to listed actions from the beginning of the letter], are inconsistent with HIV treatment standards in the U.S. and create barriers to necessary treatment. Therefore these actions are outside the realm of "reasonable medical management" and are discriminatory.

To combat this discrimination, we urge the DOI to ensure that any issuers or QHPs (including the ones listed in this letter) cease such discriminatory practices and comply with federal laws. The DOI must make clear to all issuers that discriminatory practices are unacceptable and that issuers that undertake these practices will be prohibited from offering discriminatory plans in the marketplace.

Thank you for your attention to these matters and for your efforts to ensure that individuals living with HIV can access the life-saving care and treatment they need.

Sincerely,

(**Name**)

(**Affiliation, if any**)

[38] 45 C.F.R. 150.201; *see also* 78 Fed. Reg. 12834, 12847 (Feb. 25, 2013).

[39] While HHS has clarified that the anti-discrimination provisions are not meant to prevent the implementation of "reasonable medical management" techniques such as prior authorization, "an issuer . . .could not [for example] implement prior authorization in a manner that discriminates on the basis of membership in a particular group based on factors such as…disability…that are not based on nationally recognized, clinically appropriate standards of medical practice evidence or not medically indicated and evidence based." 78 Fed. Reg. at 12847.

PostPartisan

States not expanding Medicaid hobble the fight against HIV/AIDS

By Jonathan Capehart October 6, 2014

As we begin to worry about the possibility of an Ebola epidemic taking hold in the United States, we must not forget the epidemic already firmly rooted here. The HIV/AIDS epidemic has raged for more than 30 years in this country with more than 1.1 million people in the U.S. living with HIV/AIDS and African Americans experiencing "the most severe burden of HIV," according to the Centers for Disease Control. While a positive diagnosis no longer means guaranteed death, it does mean a life of expensive medications and care to manage the chronic disease. Lack of awareness and of access to care continue to help spread an infection that is relatively easy to avoid.

The arrival of the Affordable Care Act in 2010 improved health care options for people living with HIV/AIDS. Insurance coverage was finally possible because the law prohibited insurers from denying health coverage because of a preexisting condition. And that meant access to care and medications that prolong life and help slow the epidemic's rate of transmission. The expansion of Medicaid would loop even more people with HIV/AIDS into care.

The imperative of doing so was vividly demonstrated in three maps presented by Lauren Banks of AIDS Alabama during a panel I moderated on HIV/AIDS at the Congressional Black Caucus Foundation legislative conference late last month. Right now, only 27 states and the District of Columbia have expanded Medicaid. The states that have yet to extend the federal government health care program are also home to some of the highest concentrations of HIV infections and those living with HIV/AIDS. To see those maps is to wonder why governors and state legislators in those states seem willing to deprive their citizens of health care and the life-prolonging and life-saving treatment that come with it.

The first map Banks presented showed the "rates of persons living with an HIV diagnosis, by county." The heavy concentrations in the South, Northeast and urban areas are hard to miss. Those counties in the deepest red reported a rate of more than 384 persons per 100,000 living with HIV or an AIDS diagnosis as of 2010.

The second map Banks presented showed the data filtered to just show the rate of African Americans living with an HIV or AIDS diagnosis. The first thing you notice is that the areas of highest concentration on this map are almost identical to those in the map above. Those counties in the deepest red reported a rate of more than 1,061 persons per 100,000 living with HIV

or an AIDS diagnosis as of 2010.

Now, look at the map below to see the stark and disparate impact of this epidemic on blacks and whites. Banks didn't show this next map, but I found it while researching this post.

According to the latest data from the CDC, an estimated 50,000 people tested positive for HIV in the United States in 2011. African Americans "accounted for an estimated 44 percent of new HIV infections in 2010" and "accounted for 44 percent of people living with HIV infection in 2009."

Other data from the CDC show the South had the highest percentage of new AIDS diagnoses (45 percent) at the end of 2010. The South had the highest percentage of people "living with an AIDS diagnosis" (40 percent) in 2009. And the South "accounted for 48 percent of the 17,774 persons with a diagnosis of AIDS who died in the 50 states and the District."

And this brings me to the third map Banks presented during the panel, which shows the status of Medicaid expansion. You don't need to be a geography whiz to see that the HIV/AIDS epidemic rages in the Southern states that are "not moving forward at this time" on Medicaid expansion.

Kaiser Health News (KHN) reported last March on a study which estimated that "nearly 115,000 uninsured, low-income people living with HIV/AIDS would be eligible for Medicaid if all states adopted the expansion." But it added, "Of these, nearly 60,000 live in states not moving forward with the Medicaid expansion." The KHN story notes that "About 70 percent of the group living in states not expanding Medicaid earn too little to qualify for financial help to buy insurance in the marketplaces created by the health law."

Sylvia Burwell, the secretary of health and human services, is in talks with the governors of Tennessee, Utah and Indiana to expand Medicaid in their states. This is great, but there is no action in the states where it is needed most in the fight against HIV/AIDS. And an HHS official told me Friday that the agency has "worked with both Democratic and Republican Governors to be flexible so they can design a solution that works best for their states and their low-income residents." The official added, "As we approach open enrollment for 2015, we urge all Governors to help people both get covered and stay covered, and we are committed to working with all states to implement Medicaid expansion in a way that maximizes coverage options for uninsured residents."

If the moral argument for the need to extend health coverage to all those who want and need it doesn't hold sway then perhaps the economic one will. The ACA mandates full federal financing of a state's Medicaid expansion. Starting in 2017, that 100 percent federal match will gradually taper to and remain at 90 percent by 2020. Thus, the remaining 23 states that haven't done so are leaving money on the table that could help thousands of people living with HIV/AIDS to get health coverage, care and treatment for "a big disease with a little name." Knowing that, it takes a special kind of callousness to continue to say no to those in need.

Follow Jonathan on Twitter: @Capehartj

Jonathan Capehart is a member of the Post editorial board and writes about politics and social issues for the PostPartisan blog.

amfAR
MAKING AIDS HISTORY
The Foundation for AIDS Research

February 2015

ISSUE BRIEF

Hepatitis C and Drug Pricing: The Need for a Better Balance

Hepatitis C virus (HCV) is transmitted by contact with the blood of a person living with HCV. HCV can be transmitted through multiple routes, including needle sharing, unsterilized medical equipment, contaminated blood products, sexual contact, and perinatally.[1]

Globally, approximately 185 million people are living with HCV. The majority of individuals who have HCV are unaware of their status. While most new HCV infections never result in significant disease, some 15–30% of chronic HCV cases will result in cirrhosis of the liver and 5–7% will result in liver failure.[2] Untreated individuals may also develop advanced liver fibrosis and hepatocellular carcinoma (liver cancer).[3] Approximately 350,000 people across the globe die every year from liver complications associated with HCV.[4]

HCV has six circulating genotypes (numbered 1 through 6) along with various subtypes. Global prevalence, treatment options, and treatment success rates for each genotype vary considerably. Genotype 1 is the most prevalent in the United States.

In this brief, we review drug pricing for new hepatitis C medications and pose basic questions of fairness and medical ethics. Although we focus on Gilead and its hepatitis C drug sofosbuvir (marketed as Sovaldi®), the issues we highlight are broadly applicable to other manufacturers of hepatitis C medications.

Summary

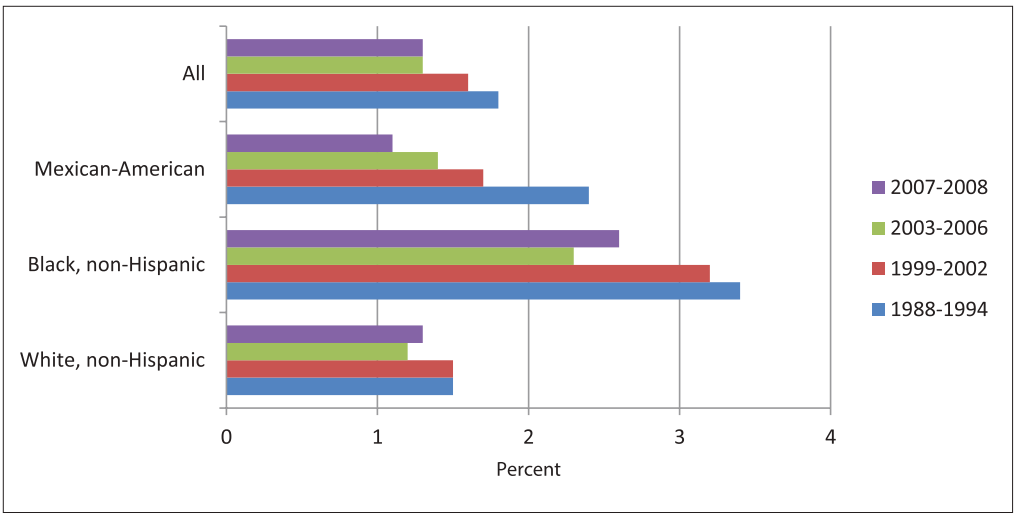
- **Background:** New pharmaceutical breakthroughs have made curing hepatitis C (HCV) infection easier and more effective.
- **The Issue:** These new drugs have been priced at aggressively high rates that bear no relation to the cost of research and development. With as many as 185 million people living with HCV globally, including three million Americans, this aggressive drug pricing will place an unjustifiable and unsustainable burden on domestic and global health system budgets.
- **amfAR's View:** Despite important price reductions for low- and middle-income countries, the astronomical prices demanded by Gilead and AbbVie for their HCV treatments will inevitably limit access to the drugs, leading to unnecessary loss of life.

Impact of Hepatitis C in the United States

Roughly 3.2 million Americans have chronic HCV infection[5] and approximately 12,000 Americans die every year from chronic liver disease associated with the virus.[6] Those at greatest risk for HCV include recipients of blood transfusions and organ donations prior to 1992,[7] people with hemophilia, hemodialysis patients, people living with HIV, and people who inject drugs.[8,7] HCV infections in the United States declined steadily from 1982 to 2010, averaging approximately 200,000 infections per year from 1982 to 1991, 43,600 per year from 1992 to 2001, and 19,100 per year from 2002 to 2010.[10] However, there has been a 75% increase in reported cases from 2010 to 2012.[11]

The burden of HCV in the U.S. is disproportionately borne by racial and sexual minority populations. HCV prevalence among African-Americans and some Latino communities (Mexican-Americans) is consistently higher than among white Americans, with an HCV rate among African-Americans almost double that of the general population. And infection rates among gay and bisexual men in the U.S. have steadily increased in the past decade, particularly among those living with HIV.[12]

Figure 1. HCV Prevalence Among Persons Six Years and Older in the United States for Select Years by Race/Ethnicity



Source: McQuillan GM, Kruszon-Moran D, Denniston MM, and Hirsch R. Centers for Disease Control and Prevention. National Center for Health Statistics Data Brief. Viral Hepatitis*. March 2010. http://www.cdc.gov/nchs/data/databriefs/db27.pdf*

A Costly Cure for Hepatitis C

Historically, HCV treatment has been lengthy and of uncertain effectiveness. Standard treatment regimens required 24–48 weeks and cure rates ranged from 50% to 80% of cases. Since late 2013, new direct-acting antiviral (DAA) drugs have been approved for the treatment of HCV by the U.S. Food and Drug Administration (FDA). These new treatment regimens (in combination with older HCV drugs) have reduced treatment duration to 12–24 weeks, decreased side effects, and improved outcomes, with cure rates of 85–95% across all patient populations.

The FDA has approved four new HCV treatment regimens since late 2013 (Table 1). While the new medications are welcome advances, they come with a hefty price tag. For example, sofosbuvir has been priced in the United States at $84,000 for a 12-week course of treatment. Such exorbitant price setting has once again brought the issue of drug pricing to the fore in the U.S. and around the world.

Implications of new HCV medications: a burden on U.S. health systems

The costs associated with the wave of new treatments for HCV have generated controversy. Most of the criticism to date has been directed toward Gilead over the pricing of sofosbuvir at approximately $1,000 per pill.[22] Gilead, however, is not alone in this regard, as AbbVie's recently approved Viekira Pak

Table 1. HCV Treatment Regimens Since 2013

Active Ingredient	Brand Name	Treatment Formulation	Genotype Approval	Treatment Duration	Pharmaceutical Company	List Price*	Total Regimen Cost*
simeprevir[13]	Olysio	simeprevir + peginterferon alfa + ribavirin	1	12 weeks (simeprevir) 24–48 weeks (total)	Medivir & Janssen Pharmaceutical	$66,360	$85,960[14]
sofosbuvir[15]	Sovaldi	sofosbuvir + pegylated interferon + ribavirin	1, 4	12 weeks	Gilead Sciences	$84,000	$103,600[16]
		sofosbuvir + ribavirin	2	12 weeks		$84,000	$85,100[17]
		sofosbuvir + ribavirin	3	24 weeks		$168,000	$169,100[18]
ledipasvir/ sofosbuvir[19]	Harvoni	ledipasvir + sofosbuvir	1	12 weeks	Gilead Sciences	$94,500	$94,500
ombitasvir/ paritaprevir/ ritonavir[20]	Viekira Pak	ombitasivir + paritaprevir + ritonavir + dasabuvir	1	12–24 weeks	AbbVie Inc.	$83,319	$83,319

** The prices here do not consider all possible prescribed regimens but are indicative of the total list price for a treatment regimen. List prices for all drugs sourced from University of Washington, Hepatitis C Online project.[21]*

Even accounting for all available discounts, treating all HCV-infected individuals in the United States would cost approximately $110 billion.

(ombitasvir, paritaprevir and ritonavir) has only slightly undercut Gilead,[23] and the overall cost of a treatment regimen with Janssen's simeprevir is approximately $85,000.

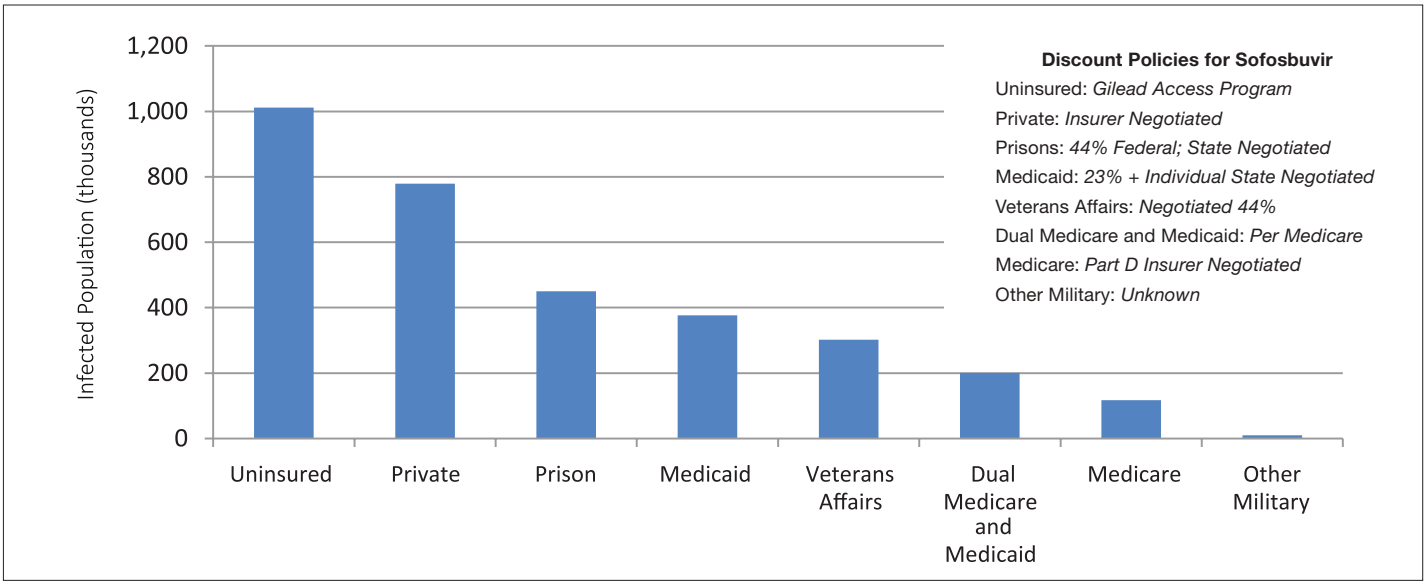
Using just list prices, one estimate found that treating all HCV-infected individuals in the U.S. with sofosbuvir would cost more than $268 billion.[24] However, virtually all providers get some sort of discount off the list price (Figure 2). But even taking these into account, the cost of treating all HCV-infected individuals in the U.S. would still be approximately $110 billion, a figure completely unrelated to the cost of developing the drug.[25]

Controversial pricing of HCV medication has led to outcries from virtually all corners of the U.S. Senators Ron Wyden and Chuck Grassley from the Senate Finance Committee have written to Gilead requesting the evidence and basis to support their pricing.[26] House Committee on Energy and Commerce members Frank Pallone, Jr., Diana DeGette and Henry Waxman (retired, 2014) have requested a similar briefing from Gilead.[27] State Medicaid directors have also written to both Senate and House committees about the difficulty states have experienced in securing steeper discounts from Gilead, and the unsustainable effect the price of sofosbuvir is having on state Medicaid budgets.[28]

It is estimated that as many as one million Americans with hepatitis C are at 'highest' or 'high' priority for immediate treatment based upon established medical guidelines.[29] Many Americans with hepatitis C are uninsured, but the majority have access to some form of insurance, either through public government programs or private coverage. However, the new HCV drugs will still be out of reach for many insured individuals who are clinically eligible for treatment because payers are limiting access to these costly regimens:

- **Medicaid**: By law, Medicaid is required to provide access to all FDA-approved outpatient drugs so long as the manufacturer provides a minimum 23% rebate.[30] However, the price of new hepatitis C drugs has prompted cost-saving measures by Medicaid, such as the creation of numerous hurdles that patients must overcome before they can access treatment. In Illinois, patients are required to meet 25 different criteria before they may be prescribed sofosbuvir.[31] Other states, such as Arizona, have imposed a once-in-a-lifetime rule that denies patients who have previously received treatment with sofosbuvir any further coverage for the drug in the event they become infected again.[32] Molina Healthcare, which operates Medicaid managed-care plans for 11 states, has told state officials that it would not be able to afford covering the drug.[33]
- **Medicare**: Medicare is also greatly affected by the cost of sofosbuvir. According to one estimate, if only 7% of HCV-infected Medicare Part D enrollees were treated with sofosbuvir, Medicare spending would increase by $2 billion in new Part D drug costs in 2015 over 2014.[34] This would

Figure 2. HCV Burden by Insurance Type and Associated Discount Policy, U.S.



Source: Epidemiology data; Milliman, Inc., NY. Health Care Reform and Hepatitis C: A Convergence of Risk and Opportunity. *December 10, 2013. http://us.milliman.com/uploadedFiles/insight/2013/convergence-of-risk-and-opportunity.pdf. Discount data; per citations in text.*

If only 7% of HCV-infected Medicare Part D enrollees were treated with sofosbuvir, Medicare spending would increase by $2 billion in new Part D drug costs in 2015 over 2014.[34] **This would represent a 3% increase in federal Part D outlays and Part D premiums, due to sofosbuvir alone.**

represent a 3% increase in federal Part D outlays and Part D premiums due to sofosbuvir alone.[35] If 21% were treated, Medicare spending would increase by $6.5 billion in new Part D drug costs in 2015 over 2014.[36] This, in turn, would represent an 8% increase in federal Part D outlays and Part D premiums.[37]

It is important to keep in mind that these estimates are conservative—they represent only the cost increase due to sofosbuvir, and do not account for the increased cost due to other medications that are often prescribed alongside sofosbuvir, or the laboratory and medical costs involved in delivering treatment.[38] Although these figures also do not discount savings Medicare will experience from reduced numbers of hospitalizations and liver transplants associated with HCV infection, the current price of HCV treatment remains prohibitively high and out of reach for many, even when such discounts are applied.

- **Federal prison system**: Current Federal Bureau of Prisons (BOP) guidance for treatment of HCV recommends treatment with sofosbuvir for all genotypes for inmates with advanced disease or HIV co-infection.[39] While the BOP has secured a 44% discount from Gilead,[40] the cost implications for the prison system and taxpayers are still prohibitive. The CDC estimates that 12–35% of prison inmates have chronic HCV infection.[41] Even if only one-third of those with chronic HCV infection in Federal prisons require treatment per BOP guidelines, it could push the per inmate cost of incarceration up between 6% and 19%.[42]

- **State prison systems**: For state prison systems, medication discounts must be negotiated individually at the state level. Without discounts, the per inmate cost of state prison systems could be pushed up 12–34%, depending on the prevalence of HCV among inmates.[43] This has enormous budgetary implications for states, and most prisons are actively denying inmates access to sofosbuvir (and other similar HCV medications) unless individual cases become clinically urgent or there are compelling financial reasons to provide the treatment, such as avoiding the high cost of a liver transplant for inmates with lengthy prison sentences.[44]

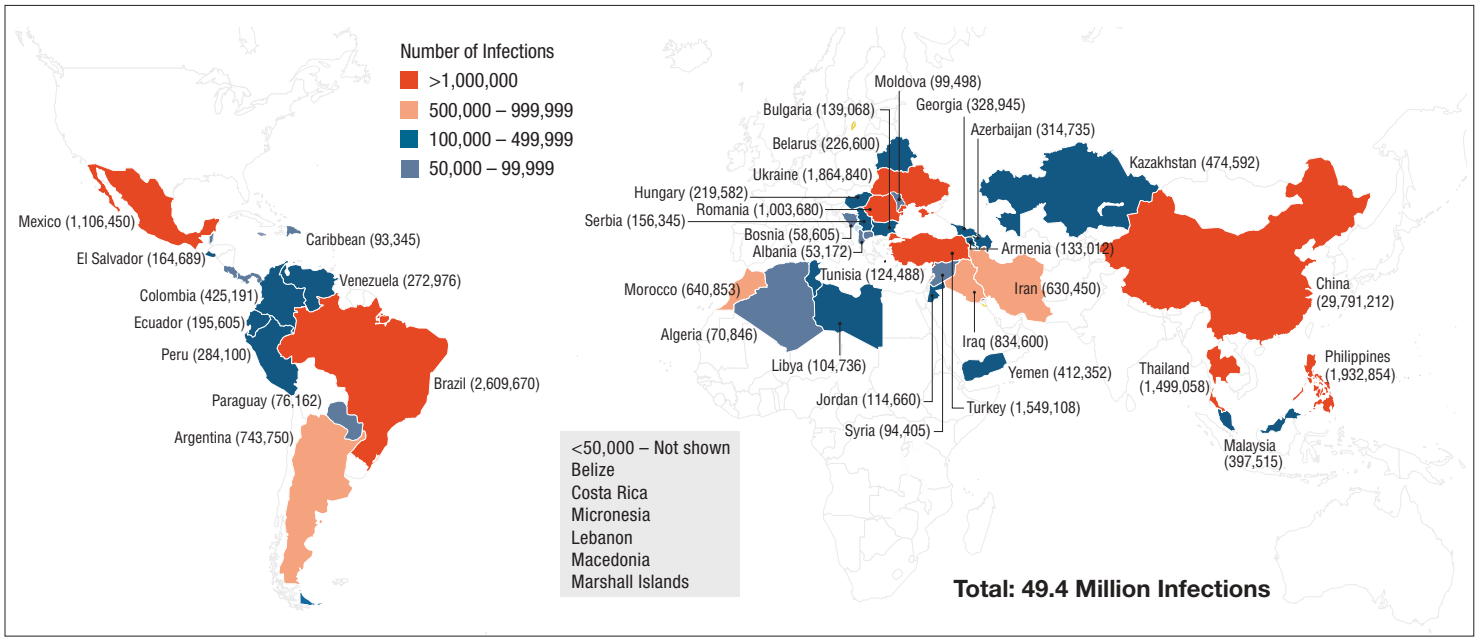
- **Private insurers**: For private insurers, the introduction of AbbVie's Viekira Pak has initiated a flurry of price negotiations that are seemingly driving the price down while expanding access to more patients. Shortly after being approved for marketing, Express Scripts—the largest prescription drug benefit manager in the U.S.—made Viekira Pak the preferred pharmacy formulation over Sovaldi/Harvoni, presumably because AbbVie was willing to discount its product more than Gilead.[45] Conversely, Gilead has negotiated with several providers including CVS, Aetna, and Humana to exclusively offer Sovaldi/Harvoni unless a patient has a clinical indication for Viekira Pak.[46] Indications are now that the level of discounts insurers have been able to secure are more than double what they were in 2014. While these are positive movements in terms of the resulting price reductions for the healthcare system overall, they make patients further subject to the business arrangements of insurance providers over their own, or their physician's, preferred choice of medications.

The high cost of treating HCV globally

The global impact of HCV is staggering. The World Health Organization (WHO) estimates that as many as 185 million people are living with hepatitis C, with up to 350,000 deaths annualy due to HCV-related liver disease.[47] Given the prevalence of HCV worldwide, these new HCV medications could have a profound impact on global health. However, price reductions for some countries do not necessarily make these drugs affordable. For instance, while the cost of treatment with sofosbuvir is highest in the United States at $84,000, it is estimated that it will cost approximately $55,000–57,000[48] in the United Kingdom and Canada and $66,000–$68,000 in Germany.[49] Though they represent three of the wealthiest countries in the world,[50] sofosbuvir is still considered all but unaffordable by the national health systems in the U.K. and Canada, and it remains to be seen at what price and for how many patients the German government will approve covering the drug.[51]

At the same time, some countries will have access to dramatic price reductions. Through an agreement negotiated between Gilead and the Egyptian government, sofosbuvir will be priced

Figure 3. HCV Burden in Middle-Income Countries Excluded from Gilead's Voluntary License



Source: Lavanchy, D. Evolving epidemiology of hepatitis C virus, Clin Microbiol Infect *2011; 17: 107–115 (2011).*

in Egypt at $900 for a 12-week course.[52] Subsequently, Gilead extended this pricing to other countries including India and Brazil.[53] In September 2014, Gilead also signed a voluntary license agreement with seven pharmaceutical companies in India, allowing them to sell generic sofosbuvir formulations in 91 developing countries, with a 7% royalty going to Gilead.[54]

The significance of this voluntary license has yet to be seen as prices for the generic formulations have not been released and guidelines for laboratory monitoring of treatment in resource-constrained settings have yet to be developed. In addition, many developing countries continue to lack sufficient infrastructure or the trained healthcare workers necessary to implement broad HCV treatment programs; and it likewise remains unclear whether political leaders will be able to mobilize the resources necessary to develop such capacity. Thus, while an estimate of the cost of manufacturing generic sofosbuvir has suggested prices could be as low as $68–136 for a 12-week course of treatment,[55] a major obstacle to the availability of HCV treatment in developing countries covered by voluntary licenses may actually be programmatic. Other potential barriers, such as the anti-diversion mechanisms that are part of the voluntary license agreement and are meant to prevent the re-selling of sofosbuvir to wealthy countries, have yet to be made public and could severely hamper genuine access to generic sofosbuvir in low- and middle-income countries.[56]

Although voluntary licenses may reduce the cost of HCV medications in certain low-income countries, such medications may remain out of reach for those in middle-income countries not covered by the licenses. In particular, Gilead has not made clear the criteria it used to determine the geographic range of the agreement. The 91 countries included in the agreement account for all countries designated as low-income by the World Bank, 37 lower-middle-income, 17 upper-middle-income, and two high-income countries, but exclude 13 lower-middle-income and 38 upper-middle-income countries.

For countries left out of the agreement (Figure 3), the default rules established under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are maintained. This means that Gilead retains the exclusive right to sell sofosbuvir in these countries without any generic competition. While few would argue that high-income countries should have been included, Gilead's rationale for including Equatorial Guinea, for example, while excluding countries such as El Salvador or the Philippines has not been explained. Excluded lower- and upper-middle-income countries are estimated to have more than 49 million people with chronic HCV,[57] including more than 29 million in China alone, but will be required to negotiate prices with Gilead directly rather than being able to rely on the open terms of the voluntary license.

It must be noted that the initial patent application for sofosbuvir was recently rejected by the Indian Patent Office.[58] The significance of the rejection is not yet clear as

another patent application relating to sofosbuvir in India is still pending[59] and Gilead has already indicated it will appeal the decision.[60] In other countries, patents on sofosbuvir may already have been granted or patent applications may still be pending in the local patent office barring any production or importation without Gilead's consent.

In a more ideal setting, Gilead would enable the generic licensees to manufacture for all countries, with varying royalty rates being established for each country or country group. Doing so would ensure that generic manufacturing was done at a scale that would drive production to the lowest possible price while enabling Gilead to maintain a transparent tiered pricing strategy across countries.

Discrepancies in HCV Medication Development vs. Pricing: Sofosbuvir

Public records from the U.S. Securities and Exchange Commission (SEC) provide clues to the costs associated with the development of sofosbuvir. Prior to being purchased by Gilead, sofosbuvir was initially developed by Pharmasset, Inc., a small pharmaceutical company dedicated primarily to HCV treatments with no drugs yet approved by the FDA and three drugs (including sofosbuvir) in clinical development.[61] Public data for Pharmasset are available from 2001 on, and they show that its total research and development budget between January 2001 and September 2011 amounted to $281 million.[62,63] Including operating expenses, Pharmasset's total operations only amounted to $373 million.

With this research and development budget, Pharmasset managed to move sofosbuvir through phase 1 and several phase 2 human clinical trials and initiate phase 3 clinical trials. This was in addition to developing other hepatitis B, hepatitis C, and HIV drug candidates, some of which had made it to phase 2 testing.[64] Pharmasset's revenues over this period were $59 million. In 2011, when Gilead purchased the company for more than $11 billion, it reported earnings of only $897,000.

Clinical trials are generally the most expensive aspect of drug development, and after acquiring Pharmasset, Gilead incurred the expense of conducting phase 3 trials, seeking marketing approval from the FDA, and conducting ongoing post-market trials (see Figure 4).[65] Nonetheless, Gilead would be hard-pressed to suggest that the research and development costs of the phase 3 trials, on top of the $373 million in operations costs at Pharmasset, could justify its pricing of sofosbuvir.

This disparity between the purchase price for Pharmasset and the company's revenues over the previous decade reveals that Gilead was consciously aware that it was purchasing a future revenue stream. Interim or complete phase 2 trial data were already available by November 2011 that showed strong efficacy and good safety data, and led Pharmasset to initiate the phase 3 trials necessary for FDA approval.[66] That Gilead was willing to spend $11 billion for Pharmasset attests to this fact, and also to the point that the purchase price of Pharmasset is irrelevant to the discussion on the appropriate pricing of medications in relation to their development costs, or else any price could be justified based on poor valuations of companies and accounting gimmicks.

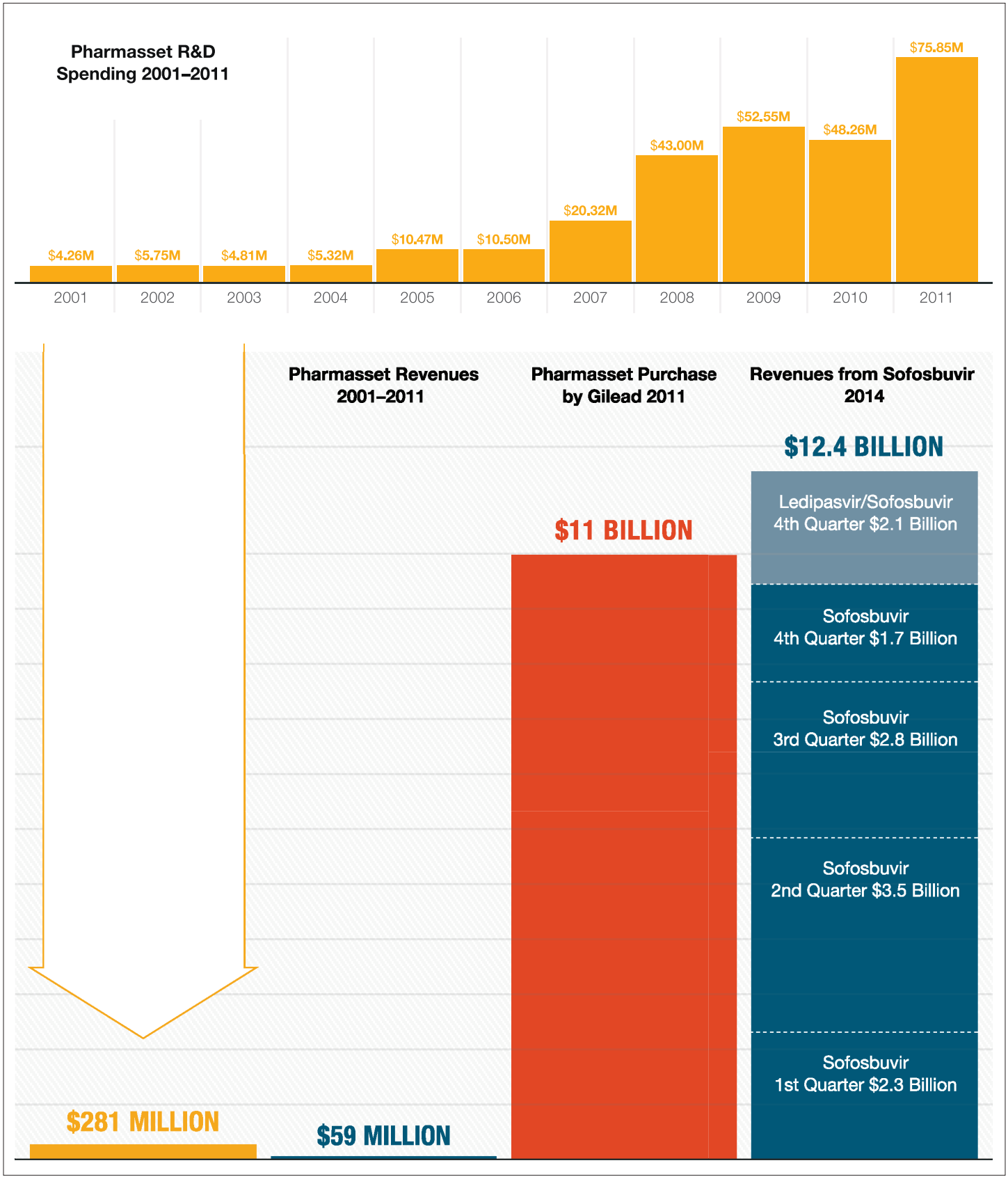
A Call for a Humane Balance Between Profit and Health

Intellectual property law is based on the principle that inventors, including large pharmaceutical companies, require protection from competition in order to incentivize investment in the products they create. The granting of a temporary monopoly is meant to encourage inventors to disclose their inventions and enter them into the market. In the case of pharmaceuticals, these protections have been combined with a policy environment in the U.S. in which pharmaceutical companies have the freedom to price their products, even at extremely disproportionate rates, without fear of government-imposed price controls. This contrasts with the practice in most other countries.[67]

Since its market debut, sofosbuvir alone has had sales revenue of $10.28 billion for Gilead. Including sales of Harvoni (ledipasvir/sofosbuvir), Gilead earned $12.41 billion from sofosbuvir in a single calendar year.

As this brief illustrates, we believe that Gilead should be criticized for the egregious pricing that impinges upon access in the U.S. and around the world. But this issue is bigger than one manufacturer and one health condition. Few pharmaceutical products are developed solely in the laboratories of for-profit corporations. Indeed, many drugs depend on basic research and other findings developed with taxpayer support to underpin or lay the foundations for advances brought to us by modern pharmaceutical

Figure 4. Gilead and Pharmasset: A Disproportionate Investment



manufacturers. When companies such as Gilead, Abbvie and others believe their primary responsibility is to their shareholders, there is a policy imbalance between public sector contributions to research and private sector reward. Therefore, broader structural changes are needed to alter the pricing incentives for manufacturers and not to allow the sky to be the limit for every new drug product, even ones that are as exciting and effective as new hepatitis C treatments.

In the case of sofosbuvir, the manner in which Gilead has both priced the drug and resisted calls for deep discounts to public payors and volume purchasers is legal, but the impact on people who need access to care and the programs that support them is unsustainable and unethical. Since its market debut, Sovaldi alone has had sales revenue of $10.283 billion[68] for Gilead, nearly equaling in a single year the total purchase price of Pharmasset. Including sales of Harvoni, revenue on sofosbuvir for Gilead was $12.41 billion in just 12 months. Gilead has made huge profits from sofosbuvir in less than one year and will continue to own the patent on it through at least 2030.[69] This has grave implications for populations at greatest risk for HCV—racial and sexual minorities, low-income individuals, disenfranchised populations (e.g., people who inject drugs), and (in some cases) the under- or uninsured.

All this is not to deny the groundbreaking achievements pharmaceutical companies have made in science and medicine. Corporations like Gilead have allowed us to advance the fight against the HIV epidemic, to treat and cure numerous other illnesses, and to vaccinate against communicable diseases. But the price of a medication should not be so high that it is virtually inaccessible to the populations that need it most, be it in the United States or around the world. And it should not be so high that it places an unsustainable burden on healthcare systems even in the world's wealthiest nations. Indeed, exorbitant pricing for medications like sofosbuvir continues to move us further away from a national goal of broad access to pharmaceutical products and toward a world in which only the wealthiest can access the best treatments, while others are forced to delay or accept inferior treatment. There must be a better balance between the cost of development and manufacturing, profit margins, and domestic and global public health needs.

There must also be a greater effort—whether on the domestic level through negotiations between countries and pharmaceutical companies or on the international level through modifying current intellectual property systems—to ensure broader access to generic drugs for countries that are frequently excluded from discounted drug pricing agreements. In the fight to gain access to affordable HCV treatment, countries with some of the largest HCV epidemics around the world are being left behind. A change must be made.

References

1. World Health Organization. Hepatitis C Fact Sheet N°164. April 2014. http://www.who.int/mediacentre/factsheets/fs164/en/; Centers for Disease Control and Prevention. *Hepatitis C FAQs for the Public*. http://www.cdc.gov/hepatitis/c/cfaq.htm.
2. World Health Organization. Guidelines for the Screening, Care and Treatment of Persons with Hepatitis C Infection. April 2014. http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf?ua=1&ua=1.
3. Ibid.
4. Ibid.
5. Centers for Disease Control and Prevention. *Hepatitis C FAQs for the Public*. http://www.cdc.gov/hepatitis/c/cfaq.htm.
6. Centers for Disease Control and Prevention. Disease Burden from Viral Hepatitis A, B, and C in the United States. http://www.cdc.gov/hepatitis/pdfs/disease_burden.pdf.
7. The United States began screening blood and organ donations for HCV in July 1992. Centers for Disease Control and Prevention. *Viral Hepatitis Statistics & Surveillance. Historical reported cases and estimates*. http://www.cdc.gov/hepatitis/Statistics/IncidenceArchive.htm.
8. Gonzalez SA and Davis, GL. *Demographics of Hepatitis C Virus Today*. Clinical Liver Disease. March 6, 2012. http://onlinelibrary.wiley.com/doi/10.1002/cld.3/pdf.
9. Injection drug use is the most common means of HCV transmission in the United States. Gonzalez SA and Davis, GL. *Demographics of Hepatitis C Virus Today*. Clinical Liver Disease. March 6, 2012. http://onlinelibrary.wiley.com/doi/10.1002/cld.3/pdf.
10. Centers for Disease Control and Prevention. *Viral Hepatitis Statistics & Surveillance. Historical reported cases and estimates*. http://www.cdc.gov/hepatitis/Statistics/IncidenceArchive.htm.
11. Centers for Disease Control and Prevention, *Viral Hepatitis Surveillance*, 2012 http://www.cdc.gov/hepatitis/Statistics/2012Surveillance/PDFs/2012HepSurveillanceRpt.pdf
12. Witt, et. al., *Incident Hepatitis C Virus Infection in Men Who have Sex with Men: A Prospective Cohort Analysis, 1984-2011*, Clinical Infectious Diseases, 2013:57(1):77-84.
13. Food and Drug Administration, *Prescribing Label: simeprevir*, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/205123s001lbl.pdf
14. Simeprevir ($66,360) + peginterferon alfa ($18,500) + ribavirin ($1,100)
15. Food and Drug Administration, *Prescribing Label: sofosbuvir*, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204671s000lbl.pdf
16. Sofosbuvir ($84,500) + peginterefferon alfa-2a ($18,500) + ribavirin ($1,100)
17. Sofosbuvir ($84,500) + ribavirin ($1,100)
18. Sofosbuvir ($168,000) + ribavirin ($1,100)
19. Food and Drug Administration, *Prescribing Label: ledipasvir and sofosbuvir*, http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205834s000lbl.pdf
20. Food and Drug Administration, *Bulletin, FDA Hepatitis Update, 2014*, http://content.govdelivery.com/accounts/USFDA/bulletins/e45497
21. http://www.hepatitisc.uw.edu/page/treatment/drugs/
22. New York Times, *$1,000 Hepatitis Pill Shows Why Fixing Health Costs Is So Hard*, Aug. 2, 2014, http://www.nytimes.com/2014/08/03/upshot/is-a-1000-pill-really-too-much.html
23. New York Times, *AbbVie Deal Heralds Changed Landscape for Hepatitis Drugs*, Dec. 22, 2014, http://www.nytimes.com/2014/12/22/business/pharmacy-deal-heralds-changed-landscape-for-hepatitis-drugs.html?ref=business&_r=0
24. CNN, *We all pay for $1,000 a pill drug*, Jul. 24, 2014, http://www.cnn.com/2014/07/07/opinion/ignagni-hepatitis-c-drug/
25. Author's calculation utilizing the prevalence data from Figure 2, known discounts, and the following assumptions: 100% of uninsured will be covered by Gilead's Patient Assistance Program; private insurers receive a 46% discount; Medicare part D providers receive a 10% discount, and all prisons (including state prisons) and military personal are covered by the 44% discount Gilead negotiated with the VA.
26. http://www.finance.senate.gov/imo/media/doc/Wyden-Grassley%20Document%20Request%20to%20Gilead%207-11-141.pdf
27. http://democrats.energycommerce.house.gov/sites/default/files/documents/Martin-Gilead-Sciences-Hepatitis-C-Drug-Sovaldi-Pricing-2014-3-20.pdf
28. http://medicaiddirectors.org/sites/medicaiddirectors.org/files/public/namd_sovaldi_letter_to_congress_10-28-14.pdf
29. http://www.hivandhepatitis.com/hcv-policy-advocacy/4979-aasld-2014-1-million-people-with-hepatitis-c-in-the-us-meet-high-priority-criteria-for-treatment
30. National Association of Medicaid Directors, *Letter to Congress,* October 28, 2014, http://medicaiddirectors.org/sites/medicaiddirectors.org/files/public/namd_sovaldi_letter_to_congress_10-28-14.pdf
31. Vlohl & Associates for Medicaid Health Plans of America. *The Sovaldi Squeeze: High Costs Force Tough State Decisions. Coverage Decisions and Restrictions in State Medicaid Programs*. September 29, 2014. http://www.mhpa.org/_upload/SovaldiSqueeze-Oct2014.pdf.
32. Ibid.
33. Sandhya Somashekhar. Washington Post. *Costly hepatitis drug Sovaldi rattles industry*. March 1, 2014. http://www.washingtonpost.com/national/health-science/costly-hepatitis-drug-sovaldi-rattles-industry/2014/03/01/86cab0b4-a091-11e3-9ba6-800d1192d08b_story.html.
34. Tricia Neuman, Jack Hoadley, and Juliette Cubanski. Health Affairs. *The Cost of a Cure: Medicare's Role in Treating Hepatitis C*. June 5, 2014. http://healthaffairs.org/blog/2014/06/05/the-cost-of-a-cure-medicares-role-in-treating-hepatitis-c/.
35. Ibid.
36. Ibid.
37. Ibid.
38. Ibid.
39. Federal Bureau of Prisons. Clinical Practice Guidelines. *Interim Guidance for the Management of Chronic Hepatitis C Infection*. June 2014. http://www.bop.gov/resources/pdfs/hepatitis_c_current.pdf.
40. Wall Street Journal, *New Hepatitis Drugs Vex Prisons*, Apr. 24, 2014, http://www.wsj.com/articles/SB10001424052702304311204579510054146055222
41. Centers for Disease Control and Prevention. *Viral Hepatitis Specific Settings: Correctional Facilities and Viral Hepatitis*. http://www.cdc.gov/hepatitis/Settings/corrections.htm.
42. The Office of the Federal Register estimates the per inmate cost of incarceration at $28,893.40 (https://www.federalregister.gov/articles/2013/03/18/2013-06139/annual-determination-of-average-cost-of-incarceration). Assuming a chronic HCV prevalence of 12% and Sovaldi at $47,040 (44% discount) and treating only 33% of chronic patients, the per inmate cost of incarceration would rise to $30,756.18 or 6%. At high 35% HCV prevalence, the per inmate cost of incarceration would rise to $34,326.52 or 19%. With undiscounted Sovaldi, the per inmate cost increases would be between 12% and 34%.

43. Ibid.
44. Greg Dober. Prison Legal News. *Prisoners Unlikely to Benefit from New, Highly Effective Hepatitis C Treatment*. July 9, 2014. https://www.prisonlegalnews.org/news/2014/jul/9/prisoners-unlikely-benefit-new-highly-effective-hepatitis-c-treatment/.
45. New York Times, A*bbVie Deal Heralds Changed Landscape for Hepatitis Drugs*, Dec. 22, 2014, http://www.nytimes.com/2014/12/22/business/pharmacy-deal-heralds-changed-landscape-for-hepatitis-drugs.html?ref=business&_r=0a
46. New York Times, *Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion*, Feb. 3, 2015. http://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html
47. World Health Organization. Guidelines for the Screening, Care and Treatment of Persons with Hepatitis C Infection. April 2014. http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf?ua=1&ua=1
48. Bill Berkrot and Deena Beasley. Reuters. *U.S. lawmakers want Gilead to explain Sovaldi's hefty price*. March 21, 2014. http://www.reuters.com/article/2014/03/21/gilead-sovaldi-idUSL2N0MI0UP20140321; Steve Miller. Forbes. *The Sovaldi Tax: Gilead Can't Justify the Price It's Asking for Hepatitis C Therapy*. June 17, 2014. http://www.forbes.com/sites/theapothecary/2014/06/17/the-sovaldi-tax-gilead-cant-justify-the-price-its-asking-americans-to-pay/.
49. Bill Berkrot and Deena Beasley. Reuters. *U.S. lawmakers want Gilead to explain Sovaldi's hefty price*. March 21, 2014. http://www.reuters.com/article/2014/03/21/gilead-sovaldi-idUSL2N0MI0UP20140321; Steve Miller. Forbes. *The Sovaldi Tax: Gilead Can't Justify the Price It's Asking for Hepatitis C Therapy*. June 17, 2014. http://www.forbes.com/sites/theapothecary/2014/06/17/the-sovaldi-tax-gilead-cant-justify-the-price-its-asking-americans-to-pay/; Simeon Bennett. Bloomberg. *Gilead's Sovaldi Has Unclear Cancer Benefit, German Agency Says*. May 2, 2014. http://www.bloomberg.com/news/2014-05-02/gilead-s-sovaldi-has-unclear-cancer-benefit-german-agency-says.html.
50. World Bank, Databank, databank.worldbank.org/data/Popular_indicators/id/af3ce82b
51. Internal documents from the United Kingdom's National Health Service have labeled the estimated cost of providing Sovaldi to 20,000 patients "prohibitive." (Pharmafile. Sovaldi 'unaffordable' says NHS documents. July 10, 2014. http://www.pharmafile.com/news/195112/sovaldi-unaffordable-says-nhs-documents.) While some Canadian citizens can access Sovaldi through their private health insurance, none of the provincial health insurance plans are covering the cost of treatment. (CTV News (Canada). *Hepatitis C drugs show promise, but price is too high for most patients*. May 25, 2014. http://www.ctvnews.ca/health/hepatitis-c-drugs-show-promise-but-price-is-too-high-for-most-patients-1.1837917.); Simeon Bennett. Bloomberg. *Gilead's Sovaldi Has Unclear Cancer Benefit, German Agency Says*. May 2, 2014. http://www.bloomberg.com/news/2014-05-02/gilead-s-sovaldi-has-unclear-cancer-benefit-german-agency-says.html.
52. Maggie Fick and Ben Hirschler. Reuters. *Gilead offers Egypt new hepatitis C drug at 99 percent discount*. March 21, 2014. http://www.reuters.com/article/2014/03/21/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321.
53. NATAP, *Sovaldi Global Access*, http://www.natap.org/2014/HCV/041414_02.htm
54. Sean Mclain and Jonathan D. Rockoff. Wall Street Journal. *Gilead to Allow Cheaper Hepatitis C Drug in Developing Countries*. September 15, 2014. http://online.wsj.com/articles/gilead-to-allow-cheaper-hepatitis-c-drug-1410779963.
55. Hill A, Khoo S, Fortunak J, Simmons B, Ford N. *Minimum costs for producing hepatitis C direct-acting antivirals for use in large-scale treatment access programs in developing countries*. Clin Infect Dis. 2014 Apr;58(7):928-36.
56. MSF, *Barriers to access and scale up of Hepatitis C (HCV) treatment – Gilead's Anti–diversion program MSF Briefing document*, December 2014
57. Lavanchy, D. *Evolving epidemiology of hepatitis C virus*, Clin Microbiol Infect 2011; 17: 107–115 (2011). http://onlinelibrary.wiley.com/doi/10.1111/j.1469-0691.2010.03432.x/full
58. http://164.100.176.38/decision/6087-DELNP-2005-8837/6087DNP2005.pdf
59. http://patentoppositions.org/drugs/51dfee9097961f0002000020
60. http://spicyip.com/2015/01/gilead-to-appeal-sofosbuvir-patent-rejection.html
61. Securities and Exchange Commission, *Pharmasset 10-K For the Fiscal Year Ended September 30, 2011*, http://www.sec.gov/Archives/edgar/data/1301081/000119312511311300/d225717d10k.htm#tx225717_8
62. Securities and Exchange Commission, *Pharmasset Selected Consolidated Financial Data*, http://sec.edgar-online.com/pharmasset-inc/s-1-securities-registration-statement/2006/05/08/section15.aspx
63. Securities and Exchange Commission, *Pharmasset 10-K Filings*, http://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0001301081&type=10-K&dateb=&owner=exclude&count=40
64. Ibid.
65. U.S. National Institutes of Health, *Clinical Trials Database*, https://clinicaltrials.gov/ct2/results?term=sofosbuvir&Search=Search
66. Securities and Exchange Commission, *Pharmasset 10-K For the Fiscal Year Ended September 30, 2011*, http://www.sec.gov/Archives/edgar/data/1301081/000119312511311300/d225717d10k.htm See also: Gane, E, et al., *Nucleotide Polymerase Inhibitor Sofosbuvir plus Ribavirin for Hepatitis C*, N Engl J Med 2013; 368:34-44 (2013), http://www.nejm.org/doi/full/10.1056/NEJMoa1208953 (published subsequently).
67. John A. Vernon. Health and Medicine. *Drug Research and Price Controls*. Winter 2002 – 2003. http://object.cato.org/sites/cato.org/files/serials/files/regulation/2002/12/v25n4-7.pdf.
68. Gilead Sciences, *Fourth Quarter and Full Year 2014 Financial Results,* 3 Feb, 2015: http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle&ID=2013213
69. Generic Sovaldi Availability http://www.drugs.com/availability/generic-sovaldi.html

amfAR

MAKING AIDS HISTORY

amfAR, The Foundation for AIDS Research
www.amfar.org

Public Policy Office
1150 17th Street, NW
Suite 406
Washington, DC 20036
USA
+1.202.331.8600

Washington Post

http://www.washingtonpost.com/national/health-science/medicare-spent-45-billion-on-new-hepatitis-c-drugs-last-year-data-shows/2015/03/29/66952dde-d32a-11e4-a62f-ee745911a4ff_story.html

New hepatitis C drugs are costing Medicare billions

By Charles Ornstein | ProPublica March 29, 2015

The hepatitis C medication Sovaldi costs $84,000 for a 12-week course of treatment and accounted for more than $3 billion in Medicare spending. (Courtesy of Gilead Sciences/AP)
By Charles Ornstein | ProPublica March 29

Medicare spent $4.5 billion last year on new, pricey medications that cure the liver disease hepatitis C — more than 15 times what it spent the year before on older treatments for the disease, previously undisclosed federal data shows.

The extraordinary outlays for these breakthrough drugs, which can cost $1,000 a day or more, will be borne largely by federal taxpayers, who pay for most of Medicare's prescription drug program. But the expenditures will also mean higher deductibles and maximum out-of-pocket costs for many of the program's 39 million seniors and disabled enrollees, who pay a smaller share of its cost, experts and federal officials said.

The spending dwarfs the approximately $286 million that the program, known as Part D, spent on earlier-generation hepatitis C drugs in 2013, said Sean Cavanaugh, director of Medicare and deputy administrator at the Centers for Medicare and Medicaid Services (CMS).

The most-discussed of the new drugs, Sovaldi, which costs $84,000 for a 12-week course of treatment, accounted for more than $3 billion of the spending. Spending on another drug, Harvoni, hit $670 million even though it came on the market only in October. Bills for a third drug, Olysio, often taken in conjunction with Sovaldi, reached $821 million.

Medicare also spent $157 million on older hepatitis C drugs in 2014, bringing the total spending for the category to more than $4.7 billion.

The spending surge is unlike anything Part D has seen. The nine-year-old program has benefited in recent years from a slowdown in prescription drug costs as several blockbusters, including the cholesterol-lowering drug Lipitor and the blood thinner Plavix, lost patent protection and have faced competition from generics.

The new hepatitis C drugs, along with other expensive specialty medications in the pipeline, threaten to drastically increase the program's costs. The federal government spent $65 billion on Part D in 2013, according to the Medicare Payment Advisory Commission. That figure doesn't include monthly premiums paid by patients.

An analysis published last year on the Web site of the health-policy journal Health Affairs suggested that 350,000 Medicare beneficiaries have hepatitis C, although many don't know it.

It generally takes the government more than a year to compile data on drug spending, but CMS provided the data on hepatitis C drugs to ProPublica in response to a Freedom of Information Act request and follow-up inquiries.

Medicare officials said they are watching the costs carefully, and early indications suggest that this year's spending is on track to match or even exceed last year's, Cavanaugh said.

"We're all waiting to see when it plateaus or when it possibly goes back down," he said in an interview. "When will that pent-up demand be sated?"

Medicare's costs for the drugs, at least in 2014, appear to be far higher than those incurred by state Medicaid programs for the poor, which collectively spent $1.2 billion on the drugs in the first nine months of the year. (This data is preliminary; data for the entire year is not yet available.)

Many Medicaid programs, as well as private insurance companies, took a more restrictive approach toward the drugs than Medicare did, often requiring that patients have advanced liver disease to be eligible to receive the pills.

Medicare has a more permissive standard, requiring the insurance companies that administer Part D on its behalf to cover medically necessary drugs for any indication approved by the Food and Drug Administration or recommended in clinical guidelines.

The new hepatitis C drugs have a higher cure rate — 90 percent or higher — than previous treatments, as well as fewer harmful side effects. Some studies have shown that, despite their price tag, the drugs justify their cost based on the better quality of life they provide and the health expenses that patients avoid in the future.

"Curing hepatitis C will likely go on to prevent liver cancer, go on to prevent patients needing liver transplantation, go on to save health-care dollars down the road," said Adam Peyton, a liver specialist at the University of Miami Health System in Florida who prescribed $13.5 million worth of hepatitis C drugs in Part D last year. "It's upsetting that there's been so much negative publicity for such a positive breakthrough in medicine."

Still, the drugs may not save money for Medicare, even in the long run. A recent study in the Annals of Internal Medicine suggested that only about one-quarter of the $65 billion needed to pay for the new drugs for eligible patients (not just those on Medicare) would be offset by avoiding hospitalizations and other treatment costs. The vast majority of patients with hepatitis C do not go on to get liver transplants.

Federal taxpayers cover the preponderance of the cost of treating patients in Part D, but enrollees also have to pick up a share, which can vary based on their drug usage. Once a Medicare enrollee spends $4,700 out of pocket on drugs — in this case, just a few days of a prescription — "catastrophic" coverage kicks in. At that point, Medicare picks up 80 percent of the cost, the health plan pays 15 percent, and the patient pays the remaining 5 percent.

Some costs probably will be passed along to Medicare beneficiaries who do not have hepatitis C, in the form of higher deductibles and maximum out-of-pocket costs, said Jack Hoadley, a research professor in the Health Policy Institute at Georgetown University.

For example, next year the standard drug deductible in the program — the amount a patient has to spend before coverage kicks in — will increase to $360 from $320.

Sen. Bernard Sanders (I-Vt.) has been a critic of the high price of the new drugs, particularly Sovaldi. "The cost of Sovaldi is not only an economic issue in terms of the impact of the cost of this drug on the VA, on Medicaid, on Medicare, it is a moral issue, and that is how many people in this country will suffer, how many will die very painful deaths because of the excessive costs of this particular product," Sanders said in a written statement to ProPublica.

This year, an additional competitor has come on the market, the Viekira Pak made by AbbVie, giving insurance companies leverage to negotiate larger rebates in exchange for a spot on their preferred-drug lists. Those rebates can slice 40 percent to 50 percent off the list prices of the drugs.

The law that created Medicare Part D does not allow the government to negotiate rebates directly, but it allows the private insurance companies that administer the program to do so. Details of the rebates are confidential.

Gilead Sciences, the maker of Sovaldi and Harvoni, has defended its prices, saying they are fair given the value the drugs provide to patients. In a statement, the company said that it has "established one of the most comprehensive patient assistance programs in the industry to help ensure cost is not a barrier to Sovaldi and Harvoni for patients in the U.S. with high co pays or who lack adequate insurance."

Medicaid experts acknowledge that anticipated legal challenges may compel state Medicaid programs to stop rationing the new drugs.

Medicare patients with hepatitis C recognize how much the drugs cost but say the results have changed their lives.

Robert Serrano, 61, one of Peyton's patients, who said he is on Medicare because he is disabled, said Sovaldi cured him. He had a liver transplant in October 2008, but the disease had started to attack his new liver.

"It was a long road for me with this condition that I had and the medications," he said. "Now at least I'm able to cut grass and do the little things I didn't do in life. It's been a blessing."

ProPublica is an independent, nonprofit newsroom that produces investigative journalism in the public interest. A version of this article is available at www.propublica.org. ProPublica data reporter Ryann Grochowski Jones contributed to this report.

10:17 am ET
May 26, 2015 HEPATITIS C

Consumers Sue Anthem for Denying Coverage for a Gilead Hepatitis C Drug

ARTICLE COMMENTS (24)

PREVIOUS
Pharmalot.. Pharmalittle.. Good Morning: We're Catching up on AstraZeneca, Glaxo and Lots More!!

NEXT
Pharmaceutical Industry Must Pay for Drug Take-Back Programs

ABBVIE ANTHEM BLUE CROSS FIBROSIS GILEAD SCIENCES HARVONI HEPATITIS C

Email Print 69 50

SEARCH PHARMALOT

By ED SILVERMAN

— Max Whittaker/Prime for The Wall Street Journal

The controversy over the new crop of hepatitis C treatments has taken yet another turn as consumers are starting to file lawsuits against insurers that deny them access to the medicines. Over the past two weeks, two different women alleged that Anthem Blue Cross refused to pay for the Harvoni treatment sold by **Gilead Sciences** GILD +2.25% because it was not deemed "medically necessary."

The issue emerges after more than a year of debate over the cost of the medicines and complaints by public and private payers that the treatments have become budget busters. The new hepatitis C treatments, which are sold by Gilead Science and AbbVie, cure more than 90% of those infected and, in the U.S., cost from $63,000 to $94,500, depending upon the drug and regimen, before any discounts.

In response, drug makers have been pressured to offer discounts and some state Medicaid programs, for instance, set restrictions before providing coverage to some hepatitis C patients. By setting restrictions, payers hope to limit the number of patients for whom coverage is provided. And this is the tack that Anthem Blue Cross has pursued, according to court documents.

Both lawsuits claim the insurer denied coverage for Harvoni, one of two hepatitis C treatments sold by Gilead, because the amount of liver damage sustained by the women was insufficient to warrant payment for the drug. In both cases, the insurer decided that Harvoni was not medically necessary, according to the lawsuits.

"We may approve Harvoni when the liver has a certain amount of scarring on a liver biopsy. Records we received do not show that your liver has this amount of scarring on a liver biopsy," the insurer wrote last October in a **denial letter** to Shima Andre, a freelance book editor, who filed a **lawsuit** earlier this month in California state court.

"My doctor applied on my behalf three times and he was denied three times," she tells us. "My liver doesn't have any damage yet, but that's the whole point – I want to keep it that way. The drug would prevent the damage that the insurance company wants me to have before they approve the treatment. It's backwards. "

In both lawsuits, the women claim they have suffered physical injuries, emotional stress and economic damages, among other things. The law firm representing Andre, by the way, also represents the other woman who filed **a lawsuit** against Anthem.

About Pharmalot

Pharmalot explores the fast-moving, complicated world that develops and markets medicines – and the drug makers that are attempting to replenish their pipelines while grappling with pricing and regulatory dictates, among many other challenges. Writer Ed Silverman has covered the pharmaceutical industry for nearly two decades and has closely followed the many hurdles facing drug companies as they move ideas from the

An Anthem spokesman declined to comment on the lawsuits, specifically, but he did write us that "the newer hepatitis C drugs have been approved through the FDA breakthrough therapy process and tested in fewer people than typical clinical trials, which means our knowledge is more limited on these drugs.

"Given the concerns and relative benefits and harms [of the drugs], our benefits support coverage for members with more advanced stages of liver disease and those at highest risk for liver complications. Broader use of these drugs and knowledge about the long term effects and potential harms and outcome of various alternative therapies are needed on those with limited effects of infection."

Experts say the lawsuits are not surprising, and that more can be expected. "It's every man for themselves and insurance carriers will do whatever they can do to minimize their cost of doing business, including coverage provision interpretation," says Randy Vogenberg a partner at Access Market Intelligence, a consulting firm that specializes in managed care.

"Inevitably, coverage will result in lawsuits given the aggressive nature of the legal community in health care that will erode health plan defenses on financial payouts," he continues, noting that there is "a long history of this chess game" dating back to the consumer backlash that erupted more than 20 years ago with the emergence of health maintenance organizations.

ABBVIE ANTHEM BLUE CROSS FIBROSIS GILEAD SCIENCES HARVONI HEPATITIS C PRESCRIPTION DRUG COSTS PRESCRIPTION DRUG PRICES SOVALDI VIEKIRA PAK

PREVIOUS
Pharmalot.. Pharmalittle.. Good Morning: We're Catching up on AstraZeneca, Glaxo and Lots More!!

NEXT
Pharmaceutical Industry Must Pay for Drug Take-Back Programs

PHARMALOT HOME PAGE

Add a Comment

NAME

We welcome thoughtful comments from readers. Please comply with our guidelines. Our blogs do not require the use of your real name.

COMMENT

CLEAR POST

Comments (5 of 24)

View all Comments »

11:10 am May 27, 2015

Anonymous wrote:

I was cured with sovaldi , my insurance denied coverage of course, Gilead provided it to me for $5. I spent over $300,000 on health insurance and have been denied coverage for most everything. In one instance I had to turn anthem into my state attorney general to get them to pay. I hope they are forced to provide the services that they get paid for. Extortion and murder is a crime I would like to see charges filed against the the insurance companies

9:11 am May 27, 2015

jvalenti wrote:

My heart doctor at Mass General has been practicing for 50 years.They tell him medication he's giving me is outdated.He told them to stick to insurance and leave doctoring to him they approved.

8:53 am May 27, 2015

Anonymous wrote:

Gilead is too greedy

10:55 pm May 26, 2015

ron wrote:

Its to be expected. Very expensive drug and needless to say, very profitable for the drug

laboratory to the medicine chest. He started Pharmalot while at The Star-Ledger of New Jersey and previously worked at New York Newsday and Investor's Business Daily. Email Ed Silverman at **ed.silverman@wsj.com**, and follow him on Twitter **@Pharmalot**.

Popular Now

What's This?

Mobile Isn't Killing the Desktop Internet

2 CFOs Seek to Avoid Bite of Health Law's 'Cadillac Tax'

Indian Heat Wave Kills Over 1,100

At MIT, Mastering the Science of Working from Home

For Hardee's and Carl's Jr., Sex Sells

Show 5 More

Pharmalot Blogroll

Generic Pharmaceutical Association
National Institute for Health and Care Excellence
National Institutes of Health
PhRMA
U.S. Food and Drug Administration

Video

Matthew Modine Discusses 'Proof' 4:02

'Pitch Perfect 2' Screenwriter Offers Inside Look 3:46

Film Clip: 'I'll See You in My Dreams' 0:38

companies.

10:00 pm May 26, 2015

Jeff wrote:

I have Blue Cross in Florida and developed liver cancer as a result of Hepatitis C. I had to appeal twice before I was approved for treatment. The insurance companies rationale for denying coverage was absurd. They did not think my scarring was severe enough. They believe that severe scarring causes cancer. I already had cancer and the Harvoni was part of my cure.

Subscribe / Sign In Back to Top

Subscribe
Why Subscribe?
WSJ+
Corporate Subscriptions
Apps
Professor Journal
Student Journal

Customer Service
Customer Center
Live Help
Redesign Guided Tour

Tools & Features
Emails & Alerts
Guides
My News
Portfolio
RSS Feeds
Topics
Video Center
Watchlist

Ads
Advertise
Advertise Locally
Commercial Real Estate Ads
Place a Classified Ad
Sell Your Business
Sell Your Home
Recruitment & Career Ads

More
Conferences
Content Partnerships
Corrections
Jobs at WSJ
Make Time
News Archive
Register for Free
Reprints

Privacy Policy Updated 5/5/15 Cookie Policy Updated 5/5/15 Copyright Policy Data Policy Subscriber Agreement & Terms of Use Your Ad Choices