

Erica Kaufman, MD

Hepatitis C Task Force Meeting

17 September 2014

My name is Erica Kaufman, and I'm an infectious disease physician in Carbondale. I was born and raised in Dolton - a south suburb of Chicago. I know what it is to live in a well-populated Cook County suburb, and I know what it is to work in a rural area. There are 240,000 people in the 7 counties around Carbondale. This encompasses approximately 2,500 square miles. In contrast, Cook County has 5.2 million people in 946 square miles. The average income is almost \$20,000 less than in Cook County. Southern Illinois is a beautiful part of the state, and it is very different than the rest of the state.

One of the major challenges in a rural setting is recruiting physicians and specialists. In the 2010 Illinois New Physician Workforce Study, only about 2% of residents/fellows who planned to stay in Illinois were interested in practicing in a rural location.

According to our data, there are 3 ID physicians and 9 Gastroenterologists serving these 7 southern counties. This is a large population that is required to travel a great distance to see a specialist. Many of our patients' primary care providers are midlevels - physician assistants and nurse practitioners. In my 4 years in Carbondale, I have been referred about 400 patients with Hep C. The number of referrals has been increasing each year.

In my experience, primary care physicians and midlevels are not knowledgeable about Hepatitis C screening and follow up. About 10% of the referrals I see have undetectable RNA - the primary provider either did not know to get an RNA for follow up or did not know that an undetectable RNA means that there is no active disease. This is a waste of time for the patients (many of whom have taken off work and driven long distances to see me). It also takes a clinic appointment away from someone else who needs it. I see many patients whose PCPs told them that HCV is not curable and give misinformation about routes of transmission. I would like to ask the Task Force to develop educational materials for PCPs, so they know the proper work up for Hepatitis C, the need to provide Hepatitis A and B vaccines, and the need to test for other similarly transmitted infections such as HIV. They need to know to educate their patients on the mode of transmission, how to keep their families safe, how alcohol exacerbates fibrosis and the importance of seeing a specialist for follow up.

One point to include in education is needle exchange programs. PCPs do not know about needle exchange programs for their patients who are still using. The Illinois Department of Public Health (IDPH) supports a needle exchange program, but it is not publicized. I cannot find any information on the IDPH website. If I can't find it, and I'm looking for it, how will anyone else find it? I just found out a few weeks ago that our pharmacies have kits for people who bring in clean needles; our local health department has tried to drop some off at each pharmacy. While I would love to for every addict to be sober, the reality is that some are not ready and we do not have enough Suboxone providers for those

who do want to get clean. We need to protect our communities through needle exchange programs and publicize them. With 75% of people who have Hep C not knowing their status, it is our responsibility to make sure people at the highest risk are protected.

My next concern to raise to the Task Force is the large stigma around Hep C. I have grandmothers who break down in my office because they've been forbidden to see their grandchildren for fear of spreading the virus. I've had wives who have moved out of their bedrooms when their husbands were diagnosed. There is a great deal of misinformation about the transmission and risk factors for Hepatitis C. The general public seems to have this notion that people with Hepatitis C are bad and dirty people. Most people who have been diagnosed with Hepatitis C have put those risky behaviors behind them. For many patients, Hep C is a large psychological drain. It reminds them of poor decisions they have made, it reminds them daily of their mortality, and it reminds them that they are infectious. I think that the psychological aspect is overlooked by physicians and policy makers. Imagine being told you have a disease that may cause cancer and organ failure and that you might on accident expose those you love to the same fate, you can probably imagine the sense of helplessness and hopelessness that people with Hep C feel. With very few psychiatrists in rural areas, and even fewer taking Medicaid, providers like myself are turning into therapists and trying to manage the depression that living with Hepatitis C brings with it.

One thing Hep C suffers from is lack of a spokesperson or organization. There is no group committed to fighting for their rights or on their behalf. We saw with the HIV epidemic that people came together to fight the misconceptions and to show that people with HIV are not dissimilar to the average American. We need to show the diversity of Hep C. We need someone to stand up and say, "I have Hep C" or "I had Hep C" and "let me tell you about this disease."

Both gastroenterologists and infectious disease physicians are familiar with Hepatitis C, and treating patients with Hepatitis C requires a lot of time from both the physician and the staff. It is important to know the patient, their home situation, their sobriety, their financial situation, etc. It's important to know the patient well enough to know if they are ready for treatment, to know what assistance they are going to need, to know how to trouble shoot ahead of time to help with compliance. In Southern Illinois, and likely in other rural areas, specialists are rare and our schedules are saturated. Our GI doctors are busy with outpatient procedures, hospital call, as well as clinic. My partner and I care for HIV as well as hepatitis patients. We do not have procedures to work around, so a lot of the hepatitis C treatment has fallen on our shoulders.

I am sure the Task Force is familiar with the 26 criteria Medicaid requires prior to treatment. These criteria for treatment are extremely narrow and limited. I understand the cost, and I am not here to debate the fairness of the pricing. I am submitting an article that touches on the health economics of the pricing of a novel, curative drug like sofosbuvir. When I fill out the 3 pages of questions, have patients sign the 2 page treatment contract, attach several pages of lab values and results, there is a small booklet that is faxed to the black box that is the Medicaid approval people. We will get, almost every time, a denial for some reason or another. The fibrosis score is too low, the patient admitted to marijuana use, the patient's wife is pregnant. We do not have case managers to manage this, so the

gathering of pages, faxing and waiting for denials falls on myself and my nurse. I then have to draft a letter and make phone calls to plead the patient's case. When I talked to one of the approval pharmacists about why there were so many criteria, she said that if we appeal, they will likely overturn a fair number of them. I do not have hours to spend on writing appeals and making phone calls. I have already spoken with one of our gastroenterologists who wants to start deferring his Hep C referrals to me, because he doesn't have the time to jump through the multiple hoops. This will place an even larger burden on me and my nurse as we try and manage denials and appeals for even more patients.

One of the things that doesn't make sense to me is the core criteria of only treating those with Metavir Stage 4 (cirrhosis). There are many problems with this, as I'm sure the physicians on the Task Force know. First is the selection bias of a biopsy and the lack of specificity of the FibroSure test. I have patients with rock-hard livers, platelets of 90k and INRs of 1.7 who have a biopsy stage 1 and FibroSure score that's less than 4. However, when I fill out that form they will get denied. The bigger picture is why we are not treating those with Stage 2 and 3 so they can avoid progressing to Stage 4. While some people with cirrhosis will have regression to a lower fibrosis score, many people will not and their risk for Hepatocellular Carcinoma remains elevated. Why are women of child bearing age being denied when there is a 5-7% risk of mother-to-child transmission? Why are people who smoke marijuana being denied, when Hep C is on the list of approved illnesses for medical marijuana? As a physician I have to gauge my patient's ability to be compliant with any medical regimen. I will not put an IV line in and arrange IV antibiotics for a patient who is homeless or whose home situation is in question. I will not start someone on HIV meds if they are active drug abusers, because I know how importance compliance is and how difficult it is to be compliant when you are getting high. Treating Hepatitis C patients like they are criminals - asking for drug testing before and during treatment in a sober patient with a remote history of drug use - is demoralizing to the patient, expensive for the state and yet another test for me to wait for and package up. I am not sure why these patients are being subjected to a special level of scrutiny. My HIV patients who will be on very expensive medications for the rest of their lives - they do not have to endure the questions and prying that my Hep C patients do. They do not have to wait until they meet AIDS criteria to get lifesaving antiretrovirals. My cancer patients who take very expensive medications that often have side effects requiring hospitalization - they do not have to agree to complete sobriety and random drug testing. My patient with lung cancer is still smoking, he didn't have to sign a paper saying he'd be tobacco free and agree to random nicotine testing. My patients with rheumatoid arthritis who take expensive immunomodulating medications - they do not have to ask for their medications every 2 weeks and fear that if something goes wrong and they are a day late in ordering, their treatment will be terminated. What other group of ill patients has to ask for refills every 2 weeks, trusting an organization to send their meds - despite a weekend or holiday? If the Task Force endorses these policies that treat Hep C patients with such contempt, we cannot gain their trust to engage in medical care and we cannot hope that the lay public will be any more excepting of them than we seem to be.

Patient's with Hepatitis C have been suffering for years. They suffered when Peg-Riba had a success rate of a whopping 30%. They suffered when we warehoused them while the protease inhibitors were being studied. They suffered through those PI regimens with success rates of 60% and more side effects on

top of the Peg-Riba reactions. Now they are suffering as we dangle cure rates of 90% in front of them, but we withhold the drugs because they are not sick enough. Hepatitis C patients are some of the bravest people I know. They come to my office and admit their past mistakes. They shoulder the embarrassment and shame of choices they made when they were too young to care. They face the stigma of Hep C from their loved ones and communities with strength. Some of my patients have endured multiple rounds of Peg-Riba and failed PI therapies, and they don't complain about the side effects or the failures. They live with months of nausea, fatigue and mood swings with rare complaining. They take erythropoietin shots when I tell them to, they get labs done weekly and will even go for a blood transfusion if I ask. They are begging to be cured. The current treatment options offer most of our patients a 90% chance of a cure - of never having to worry when they cut themselves or enter a new relationship. A 90% chance of having the psychological boulder lifted from their shoulders. A real chance at allowing their livers to heal themselves.

I implore the Task Force to look at all of the aspects of Hep C and to keep in mind those communities that are not in urban or suburban areas. I would like to ask for better education for PCPs, including needle exchange program. I would like to ask the Task Force to look for a spokesperson or group that can be the face of HCV and to be the advocate that these patients have longed for. I would like to ask for relaxed Medicaid treatment criteria so that more people can get approved with the first submission. Please do not release 2 weeks of medication at a time, that just sets up people to fail when we should be doing everything we can to help them finish this expensive and life changing treatment.

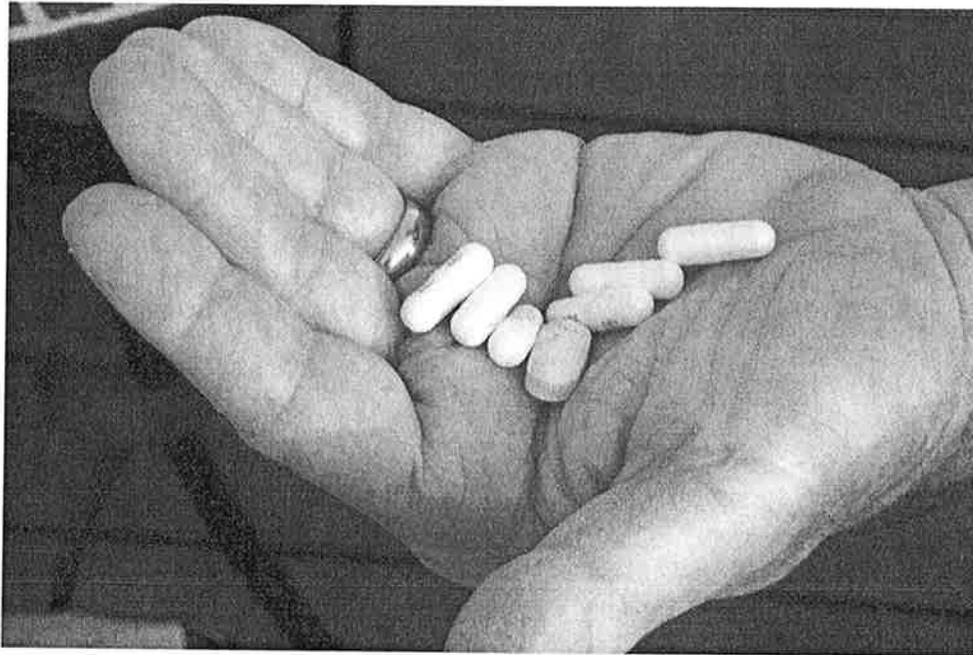
Thank you for allowing me to come before you as a rural physician, as a concerned citizen and as a voice for my patients.

Vox

Each of these Hepatitis C pills cost \$1,000. That's actually a great deal.

Updated by Sarah Kliff on July 16, 2014, 4:30 p.m. ET

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There's a new drug on the market that costs \$84,000 for a full dose of treatment. Most Americans think it's far too expensive — but health economists say it's a great deal.

Sovaldi, the new Hepatitis C treatment released earlier this year by pharmaceutical company Gilead, has been harshly criticized for its hefty price tag, which works out to about \$1,000 per pill. Four in five Americans

think the price is too high.

Sens. Ron Wyden (D-Ore.) and Chuck Grassley (R-Iowa) sent Gilead a [sharp letter](http://www.finance.senate.gov/imo/media/doc/Wyden-Grassley%20Document%20Request%20to%20Gilead%207-11-141.pdf) (<http://www.finance.senate.gov/imo/media/doc/Wyden-Grassley%20Document%20Request%20to%20Gilead%207-11-141.pdf>) Friday asking it to justify Sovaldi's high price. The \$84,000 price, they write, "appears to be higher than expected given the costs of development."

*"WOULD I
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Sovaldi was the topic du jour at the American Society of Health Economists' conference a few weeks ago in Los Angeles. But talking to people who think about drug prices for a living, I got a decidedly different take: Sovaldi, many of them argued to me, is exactly the type of drug we should reward with high prices.

"Would I rather be spending \$600,000 for a liver transplant and living a restricted life afterwards, or would I rather pay \$80,000 up front and guarantee I never have to go through that?" says Dana Goldman, executive director of University of California's Schaeffer Center for Health Policy and

Economics. "In that context, it doesn't look like such a bad deal."

Economists argue that there's a tension in setting the price for a breakthrough drug like Sovaldi. We want to encourage more pharmaceutical companies to pursue similarly big developments — a cure for Alzheimer's, for example, or diabetes — but also want patients to have access to those treatments. When push comes to shove though, many prefer that we err on the side of higher prices as a way to encourage other big, blockbuster drugs in the future.

Sovaldi is a breakthrough medical treatment





French activists protest the price of Gilead's new Hepatitis C treatment (Sylvain Golden / AFP)

Hepatitis C can be a completely manageable condition for some patients – and debilitating for others. More Americans are now killed annually by the virus, which affects just over 3 million Americans, than AIDS. Hepatitis C is the leading cause of liver transplants in the United States as well.

HEPATITIS C NOW KILLS MORE PEOPLE THAN AIDS. SOVALDI CURES IT.

The idea of a Hepatitis C cure is a significant innovation over the treatments that exist now, which rely on interferon proteins. Those medical regimes only worked for about half of patients (<http://www.medicalnewstoday.com/articles/275484.php>) and, even when successful, took longer and had worse side effects.

Most new drugs that come out annually aren't these type of breakthroughs. They are often tiny, incremental tweaks to existing treatments, like when AstraZeneca replaced Prilosec, its original blockbuster heartburn drug, with Nexium. Nexium didn't offer much in the way of better outcomes (<http://online.wsj.com/news/articles/SB1023326369679910840>) — but it did give AstraZeneca an exclusive, brand name product it could sell just as Prilosec's patent expired.

Most drugs we're familiar are also different from Sovaldi in another way: they offer treatment rather than cure. Insulin, for example, will help diabetics

THE SAME

manage their blood sugar levels without remedying the root issues. Sovaldi is a cure: in 97 percent (<http://seekingalpha.com/article/2007521-the-hep-c-race-is-heating-up-abbvie-vs-gilead>) of cases, it eliminates the Hepatitis C virus altogether. That could prevent the need for liver transplants in more severe cases, which can cost hundreds of thousands of dollars.

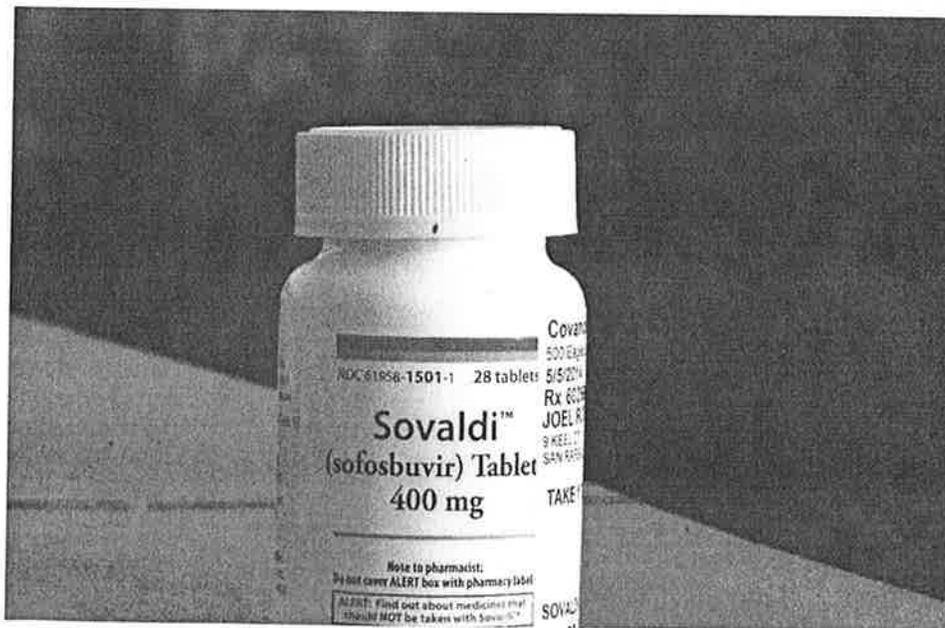
*THING THAT
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The same things that make Sovaldi so important to patients — and groups advocating for access — are what make the drug expensive. Its a breakthrough treatment that's highly valuable.

The economic case for expensive, life-saving drugs

Consumer groups have argued that the importance of this drug is a reason to charge less. But health economists make the opposite case: this is the type of innovation that should net pharmaceutical companies a large pay day, because its so much more meaningful than the drugs that make tiny, incremental advances.

"Pharmaceutical companies get criticized for lots of things like that," Craig Garthwaite, a health economist at Northwestern University's Kellogg School of Management, says. "This is an actual innovation, and that is something that they should get a reward for."





One very expensive bottle of pills (MCT)

As an economist, Garthwaite worries about what would happen if the price of Sovaldi fell dramatically. The drug would likely become more available to patients — although that looks to be an event in progress already, with some of Gilead's competitors expected to release similar Hepatitis C treatments within the next week.

The incentive for companies to create really blockbuster, breakthrough treatments would be smaller. Pharmaceutical companies are not, to nobody's surprise, benevolent non-profits. They're in the drug-making business to for the big paydays that come with a medication like Sovaldi.

"It becomes a policy question, of what we're willing to trade for less innovation," he says. "We have to be very careful because the benefits to innovation are huge. And this is really the hardest question we have in health economics is this efficiency dilemma."

The hard question to answer here is how much a pharmaceutical company — Gilead or otherwise — needs to net in reward to keep pursuing big, innovative drugs. Would a \$40,000 price tag be enough? What about \$60,000? The company is, after all, selling the drug for just \$900 (<http://www.bloomberg.com/news/2014-04-10/emerging-markets-pay-1-of-u-s-price-for-gilead-sovaldi.html>) some developing countries like Egypt. Why can't Americans have the same deal?

The health economists I spoke acknowledged this was a difficult problem, but generally preferred to err on the side of slightly overpaying, largely out of worry about the effect of undercutting innovation. The higher prices that the United States pays, their argument goes, is what makes it desirable to keep developing really blockbuster drugs — particularly those that patients won't have to take forever.

WHAT TYPE OF PROFITS DOES

"They're developing a product that's a cure that will essentially put their own treatments out of business," USC's Goldman says. "We'd love for pharmaceutical companies to come up

PHARMA NEED TO KEEP PURSUING BIG, INNOVATIVE DRUGS?

with a treatment that cures diabetes rather than just treats it. I want to pay them enough so it's possible they'll start working on cures rather than treatments."

Sovaldi could have decided to price its drug at \$40,000, as advocates would like. It could have also, hypothetically, gone higher (one J.P. Morgan analyst estimated in 2013 that Gilead could sell Sovaldi for upwards of a half-million). Gilead doesn't release internal discussions on drug pricing, but it's likely that the company decided \$84,000 is what the market here would pay for its new treatment.

At the end of the day, insurers and Medicaid agencies have the final trump card here. They could put their foot down, deny coverage for the drug and let massive protests from patients' ensue. But they haven't done that: while many publicly oppose the high price, they have also decided it's something they need to offer patients. And, even though they don't like the high price for Sovaldi, at the end of the day, they're willing to pay for the value it provides.

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