My Fight for a Hepatitis C Cure

December 20, 2012 By Lynda Dee

I thought I had dodged a bullet. I had stopped using heroin intravenously in the early ’70s and tested HIV negative. My husband wasn’t so lucky – he died of complications from AIDS in 1987, two years after our son died from SIDS. I started going to Narcotics Anonymous and Alcoholics Anonymous after my husband died, and I still go to about four meetings a week. I have a real compulsive personality and need all the help I can get.

But once I got back on my feet, I had to face another problem. All of my friends have been gay since I stopped using heroin. They were so good to me, rescuing me from my former life. So when they started getting sick, it was my turn to help them. I also experienced a very real fear of abandonment. My dearest friends were going to leave me, but they weren’t going anywhere if I could help it. I was all about trying to control the situation. I believed that if the government could put a man on the moon, they could find a cure for HIV. For the most part, nobody in power really cared about the group of people who were affected by HIV: first gay men, then IVDUs and people of color. I had been an activist in high school, protesting the Vietnam war. I am an old leftie and I am good at it. So, before my husband died, we founded AIDS Action Baltimore (AAB) – and I’m still the AAB President 25 years later.

Then in 1996, I experienced yet another blow. I was diagnosed with breast cancer. I underwent two surgeries and nine months of chemo and a month of radiation. In the middle of the chemo, my ALTs (a liver function test) started to go up and never really came back to normal levels. I haven’t been able to walk up two flights of stairs since that time. I’ve always complained to doctors about being tired and exhausted. When I’ve told them what my schedule is like, they’ve just said, “no wonder you’re tired.” Nobody really paid attention to my complaints. But I kept feeling weaker and weaker. When I had my family over for the holidays, I had to prepare everything days before. If I tried to get things together the same day, I wouldn’t be able to get off the couch by the time company arrived.

Finally in 2006, my primary care doc did an HCV (hepatitis C virus) test because my ALTs continued to increase a little more every year. They weren’t in the danger zone, but something was wrong. When the HCV test came back positive, I was glad to know I hadn’t been crazy all those years – something really was the matter. But I also felt terrible about the HCV diagnosis. I felt contaminated. I had been out of “the life” for many years and was finally feeling better about myself. Here was yet another diagnosis slapping me in the face once again. It was nice to have a cause for my symptoms, but not at the expense of having another potentially life-threatening disease.

I went to Dr. Dave Thomas at John Hopkins. Dave is a renowned national and international HCV physician and researcher and Chief of Infectious Diseases Division at Johns Hopkins. He kept telling me, contrary to what my friends said, that I didn't need a liver biopsy unless I wanted to start treatment. He suggested we use the HCV FibroSURE test instead.

FibroSURE looks at results from a number of liver tests, essentially averages them out and provides a projection of liver fibrosis score that indicates the amount of liver damage (fibrosis). I had a blood draw every six months and my levels were pretty much the same for a long time.

I decided not to take any HCV regimens containing interferon (INF). INF is part of the current standard of care for HCV treatment. I was afraid of the many side effects associated with INF. I had survived chemo, but I was older now, and much more beat up. I knew I couldn't tolerate the psych side effects. If I was any more anxious and depressed, I would be out in the street with a machine gun! I just couldn't handle being even worse mentally. I also knew that the anxiety and depression remained for many people even after INF treatment was completed.

I did know people who took INF and didn't have horrible side effects. But although drugs are usually very effective for me, I always experience a lot of side effects. Moreover, I knew that I couldn't afford to take off work for even part of the 48 weeks of required treatment. Everybody thinks of me as a strong dog, but physically I am pretty beat up from years of abuse.

I also knew that new INF-sparing drugs, called direct antiviral agents (DAAs), were coming down the pike. Because I was ready to think about starting treatment with one of these new regimens, I got a liver biopsy in 2008. My symptoms were getting worse. I recall going to a Hepatitis Community Advisory Board meeting where I was so exhausted I couldn't even walk up a hill. I thought "I can't live like this anymore." I tried to stop traveling so much, which again is a joke in the activist arena. I knew it was time for me to do something to help myself.

I was on the lookout for the best new available HCV drug combination. Two new HCV protease inhibitors had just been approved, Incivek and Victrelis, but they had to be taken with interferon as well as ribavirin (RBV). Incivek and Victrelis plus INF/RBV treatment is worse than INF/RBV alone.

I learned about a new drug from Pharmasett, called PSI-7977, or sofosbuvir. The data look fabulous. I thought, "I want this drug!". But I knew the only way to get it would be in a clinical trial. There were a couple of 7977 trials in combination with other DAA HCV durgs enrolling at the time. So, I did my homework and decided which trail was best for me. I looked at the rate of HCV viral load decline with different 7977 combinations and what side effects were reported. The longest safety and efficacy data was available on 7977 combined with Bristol-Myers Squibb drug called daclatasvir, another new HCV DAA drug which is an NS5A inhibitor. I talked to the Principal Investigator of the study and to my doctor. My doctor said he thought this regimen was safer and had a better chance of success with fewer side effects than INF/RBV therapy with one of the newly approved HCV drugs. I made an informed decision based on what I had learned from reviewing the data and speaking to other HCV activists as well as my doctors.

I knew about when the trial was going to start at Hopkins. I called them every week for months, inquiring whether the study was enrolling patients yet. I ended up being the first person enrolled in the trial at Hopkins! It was a Phase 2 study. If you would have told me I would be in a Phase 2 study a year before, I would have laughed in your face. But this trial was different than most. The dose had been established and it used a design that activists had proposed in the HIV arena for treatment-experienced patients. It was open-label, so everyone knew what drugs they were getting, and it had three arms. One arm included 7977 monotherapy for five days with daclatasvir added thereafter. The second arm included both drugs together at the start. The third arm added ribavirin to both drugs from the onset. Everyone got the study drugs for 6 months. Everyone knew what they were taking and they received their viral results in real time.

Before I started the trial, I had enlisted the aid of a doctor friend who was willing to give me ribavirin if I got assigned to the two-drug arm. I was afraid that two drugs alone were insufficient to cure my HCV. I also obtained the advice of other activists. One said, “OMG, there’s not that many people in the trial, so one person cheating could really skew the results.” Another said, “Phase 2 trials are only proof of concept trials and efficacy is not really proven until Phase 3. Take the ribavirin too just in case.” But I decided against using the ribavirin. I thought to myself, “All right, you have agreed to do this, so whatever arm you get randomized to you’re going to do.” I just didn’t feel that I could lie to my doctors who were also colleagues. I decided to honor my commitment and stick to whatever regimen I was randomized to. But truth be told, it wasn’t only altruism on my part. I was pretty convinced that the two drugs alone would do the job.

My study nurse Erica was wonderful. She made all aspects of the study so much easier for me, including the “informed consent” process. Erica was everything we’ve ever asked for when we’ve discussed this aspect of clinical trials with researchers and drug companies. I had to go to the site every day for two weeks. It was very crazy at first. Every time I went I had to get an EKG, a blood draw, and a physical exam. The problem was that I had just had foot surgery and all three procedures were in different buildings. There were a couple of days that I had to stay all day, and on those days I had blood draws at 30 minutes after taking the drug, and 1,2,4, and 8 hours thereafter. A Phase 3 study would not have been so intensive, but I’m lucky I didn’t wait until Phase 8. I will go into more detail about this later. After the first two weeks, things got a lot easier. I had to have blood draws twice a month for a time, and finally only once a month.

Luckily, I got assigned to the two-drug combination arm, and for two months I had absolutely no side effects other than indigestion. But after about 60 days, I started to get really dizzy. I don’t mean I just got dizzy when I stood up. It was like the world around me was a swinging pendulum. I got out of bed one day, tried to get into the shower and almost fell in the tub. I complained about it, but was told that nobody was complaining about dizziness. The next four months were not a lot of fun. I noticed that when I traveled I felt worse, so I tried to travel less. Once again, that was a joke. But just like when I was on chemotherapy, I worked every day. I didn’t always go into the office eight hours every day, but I went every day.

When I joined the study, my HCV viral load was around 4 million. My viral load was undetectable after just 21 days of treatment and it has never come back! The big day came six months after I

finished the protocol. Another viral load test would determine if I was “cured”. Within the week, I got the great news. I was officially “cured”. Fabulous! I still can’t believe it sometimes. In fact, just last week I got a letter from Dave Thomas that reads:

No infection was detected including on July 29, 2012, a full 24 weeks after stopping therapy. This is incontrovertible evidence she has been cured of HCV infection. She should be regarded as free of HCV infection with regard to life insurance and other medical issues.

While I am delighted about my results, I am furious with Gilead Sciences, the drug company that bought 7977 from Pharmasset. Because of business decisions, Gilead will not conduct further studies of 7977 in combination with daclatasvir.

Pharmasett was all about working with every drug company in the world to prove the efficacy of 7977, its lack of serious side effects and lack of drug-drug interactions. They designed studies like the one I was in so people would enroll quickly and results would be demonstrated quickly. They were all about selling 7977 quickly, which they did, to Gilead for $11 billion dollars.

At a meeting with activists, Gilead promised that they would continue to work with other HCV drug companies. I asked them three times during the meeting. Dr. John McHutchison, a Senior VP at Gilead, assured us that collaborations with other HCV drug companies would continue. He referred to Gilead’s record of collaboration in HIV and promised that the same would be true in the HCV arena.

Unfortunately for patients, that is not what has actually occurred. Gilead first plans to study 7977 with INF/RBV, and then with its own NS5A inhibitor, which they claim should be similar to daclatasvir. But the necessary interaction studies will take at least an additional year. Eventually, Gilead will have a combination pill that will include all Gilead drugs, to the exclusion of Bristol-Myers Squibb and every other drug company.

Gilead could have begun a large Phase 3 trial with 7977 with daclatasvir yesterday. This combination could have been approved in a relatively short time. But now the combination may never be studied together before both drugs are approved individually, and that won’t happen for another couple of years. I am one of the few people in the country lucky enough to have received 7977 with daclatasvir. I was ecstatic to learn I was cured. My happiness is quire bittersweet now that I know that I was one of only 44 people with genotype 1 (the most prevalent form of HCV in the U.S.) that will actually have access to this combination for many years to come. It is important to note that 100% of the 44 people with genotype 1 in my study were cured with 7977 and daclatasvir.

I am outraged that Gilead refuses to study 7977 with other DAAs that are farther along than their own drugs. I am outraged that people with HCV with serious liver damage who do not have the luxury of waiting at least an additional year will have to be subjected to horrible side effects that occur with the current standard of care. Many people are in much worse shape than I was and need treatment immediately. Because of Gilead’s business decision to use only their drugs in 7977

combinations, people with more serious liver damage are being forced to take regimens with less efficacy and more side effects, for longer periods of time, so that Gilead can make more money in the end.

We will be asking Gilead to provide the NIH with 7977 so the AIDS Clinical Trial group can study it with daclatasvir. Without more data on the combination, there is a real danger that insurance companies won't reimburse for this combination once both drugs are individually approved. We've also been pushing Gilead and other companies for early access to these new DAAs. But HCV is not like HIV. Once you're cured of HCV, you're cured. Companies will not continue to receive lifelong profits from HCV patients like they do HIV patients. So, I believe they don't want to open the floodgates now. They want patients to have access to these drugs only after approval and they will be sure to get astronomical prices for these drugs. Activists have started an online petition at HepC-Cured.org to request that Gilead study 7977 with daclatasvir. Please sign on. We will keep the pressure on Gilead.

So what have I learned? Besides not to trust Gilead, I know I am cured because I took the bull by the horns. I've never been the kind of person to sit and wait for something to come to me. I'd be long gone by now if that was the case. I got involved in my care the minute I was diagnosed. I learned about the availability of new drugs as well as when and where they would be accessible. I made sure I educated myself about the data, what questions to ask, and who to ask. It's really not that difficult. All this information is online for anyone who is willing to take charge of your own life and health. You can learn all this and more at sites like NATAP.org, HCVadvocate.org, treatmentactiongroup.org, and hivandhepatitis.org. Do the work. It may actually save your life.

Lynda Dee
Co-founder of AIDS Action Baltimore

Reprinted with permission from Achieve, a publication of ACRIA and GMHC.

© 2026 Smart + Strong All Rights Reserved.
http://beta.docker.poz.com/article/lynda-dee-hepatitis-gilead-15138-9610