

IN THE
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

SARAH JACKSON, on her own behalf and on)
behalf of a class of those similarly situated,)

Plaintiff,)

v.)

No. 1:15-cv-01874

SECRETARY OF THE INDIANA FAMILY)
AND SOCIAL SERVICES ADMINISTRATION,)
in his official capacity,)

Defendant.)

COMPLAINT – CLASS ACTION

CLASS ACTION COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Introductory Statement

1. In recent years, an outpatient drug marketed under the trade name Harvoni has been developed to cure Hepatitis C, a chronic disease primarily affecting the liver that can lead to cirrhosis, liver failure, cancer, and other serious and potentially life-threatening concerns. The progression of Hepatitis C is determined through a patient’s “fibrosis level,” which is measured on a scale of F0 (no fibrosis) through F4 (cirrhosis of the liver) and which reflects the degree of liver damage suffered by that patient. For persons with Hepatitis C, the early provision of Harvoni is of paramount importance: curing Hepatitis C in the early stages of fibrosis prevents pain and additional damage to the liver, and dramatically reduces the risk that a patient will develop liver failure, cancer, or other undeniably serious consequences of the disease. Nonetheless, even though Harvoni is otherwise available through the Medicaid program, the Indiana Family and Social Services Administration (“the agency”) has instituted a policy whereby it will only be

provided to Medicaid recipients with severe fibrosis (F3 or F4), unless those persons are co-infected with HIV or AIDS or are post-liver transplant. The effect of this policy is to curtail access to a potentially life-saving or life-sustaining drug to thousands of Hoosiers. The agency accordingly refuses to provide Harvoni to Medicaid recipients even when that drug is “medically necessary,” and it is therefore acting in violation of federal Medicaid law. Declaratory and injunctive relief is warranted on behalf of the named plaintiff, a Medicaid recipient diagnosed with Hepatitis C, and a class of those similarly situated.

Jurisdiction, Venue, and Cause of Action

2. This Court has jurisdiction of this case pursuant to 28 U.S.C. § 1331.
3. Venue is proper in this district pursuant to 28 U.S.C. § 1391.
4. Declaratory relief is authorized by Rule 57 of the Federal Rules of Civil Procedure and 28 U.S.C. §§ 2201 and 2202.
5. This action is brought pursuant to 42 U.S.C. § 1983 to redress the deprivation, under color of state law, of rights secured by federal law.

Parties

6. Sarah Jackson is an adult resident of Allen County, Indiana.
7. The Secretary of the Indiana Family and Social Services Administration is the duly appointed head of that agency, and is sued in her official capacity.

Class Action Allegations

8. This cause is brought by Ms. Jackson on her own behalf and a class of those similarly situated pursuant to Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure.
9. The class is defined as follows:

Any and all adult Medicaid recipients in Indiana, current and future, with a diagnosis of Hepatitis C, but with a fibrosis level lower than F3, unless those persons are co-infected with HIV or AIDS or are post-liver transplant.

10. As defined, the class meets all requirements of Rule 23(a) of the Federal Rules of Civil Procedure. Specifically:
 - a. The class is so numerous that the joinder of all members is impracticable. While the precise size of the class is currently unknown, a report generated by the Indiana State Department of Health indicates that there were 5,289 known cases of Hepatitis C in Indiana during calendar year 2014. *See* Indiana State Department of Health, Hepatitis C: January 1, 2014 – December 31, 2014, at <https://secure.in.gov/isdh/files/Hepatitis.pdf> (last visited Nov. 19, 2015). Moreover, because persons must have lower fibrosis levels before progressing to a fibrosis level of F3 or F4 and because even rapid fibrosis progression may take years, *see* Patrick Marcellin, et al., *Fibrosis and Disease Progression in Hepatitis C*, 36 *Hepatology* 47, 50 (Nov. 2002) (available at <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.327.6749&rep=rep1&type=pdf> [last visited Nov. 19, 2015]), it stands to reason that the majority of these persons have a fibrosis level lower than F3. The class will also continue to grow in number as more persons contract Hepatitis C. Additional information concerning the size of the class will be ascertained during the discovery process.
 - b. There are questions of law or fact common to the class, specifically whether the agency's limitations on which patients with Hepatitis C may receive Harvoni violate federal Medicaid law.
 - c. The claim of the representative party is typical of that of the class.
 - d. The representative party will fairly and adequately represent the class.
11. The class meets the further requirements of Rule 23(b)(2) of the Federal Rules of Civil Procedure insofar as the party opposing the class has, at all times, acted or refused to act on grounds generally applicable to the class.
12. Undersigned counsel is skilled and experienced in litigation of this type and, as such, should be appointed as class counsel pursuant to Rule 23(g) of the Federal Rules of Civil Procedure.

Factual Allegations

The Hepatitis C Virus and Harvoni

13. Hepatitis C is an infectious disease affecting primarily the liver, which is caused by the hepatitis C virus (“HCV”). HCV has six major strains, known as “genotypes.” Genotype 1 is the most common strain in the United States and, as used herein, “Hepatitis C” refers to the disease caused by Genotype 1 of the HCV (although the outpatient drug at issue in this litigation, Harvoni, is effective against at least some other genotypes as well).
14. Hepatitis C is a chronic condition that can lead to scarring of the liver and to cirrhosis, liver failure, liver cancer, the need for liver transplantation, or death.
15. For patients with Hepatitis C, the extent of liver damage is measured in terms of the fibrosis (or tissue scarring) of the liver. Fibrosis levels are scored on a five-level scale, from F0 through F4, where F0 indicates that no fibrosis has occurred and F4 indicates that the patient has suffered cirrhosis. (The fibrosis level is also sometimes referenced as the “metavir score.”)
16. Since October 2014, the two-drug combination ledipasvir/sofosbuvir has been marketed under the trade name Harvoni (and thus referenced as “Harvoni” herein). If taken daily for 12 weeks, Harvoni completely cures Hepatitis C in 94% to 99% of patients, irrespective of the fibrosis level or the presence or absence of liver cirrhosis.
17. Although persons with higher fibrosis scores (F3 and F4) are no doubt in greater need of immediate treatment with Harvoni—insofar as they are at greater risk of liver failure and liver cancer—even patients with lower fibrosis scores can and do benefit greatly from Harvoni.
18. While Harvoni is highly efficacious at curing Hepatitis C, untreated chronic Hepatitis C can result in significant fibrosis and scarring to the liver (also known as cirrhosis and

end-stage liver disease), which can be irreversible. Once a person has developed end-stage liver disease, there remains a real and significant future risk of liver-related decompensation, liver cancer (hepatocellular carcinoma), and death. The timely provision of Harvoni can prevent the further progression of liver disease in those individuals without significant fibrosis (less than F3), and can prevent the development of cirrhosis and end-stage liver-related disease—with the potential for morbidity and mortality inherent in these conditions—for these persons.

19. Even for patients with lower fibrosis scores, Harvoni serves to completely cure Hepatitis C, thus preventing any further deterioration of the liver and greatly reducing the risk of liver failure, liver cancer, or other serious conditions. If the provision of Harvoni to these persons is delayed until their liver deteriorates further and the level of fibrosis increases, the damage to their liver in the interim—and the increased risk of liver failure, liver cancer, or other serious conditions—will likely prove irreversible even with the delayed provision of Harvoni. This is because, while Harvoni *cures* Hepatitis C, it does not reverse the effects of Hepatitis C that have already been caused.
20. Thus, national guidelines published online in a joint statement by the Infectious Disease Society of America and the American Association for the Study of Liver Diseases (IDSA/AASLD) state that Hepatitis C treatment—through Harvoni—is recommended for all patients except for those with short life expectancies. In addition to halting liver fibrosis and preventing end-stage liver disease, studies have shown that quality of life—including emotional, physical, and social health—is substantially improved in individuals cured of Hepatitis C. Treating persons with lower fibrosis scores has also been shown to result in reduced mortality compared to those people with Hepatitis C who were not

treated or cured at that time. And, persons cured of Hepatitis C are no longer able to transmit the virus, such that curing persons early is of great benefit to the public health.

21. The provision of Harvoni to persons with Hepatitis C, even if they have a lower fibrosis level, is thus medically necessary.
22. On October 10, 2014, the Food and Drug Administration approved Harvoni for the treatment of persons with Hepatitis C. The provision of Harvoni to persons with Hepatitis C is thus for a medically accepted indication as defined by 42 U.S.C. § 1396r-8(k)(6). The manufacturer of Harvoni has entered into, and has in effect, a rebate agreement as described in 42 U.S.C. § 1396r-8(a).
23. On November 5, 2015, the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services issued a “Notice” to states concerning the provision of Harvoni to persons with Hepatitis C. In pertinent part, that Notice provides as follows:

CMS is concerned that some states are restricting access to . . . HCV drugs contrary to statutory requirements . . . by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to metavir fibrosis score F3, while a number of states are requiring metavir fibrosis scores of F4.

A true and correct copy of this Notice is attached and incorporated herein as **Exhibit 1**.

The Policy of the Indiana Family and Social Services Administration

24. The Indiana Family and Social Services Administration (“the State” or “the agency”) is responsible for operating the Medicaid program in Indiana.
25. On or about December 30, 2014, the agency issued a “Bulletin” establishing requirements for Medicaid recipients to receive Harvoni. In pertinent part, the agency refused to provide coverage for Harvoni to persons whose fibrosis score was lower than F4—that is,

to persons not already suffering cirrhosis. A true and correct copy of this Bulletin is attached and incorporated herein as **Exhibit 2**.

26. On or about October 1, 2015, the agency issued revised requirements for Medicaid recipients to receive Harvoni. In pertinent part, the agency refused to provide (and continues to refuse to provide) coverage for Harvoni to persons whose fibrosis level is lower than F3, unless those persons are co-infected with HIV or AIDS or are post-liver transplant. A true and correct copy of these revised requirements is attached and incorporated herein as **Exhibit 3**.
27. By refusing to provide Medicaid coverage to persons with Hepatitis C and with lower fibrosis scores, the agency is refusing to provide medically necessary treatment that could prevent permanent liver damage, cancer, or other undeniably serious conditions.

Sarah Jackson and the Putative Class

28. Sarah Jackson is an adult resident of Allen County, Indiana, and is a Medicaid recipient.
29. Ms. Jackson has been diagnosed with Hepatitis C, although her fibrosis level is lower than F3, she is not co-infected with HIV or AIDS, and she is not post-liver transplant.
30. Nonetheless, for all the reasons described above, Ms. Jackson would immediately benefit from the provision of Harvoni, which would prevent further liver damage, cancer, or other undeniably serious conditions. Immediate treatment with Harvoni is medically necessary for Ms. Jackson.
31. In fact, treatment with Harvoni is particular important for Ms. Jackson insofar as she has recently given birth. Hepatitis C may be transmitted from mother to child during breastfeeding, and so treating Ms. Jackson with Harvoni now might stop the spread of the disease to her infant. On top of this, Ms. Jackson could again carry a child and, if she is

not cured, her child would again be at risk of vertical transmission (that is, the transmission of HCV from mother to child during gestation, birth, or the post-partum period).

32. In October 2015, Ms. Jackson—through her physician—sought approval from the agency for a course of Harvoni to cure her Hepatitis C. That request was denied by the agency, with the following explanation:

The plan requires that the member have a diagnosis of chronic hepatitis C genotype 1 with >stage 2 fibrosis, co-infection with HIV or AIDS, or post liver transplant. Based on the information provided, this requirement was not met.

A true and correct copy of this denial notification is attached and incorporated herein as **Exhibit 4**. Ms. Jackson’s physician appealed this decision through a process known as administrative review, but that appeal was rejected for the same reason.

33. Moreover, Ms. Jackson is not alone. Hundreds if not thousands of Medicaid recipients in Indiana would benefit from Harvoni immediately even though their fibrosis levels are less than F3. Harvoni is medically necessary for these persons as well.

Concluding Factual Allegations

34. As a result of the actions or inactions of the defendant, the plaintiff and the putative class are suffering irreparable harm for which there is no adequate remedy at law.
35. The defendant has at all times acted or refused to act under color of state law.

Legal Claim

36. The defendant refuses to provide Harvoni to Medicaid recipients even when that drug is “medically necessary,” and it is therefore acting in violation of federal Medicaid law.

Request for Relief

WHEREFORE, the plaintiff and the putative class respectfully request that this Court do the following:

1. Accept jurisdiction of this cause and set it for hearing
2. Certify this cause as a class action pursuant to Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure, with the class as defined above.
3. Issue a preliminary injunction, later to be made permanent, enjoining the defendant from enforcing its requirement that Medicaid recipients with Hepatitis C but whose fibrosis level is lower than F3 may not receive Harvoni unless those persons are co-infected with HIV or AIDS or are post-liver transplant, and requiring the defendant to provide Harvoni to all patients for whom it is medically necessary.
4. Award the plaintiffs their costs and attorneys' fees pursuant to 42 U.S.C. § 1988.
5. Award all other proper relief.

Respectfully submitted,

/s/ Gavin M. Rose

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