

alternative medication or medical intervention that would provide Roebuck with equally beneficial results.

2. Highmark, acting directly or through one of its myriad subsidiaries, pursuant to a uniform (though not disclosed within the four-corners of its health plan) policy, will not and did not approve Roebuck's treatment with Harvoni. Highmark has put in place internal coverage restrictions that impermissibly deny all of its insureds to curative treatment for Hepatitis C because it believed it was too expensive. Instead, Highmark rations the Hepatitis C treatment and excludes coverage to the most severely ill of its insureds.

3. Highmark's restrictive internal coverage requires that infected individuals wait for treatment – possibly for years – until they demonstrate serious scarring or cirrhosis of the liver from the Hepatitis C infection. In the meantime, Roebuck and others are forced to live with a chronic inflammatory disease, including the pain, fatigue, depression, deteriorating health and increased risk of cancer and death.

4. Roebuck, on his own behalf and on behalf of all others similarly situated, has brought this lawsuit to recover benefits for those Highmark insureds who were denied coverage for Harvoni because, in effect, they were not sick enough.

JURISDICTION AND VENUE

5. This Court has jurisdiction in this ERISA matter via 28 U.S.C. § 1331.

6. Venue is appropriate in this district because Plaintiff and Highmark may be found here, and at least some of the breaches at issue took place here. 29 U.S.C. § 1132(e)(2).

7. In conformity with 29 U.S.C. § 1132(h), Plaintiff has served this Complaint by certified mail on the Secretary of Labor and the Secretary of the Treasury.

PARTIES

8. Patrick Wayne Roebuck, 46, resides at in South Semmes, Alabama.

9. Highmark, Inc., is a nonprofit health insurer, though it operates several for-profit subsidiaries, with its principal headquarters in Pittsburgh, Pennsylvania. In this Complaint, "Highmark" refers to not only the named defendant, but also all other successor, predecessor, subsidiary, parent and related entities to which these allegations pertain.

FACTS

10. Hepatitis C is a widespread contagious disease of the liver. It is estimated that about five million people in the United States are living with Hepatitis C, which represents more than 1% of the entire country's population.

11. Hepatitis C can lead to severe liver damage, infections, liver cancer and death. Nearly 20,000 people in the United States die each year due to liver disease caused by Hepatitis C. See <http://www.cdc.gov/hepatitis/Statistics/index.htm> (last visited May 18, 2017). Even before the advanced stages of the disease, individuals with Hepatitis C can suffer from heart attacks, fatigue, joint pain, depression, sore muscles, arthritis, and jaundice. Statistics from the Center for Disease Control and Prevention indicate that up to 70% of those with Hepatitis C will develop chronic liver disease; 20% will develop cirrhosis; and 5% will develop liver cancer.

12. Liver health is graded according to the level of liver scarring under a fibrosis score. The Metavir scoring system was specially designed for patients with Hepatitis C. The grade gives an indication of the activity or amount of inflammation and the stage

represents the amount of fibrosis or scarring. The grade is assigned a number based on the degree of inflammation, which is usually scored from 0-4. The amount of inflammation is important because it is considered a precursor to fibrosis. A score of 0 = no scarring; 1 = minimal scarring; 2 = scarring has occurred and extends outside the areas in the liver that contain blood vessels; 3 = bridging fibrosis is spreading and connecting to other areas that contain fibrosis; and 4 = cirrhosis or advanced scarring of the liver.

13. Until the direct-acting anti-viral medications were approved, the standard of care for the treatment of Hepatitis C was a three-drug treatment containing boceprevir, interferon and ribavirin at a cost of about \$170,000 per cure. The treatment only provided at most a 70% cure rate and was accompanied by significant adverse side effects, such as anemia, insomnia, anxiety, depression, nausea, bone pain, liver failure, joint pain, memory loss and death.

14. Since 2011, the federal Food and Drug Administration has approved direct-acting and anti-viral medications to treat Hepatitis C. It has a success rate of nearly 100% and is accompanied by few, if any, side effects. It costs substantially less than the earlier treatments for each patient cured. Harvoni was designated as a “breakthrough therapy” by the FDA, a classification that is reserved for drugs that have proven to provide substantial improvement over available therapies for patients with serious or life-threatening diseases. The FDA approved Harvoni on Oct. 10, 2014.

15. Harvoni and other direct-acting anti-viral medications are the standard of medical care for the treatment of all Hepatitis C. This includes treatment of all individuals irrespective of the individual’s fibrosis score. Treatment guidelines approved by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of

America confirm that Harvoni and other direct-acting anti-viral medications should not be reserved only for individuals with fibrosis scores of F3 and F4. Instead, the standard of care is to treat “all patients with chronic Hepatitis C infection, except to those with short life expectancies that cannot be remediated [], by transplantation, or by other directed therapy.” See <http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last visited May 18, 2017).

16. Highmark has a uniform coverage approach with respect to when, and under what conditions, it approves Harvoni and other similar direct-acting anti-viral medications. Unless an insured shows “severe extrahepatic manifestations and type 2 or 3 essential mixed Cryoglobulinemia with end-organ manifestations or Proteinuria, Nephrotic Syndrome, or Membranoproliferative Glomerular Nephritis,” Highmark will not cover Harvoni or similar direct-acting anti-viral medications. In other words, unless an insured is very sick – as reflected in his/her “F” score, Highmark will not cover Harvoni or similar treatment notwithstanding the fact that Hepatitis C is a progressive disease and nearly all persons with Hepatitis C will eventually degrade to the point where their “F” score qualifies under Highmark’s internal rules.

17. Highmark has no clinical or medical basis to deny treatment to individuals with lower fibrosis scores. On the contrary, HCV guidelines provide that because of the myriad benefits associated with successful HCV treatment, clinicians should treat HCV-infected patients with anti-viral therapy with the goal of achieving an SVR, preferably early in the course of their chronic HCV infection before the development of severe liver disease and other complications. See <http://www.hcvguidelines.org/full-report/when-and-whom->

initiate-hcv-therapy (last visited May 18, 2017). Treatment of Hepatitis C even in patients with mild liver disease decreases complications and death rate due to liver disease.

18. Highmark's insureds who meet the standards set forth by the American Association for the Study of Liver Diseases and Infectious Diseases Society of America but who are excluded under Highmark's coverage are put at risk. They are needlessly exposed to health conditions caused by Hepatitis C, including cirrhosis, cancer, heart attacks, fatigue, joint pain, depression, sore muscles, arthritis, death, unneeded liver transplants and jaundice. In addition, the lack of treatment of infected individuals increases the chances that members of the insured's household, and the public generally, will be exposed to Hepatitis C.

19. Harvoni has adopted this coverage criteria, at least in part, because of its concern over the perceived expense of Harvoni and other direct-acting anti-viral medications.

20. Plaintiff Roebuck was first diagnosed with Hepatitis C in November 2015. His request for coverage was denied in writing through a letter on BlueCross Blue Shield Louisiana letterhead on April 15, 2016, May 13, 2016, June 22, 2016, and then on Highmark Blue Shield letterhead on April 18, 2017. All three of the 2016 denials relied on the internal Highmark criteria mentioned above.

CLASS ALLEGATIONS

21. Plaintiff brings this lawsuit on his own behalf and on behalf of the following class: *All persons who are covered under any contract or plan of health insurance that is administered, underwritten or insured by Highmark who (a) have been diagnosed with*

Hepatitis C (b) but have been denied coverage for Harvoni and similar treatments (c) based on application of Highmark's internal criteria discussed above.

22. Membership in the proposed classes is so numerous that individual joinder of all class members is impracticable except by means of a class action. The disposition of the claims in a class action will benefit both the parties and the Court. The exact number of class members can be readily determined through discovery of defendants' business records.

23. Plaintiff's claims are typical of all other class members. All class members' claims are unified, as all were improperly denied coverage.

24. Plaintiff's interests are coincident with, and not antagonistic to, those of the other members of both classes. Plaintiff is a member of the classes.

25. Plaintiff will adequately represent the class because he has interests in common with the proposed class members and plaintiff has retained attorneys who are experienced in class action litigation.

26. There is a well-defined community of interest in the questions of law and fact involving and affecting the class to be represented by plaintiff. Common questions of law and/or fact predominate over any questions affecting only individual members of the class. Common questions include, but are not limited to, the following:

- a. Whether Highmark's application of its internal criteria to deny Harvoni and related drug coverage to class members infected with Hepatitis C violates its plan promise to cover all services that are medically necessary?
- b. If Highmark's coverage determination breaches its promise to cover medically necessary services, what is the appropriate remedy?
- c. What is the appropriate measure of relief?

27. The prosecution of separate actions by individual members of the class would create a risk of:

- a. Inconsistent or varying adjudications concerning individual members of the class and/or subclass that would establish incompatible standards of conduct for the defendants opposing the class; and
- b. Adjudication with respect to individual members of the class that would, as a practical matter, be dispositive of the interests of other members not parties to such adjudications, and/or substantially impair or impede the ability of other non-party class members to protect such individual interests.

28. The class action method is appropriate for the fair and efficient prosecution of this action.

29. Individual litigation of all claims that might be asserted by all members of both classes would produce such a multiplicity of cases that the judicial system, having jurisdiction of the claims, would remain congested for years. Class treatment, by contrast, provides manageable judicial treatment calculated to bring a rapid conclusion to all litigation of all claims arising out of the conduct of defendants.

30. The certification of the above classes would allow litigation of claims that, in view of the expense of the litigation, may be an insufficient amount to support separate actions.

LEGAL CLAIMS

Count 1 – Plan Enforcement under 29 U.S.C. § 1132(a)(1)(B)

31. Plaintiff restates paragraphs 1 – 30 as if fully set forth.

32. Plaintiff's first legal claim is brought under 29 U.S.C. § 1132(a)(1)(B). The class period for this claim extends four years back from the commencement of this action.

33. Plaintiff and the class are covered by health plans insured and/or administered by Highmark. Under the terms of these plans, Highmark is required to pay for

all medically necessary prescription medication benefits. Highmark violated the terms of these plans by denying Harvoni and similar drugs for this condition.

34. As a direct and proximate result of Highmark's actions, plaintiff and the class were forced financially to forego treatment altogether. Plaintiff and the class are entitled to the reasonable value of the medically necessary Harvoni treatment and related expenses.

35. As a direct and proximate result of this improper determination, plaintiff and the class have been required to incur attorneys' fees and costs. Under 29 U.S.C. § 1132(g)(1), plaintiff and the class are entitled to have such fees and costs paid by Highmark.

36. Plaintiff and the class have standing to assert claims "to recover benefits due ... under the plan" and to "clarify [his] rights to future benefits under the terms of the plan," as authorized by 29 U.S.C. § 1132(a)(1)(B).

Count 2 – Breach of Fiduciary Duty Under 29 U.S.C. § 1132(a)(3)

37. Plaintiff restates paragraphs 1 – 30 as if fully set forth.

38. Highmark acts as an ERISA fiduciary with respect to the administration and claims decisions of the group health plans it issues to employers within the meaning of 29 U.S.C. § 1109(a) and 1002(21)(A). This includes plaintiff's and class members' plans.

39. With respect to these plans, Highmark exercises discretionary authority or control respecting management of the plans, exercises authority or control respecting management or disposition of the plans' assets.

40. Highmark has categorically and improperly denied requests for Harvoni and similar drugs as described above.

41. In acting in this manner, Highmark has breached its fiduciary duties.

42. Pursuant to 29 U.S.C. § 1132(a)(3), plaintiff and the class seek equitable relief

as follows:

- An injunction that requires Highmark to retract its denial of Harvoni treatment; provide notice of this retraction in the form and manner required by ERISA to all class members; and provide for the re-review of all improperly denied claims.
- An accounting of any profits made by Highmark from the monies representing the improperly denied claims and disgorgement of any profits.

WHEREFORE, plaintiff requests the following:

- a. Certification of the class described above with the appointment of plaintiff as the class representative for the class and the undersigned attorneys as class counsel;
- b. Payment of health benefits due to plaintiff and the class under defendant's applicable plans;
- c. Reconsideration of all claims for Harvoni treatment;
- d. Disgorgement of all profits unjustly realized by Highmark as the result of its wrongful denials of authorization for Harvoni treatment;
- e. Injunctive relief as described above;
- f. Payment of all attorneys' fees and costs incurred in pursuing this action;
- g. Payment of prejudgment and post-judgment interest as permitted;
- h. Any and all other relief related to this action.

JURY DEMAND

Plaintiff demands a trial by jury on all issues that may be so tried.

Done this 28th day of June, 2017.

Respectfully submitted,

/s/Charles J. Potts
CHARLES J. POTTS (POTTTC0053)
Attorney for Plaintiff, Patrick Wayne Roebuck

OF COUNSEL:

BRISKMAN & BINION, P.C.

Post Office Box 43
Mobile, AL 36601
T: 251.433.7600
F: 251.433.4485
cpotts@briskman-binion.com

SERVICE ON DEFENDANT HIGHMARK BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED, C/O THE FOLLOWING:

Highmark, Inc.
c/o Karen L. Hanlon, Treasurer
1800 Center Street
Camp Hill, PA 17011

COURTESY COPY TO BE SENT VIA CERTIFIED MAIL TO THE FOLLOWING:

Alex Acosta
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Steven T. Mnuchin
Secretary of U.S. Department of Treasury
1500 Pennsylvania Avenue, N.W.
Washington, DC 20220