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similarly situated

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

LACY ATZIN; MARK ANDERSEN, on behalf of themselves and all others similarly situated, Plaintiffs, v. ANTHEM, INC.; ANTHEM UM SERVICES, INC., Defendants.	Case No.: 2:17-cv-6816 **CLASS ACTION** **COMPLAINT FOR BENEFITS, DETERMINATION OF RIGHTS AND BREACH OF FIDUCIARY DUTY UNDER ERISA**

Plaintiffs, Lacy Atzin and Mark Andersen, on behalf of themselves and all others similarly situated, herein set forth the allegations of their Complaint against Defendants Anthem, Inc. and Anthem UM Services, Inc.

INTRODUCTION

1. Anthem, Inc. ("Anthem") is "one of the largest health benefit companies in terms of medical membership in the United States, serving 39.9 million medical members through [its] affiliated health plans as of December 31, 2016."[1] Anthem owns "Blue" organizations in California and many other states, as well as other subsidiaries.[2] Through its wholly-owned subsidiaries, including Defendant Anthem UM Services, Inc. ("Anthem UM"), Anthem acts as a fully integrated company that is in the business of insuring and administering health insurance plans, most of which are employer-sponsored and governed by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001, *et seq*. ("Anthem plans").

2. With respect to all Anthem plans, Anthem UM serves as the claims administrator, responsible for determining whether claims are covered under Anthem plans (both fully insured and self-insured) and effectuating any resulting benefit payment. Anthem aids Anthem UM in its administrative duties by, among other things, participating with Anthem UM in the development of coverage guidelines called Medical Policies, collaborating with Anthem UM on the types of claims that will be approved or denied, and assisting Anthem UM in carrying out its

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[1] Anthem's 2016 10-K, p. 3.

[2] Anthem operates under the "Blue" moniker in California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia and Wisconsin. Anthem also conducts business through subsidiaries such as Amerigroup, Simply Healthcare Holdings, HealthLink, UniCare, and CareMore Health Group, Inc.

various other administrative duties. As such, Defendants have acted as ERISA fiduciaries with respect to all Anthem plans, including Plaintiffs' plans.

3. Plaintiffs bring this action to address Defendants' practice of denying coverage for microprocessor controlled lower limb prostheses for persons with lower limb loss. Defendants have developed and used a coverage guideline, the Anthem Medical Policy on Microprocessor Controlled Lower Limb Prosthesis, Policy No. OR-PR.00003 (hereinafter "OR-PR.00003"), to deny claims for microprocessor controlled lower limb prostheses. With respect to microprocessor controlled knee prostheses, Defendants have used erroneous criteria in OR-PR.00003 to deny most requests for these devices on the basis they are not "medical necessary." With respect to microprocessor controlled foot-ankle prostheses, Defendants have denied coverage for all such devices under OR-PR.00003 on the bases they are "investigational and not medically necessary for all indications." Contrary to Defendants' position, these devices are effective and necessary for persons with lower limb loss.

JURISDICTION AND VENUE

4. This action is brought under 29 U.S.C. §§ 1132(a), (e), (f) and (g) as it involves claims by Plaintiffs for employee benefits under employee benefit plans regulated and governed by ERISA. Subject matter jurisdiction is predicated under these code sections as well as 28 U.S.C. § 1331 as this action involves a federal question.

5. The Court has personal jurisdiction over Defendants because ERISA provides for nationwide service of process, and each defendant has minimum contacts with the United States. *See* 29 U.S.C. § 1132(e)(2).

6. The claims of Plaintiffs and the putative class arise out of policies Defendants issued, administered, and/or implemented in this District. Thus, venue is proper in this judicial district pursuant to 29 U.S.C. § 1132(e)(2) (setting forth special venue rules applicable to ERISA actions).

THE PARTIES

7. Plaintiffs were at all relevant times covered under an employee welfare benefit plans regulated by ERISA and pursuant to which Plaintiffs are entitled to health care benefits.

8. Anthem and Anthem UM are corporations with their principal place of business in Indianapolis, Indiana. They administer and make benefit determinations related to ERISA health care plans around the country.

9. Defendants do not operate independently and in their own interests, but serve solely to fulfill the purpose, goals and policies of each other.

SUBSTANTIVE ALLEGATIONS

A. Microprocessor controlled knee and foot-ankle prostheses.

10. There are approximately 2 million people living with limb loss in the United States. Approximately 185,000 amputations occur in the United States each year, about 500 a day.

11. People with limb loss require the use of a prosthesis, an artificial extension that replaces a missing body part such as an upper or lower body extremity. The development of prostheses is part of the field of biomechatronics, the science of fusing mechanical devices with human muscle, skeleton, and nervous systems to assist or enhance motor control lost by trauma, disease, or defect. The type of prosthesis used is determined largely by the extent of an amputation or loss and location of the missing extremity.

12. The two types of lower limb prostheses are the transfemoral (above the knee) prosthesis and the transtibial (below the knee) prosthesis. Improvements in technology have allowed manufacturers to use microprocessors to power artificial knees and feet-ankles in these devices. Microprocessor technology has been used in prosthetics for decades-and has long been "standard" issue in the industry.

13. Microprocessor controlled knees feature sensors, a microprocessor, software, a resistance system and a battery. The knee's internal computer

(microprocessor) controls an internal fluid, which may be hydraulic or pneumatic. The microprocessor monitors each phase of a person's gait cycle using a series of sensors. The sensors detect and monitor changes in the environment, such as walking on a different surface, going up or down a slope or walking at a different speed. Based on that feedback, the microprocessor adjusts the resistance to knee flexion (bending) and extension (straightening) to accommodate walking speed and terrain. This enhances stability and security for the user, decreases the incidence of stumbles and falls, and provides improved ambulation on all surfaces. The primary advantage of microprocessor technology over the alternative is safety and stability-not speed of ambulation or ability to engage in athletic endeavors. There are other, very different, types of prosthetics whose primary purpose is to increase speed of ambulation and/or maximize athletic performance. Microprocessor knees are primarily for "everyday walking around" activities of daily living and are beneficial and necessary for amputees of virtually every demographic.

14. Microprocessor controlled foot-ankle devices use the same technology to simulate the movements of a normal foot and ankle. The device responds to constant feedback from sensors to the microprocessor, which changes the resistance to plantarflexion (downward motion) and dorsiflexion (upward motion) of the foot based on walking speed, incline, decline and type of terrain. Adjustments are made in real time. This creates stability, decreases stumbles and falls, improves ambulation on all services, and decreases the discomfort and pain associated with a prosthetic device.

15. Given the benefits of microprocessor controlled lower limb prostheses for persons with lower limb loss in everyday settings, the devices are established and accepted by the medical community at large as "standard" prostheses, and they are routinely prescribed prosthetic options for individuals meeting appropriate medical criteria.

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B. Defendants' Medical Policies.

16. To enable their administration of fully insured and self-insured health plans, Defendants have developed Medical Policies, that is, written directives on coverage positions they take with respect to certain medical treatments. *Inter alia*, the Medical Policies provide Defendants' coverage position on whether certain treatments are medically necessary and/or investigational.

17. As stated in Anthem's "Medical Policy Formation" document:

> The Office of Medical Policy & Technology Assessment (OMPTA) develops medical policy and clinical UM guidelines (collectively, "Medical Policy") for the company. The principal component of the process is the review for development of medical necessity and/or investigational policy position statements or clinical indications for certain new medical services and/or procedures or for new uses of existing services and/or procedures.

18. Defendants use the Medical Policies to administer claims under Anthem plans. As set forth below, Defendants have used OR-PR.00003 to deny requests for microprocessor controlled lower limb prostheses.

C. Defendants' denials of requests for microprocessor controlled lower limb prostheses.

19. Anthem plans do not cover services that are not "medically necessary" and they define that term in substantially the same manner as services that are:

> 1. Appropriate and necessary for the diagnosis or treatment of the medical condition;
>
> 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease;
>
> . . .
>
> 7. The most appropriate procedure, supply, equipment or service which can safely be provided. The most appropriate procedure, supply, equipment or service must satisfy the following requirements:
>
> a. There must be valid scientific evidence demonstrating that the expected health benefits from the procedure, supply, equipment or service are clinically significant and produce a greater likelihood of

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> benefit, without a disproportionately greater risk of harm or complications, for you with the particular medical condition being treated than other possible alternatives; and
>
> b. Generally accepted forms of treatment that are less invasive have been tried and found to be ineffective or are otherwise unsuitable.

20. Anthem plans also exclude "investigational" services and they define that term in substantially the same manner as services:

> 1) that have progressed to limited use on humans, which are not generally accepted as proven and effective procedures within the organized medical community; or 2) that do not have final approval from the appropriate governmental regulatory body; or 3) that are not supported by scientific evidence which permits conclusions concerning the effect of the service, drugs or device on health outcomes; 4) that do not improve the health outcome of the patient treated; or 5) that are not as beneficial as any established alternative; or 6) whose results outside the Investigational setting cannot be demonstrated or duplicated; or 7) that are not generally approved or used by Physicians in the medical community.

21. Defendants deny requests for microprocessor controlled knee prostheses based on erroneous criteria set forth in OR-PR.00003. Under this Medical Policy, Defendants deem requests for these prosthetics not "medically necessary" and not covered unless ***all*** of the following criteria are met:

> 1. Individual has adequate cardiovascular reserve and cognitive learning ability to master the higher level technology and to allow for faster than normal walking speed; **and**
>
> 2. Individual has demonstrated the ability to ambulate faster than their baseline rate using a standard swing and stance lower extremity prosthesis; **and**
>
> 3. Individual has a documented need for daily long distance ambulation (for example, greater than 400 yards) at variable rates. (In other words, use within the home or for basic community ambulation is not sufficient to justify the computerized limb over standard limb applications)**; and**
>
> 4. Individual has a demonstrated need for regular ambulation on uneven terrain or regular use on stairs. Use of limb for limited stair climbing in the home or place of employment is not sufficient to justify the computerized limb over standard limb applications.

(Emphasis in original.)

22. Defendants have wrongly denied requests for microprocessor controlled knee prostheses because all of the criteria in OR-PR.00003 are erroneous.

Criteria 1 and 2 are predicated on a person with a prosthetic leg demonstrating the ability to master "a faster than normal walking speed" and doing so with a "standard swing and stance" device. While a microprocessor controlled knee prosthesis may allow a person to walk faster, this is only one benefit of the device. Because the device approximates the action of a real knee, it allows persons without lower limbs to accomplish "normal" activities of daily living. *Inter alia*, a microprocessor controlled knee prosthesis creates better stability and, therefore, reduces the incidence of stumbles and falls, lessens the extra energy it takes to move an artificial leg, decreases discomfort and pain, and aids walking at a variable cadence, over uneven terrain, or using steps—activities that individuals with artificial legs encounter in every setting, including their homes. Criterion 3 creates an unreasonable distance requirement, walking at least 400 hundred yards everyday. Use of a device that is safer and aids mobility in everyday settings has nothing to do with daily long distance use. Similarly, Criterion 4 makes unreasonable demands regarding "regular" use of uneven terrain or stairs while excluding the use of home or workplace stairs.

23. Defendants have also wrongly denied coverage for all requests for microprocessor controlled foot-ankle prostheses pursuant to a directive in OR-PR.00003.

> The use of a microprocessor controlled foot-ankle prosthesis (for example, Proprio Foot of the PowerFoot Biom) is considered **investigational and not medically** necessary for all indications.

(Emphasis in original.)

24. OR-PR.00003 acknowledges that there are studies demonstrating the benefits created by microprocessor controlled foot-ankle prostheses. For instance, with respect to the Proprio Foot device, OR-PR.00003 references a study where "[t]he authors concluded that the Proprio device contributes significantly to an increased minimum to clearance measurement which may provide a significant contribution to decreased likelihood of tripping." Indeed, OR-PR.00003 cites seven

different peer reviewed studies in support of it's conclusion that microprocessor ankle-feet are "experimental and investigational." Yet *every one* of those studies concluded that microprocessor ankle-feet *provided significant benefits* over mechanical ankle-feet. None of the studies cited by Anthem actually supports its conclusion that the technology is "experimental and/or investigational." And Anthem ignores numerous other studies that also support the efficacy of microprocessor foot-ankle technology. Yet OR-PR.00003 concludes "further study is needed to establish a meaningful outcome benefit of the Proprio Foot over the conventional ankle-foot prosthesis."

25. Defendants' "investigational" position on microprocessor controlled foot-ankle prostheses is erroneous. There is more than sufficient evidence of the effectiveness of these devices. They respond to constant feedback from sensors to the onboard computer, which changes the resistance to plantarflexion (downward motion) and dorsiflexion (upward motion) of the foot based on walking speed, incline, decline and type of terrain. The devices allow for a more normal bend at the ankle when walking so that there is a reduction in toe drag and better balance. This creates better stability and reduces stumbles and falls. Rigid ankles also cause pain and stiffness of the residual limb that is reduced by an active ankle. The substantial benefits of these devices for those with lower limb loss have been well documented and are well known to Defendants.

D. Defendant's denial of Plaintiff Lacy Atzin's request for a microprocessor controlled knee device.

26. Ms. Atzin was diagnosed with a cancer tumor in her left leg when she was 11 years old. Her left leg was amputated above the knee. She was then fitted with a prosthetic device. She is currently married with five children.

27. In April of 2016, Ms. Atzin was referred to Hanger Clinic, a nationwide provider of prosthetic services. A certified prosthetist in Hanger Clinic's Lower Extremity Prosthetics Program determined that Ms. Atzin needed a prosthetic leg

with a microprocessor-controlled knee. Hanger Clinic sought authorization from Defendants for this device.

28. On May 3, 2016, Defendants' delegated medical group, Sharp Rees-Stealy Medical Group, denied coverage stating that the microprocessor controlled knee prosthesis was not "medically necessary" because Ms. Atzin did not satisfy the erroneous criteria of OR-PR.00003. Pursuant to its agreement with Defendants and their subsidiaries, Sharp Rees-Stealy Medical Group was required to follow OR-PR.00003 when it received a request for a microprocessor controlled knee prosthesis under an Anthem plan.

29. Ms. Atzin appealed this decision. On June 6, 2016 Anthem UM sent Ms. Atzin a letter advising that "Anthem UM Services, Inc. provides utilization management services for Anthem Blue Cross and Anthem Blue Cross Life and Health Insurance Company." Anthem UM stated it was denying Ms. Atzin's appeal because she did not meet the criteria of OR-PR.00003:

> You must be able to walk faster than the normal walking speed of someone with a standard prosthesis. There must be a need for walking more than 400 yards a day at different speeds. There must also be a need to walk over uneven ground or to use stairs often outside of your home or workplace. You must also be able to control a complex device. We do not see this is the case for you. For this reason, we believe this prosthesis is not medically necessary for you. We based this decision on the health plan medical policy, Microprocessor Controlled Lower Limb Prosthesis (OR-PR.00003).

30. Ms. Atzin's orthopedist requested a re-review of Anthem UM's decision. On October 19, 2016, Defendants, acting through their subsidiary Anthem Blue Cross, advised they would cover the request for an above the knee prosthetic leg but would not approve the request for one that is controlled by a microprocessor controlled knee. Defendants advised that "[w]e base this decision on the health plan medical policy, Microprocessor Controlled Lower Limb Prosthesis (OR-PR.00003)."

31. Because it was Defendants' policy and practice to deny coverage for requests for microprocessor controlled knee prostheses as not medically necessary

when the requests did not meet all of its erroneous criteria, Defendants did not assess whether Ms. Atzin met any valid individual medical criteria for receiving the device.

E. Defendants' denial of Plaintiff Mark Andersen's request for microprocessor controlled foot-ankle prostheses.

32. Mr. Andersen underwent bilateral below the knee amputations following a boating accident in 2000. He was subsequently fitted with below the knee prosthetic devices. Mr. Andersen operates a small moving and storage company.

33. In February of 2015, Mr. Andersen was evaluated for new prostheses by a certified prosthetist at Achilles Prosthetics and Orthotics. The prosthetist determined that Mr. Andersen needed below the knee prostheses with microprocessor controlled foot-ankle systems. Achilles Prosthetics and Orthotics sought authorization from Defendants for the devices.

34. On June 9, 2015, Anthem UM sent Mr. Andersen a letter advising that "Anthem UM Services, Inc. provides utilization management services for Anthem Blue Cross and Anthem Blue Cross Life and Health Insurance Company." Anthem UM stated it was denying the request for microprocessor controlled foot-ankle prosthesis because "[y]ou must have an above amputation." Anthem UM also indicated that Mr. Andersen did not meet the criteria of OR-PR.00003 and stated that "[w]e based this decision on the health plan medical policy, Microprocessor Controlled Lower Limb Prosthesis (OR-PR.00003)."

35. Mr. Andersen appealed this decision. On August 5, 2015 Anthem UM sent Mr. Andersen a letter advising that "Anthem UM Services, Inc. provides utilization management services for Anthem Blue Cross." Anthem UM stated it was denying Ms. Andersen's appeal because the microprocessor controlled foot-ankle prostheses "are considered investigational" and "[w]e based this decision on the health plan medical policy, Microprocessor Controlled Lower Limb Prosthesis (OR-PR.00003)."

36. Because it was Defendants' policy and practice to deny all requests for microprocessor controlled foot-ankle prostheses as "investigational and not medically necessary for all indications," Defendants did not assess whether Mr. Andersen met any individual medical criteria for receiving the devices.

CLASS ACTION ALLEGATIONS

37. Plaintiffs bring this action on behalf of themselves and all others similarly situated as a class action pursuant to Federal Rules of Civil Procedure Rule 23. Pursuant to Rule 23(b)(1) and (b)(2), Plaintiffs seek certification of the following class:

> All persons covered under Anthem plans, governed by ERISA, self-funded or fully insured, whose requests for microprocessor controlled knee or foot-ankle prostheses have been denied during the applicable statute of limitations pursuant to Anthem's Medical Policy on Microprocessor Controlled Lower Limb Prosthesis, Policy No. OR-PR.00003.

38. Plaintiffs and the class members reserve the right under Federal Rule of Civil Procedure Rule 23(c)(l)(C) to amend or modify the class to include greater specificity, by further division into subclasses, or by limitation to particular issues.

39. This action has been brought and may be properly maintained as a class action under the provisions of Federal Rules of Civil Procedure Rule 23 because it meets the requirements of Rule 23(a) and Rule 23(b)1 and (b)(2).

A. Numerosity

40. The potential members of the proposed class as defined are so numerous that joinder of all the members of the proposed class is impracticable. While the precise number of proposed class members has not been determined at this time, Plaintiffs are informed and believe that there are a substantial number of individuals covered under Anthem Plans who have been similarly affected.

B. Commonality

41. Common questions of law and fact exist as to all members of the proposed class.

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C. Typicality

42. The claims of the named Plaintiffs are typical of the claims of the proposed class. Plaintiffs and all members of the class are similarly affected by Defendants' wrongful conduct.

D. Adequacy of representation

43. Plaintiffs will fairly and adequately represent and protect the interests of the members of the proposed class. Counsel who represent Plaintiffs are competent and experienced in litigating large and complex class actions.

E. Superiority of class action

44. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Individual joinder of all members of the proposed class is not practicable, and common questions of law and fact exist as to all class members.

45. Class action treatment will allow those similarly situated persons to litigate their claims in the manner that is most efficient and economical for the parties and the judicial system. Plaintiffs are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

F. Rule 23(b) requirements

46. Inconsistent or varying adjudications with respect to individual members of the class would establish incompatible standards of conduct for Defendants.

47. Adjudications with respect to individual class members would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests.

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48. Defendants have acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole.

FIRST CLAIM FOR RELIEF
DENIAL OF PLAN BENEFITS AND FOR CLARIFICATION OF RIGHTS UNDER AN ERISA PLAN [29 U.S.C. § 1132(a)(1)(B)]

49. Plaintiffs and the class members repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as if fully set forth herein.

50. 29 U.S.C. § 1132(a)(1)(B) entitles Plaintiffs to recover benefits due and to enforce and clarify their rights to the benefits at issue.

51. As set forth above, Defendants have denied requests for microprocessor controlled knee and foot-ankle prostheses pursuant to the provisions of OR-PR.00003. With respect to microprocessor controlled knee prostheses, Defendants use erroneous criteria to deny coverage for these devices on the basis they are not "medical necessary." With respect to microprocessor controlled foot-ankle prostheses, Defendants deny coverage for the devices on the basis they are "investigational and not medically necessary for all indications."

52. Defendants denied Plaintiff Lacy Atzin's request for a microprocessor controlled knee prosthesis on the basis it was not "medically necessary" because she did not meet the erroneous criteria of OR-PR.00003 for that type of device. Defendants did not evaluate Ms. Atzin's request for the device under valid medical necessity criteria.

53. Ms. Atzin has exhausted her administrative remedies, as alleged above.

54. Defendants denied Plaintiff Mark Andersen's request for microprocessor controlled foot-ankle prostheses on the erroneous basis they are "investigational not medically necessary for all indications" pursuant to the directive in OR-PR.00003 for that device. Defendants did not evaluate Ms. Atzin's request for the devices under any medical necessity criteria.

55. Mr. Andersen has exhausted his administrative remedies, as alleged above.

56. Based on the foregoing, Plaintiffs and the class members seek the payment of medical expenses, interest thereon, a clarification of rights, and attorneys fees.

SECOND CLAIM FOR RELIEF
BREACH OF FIDUCIARY DUTY AND EQUITABLE RELIEF UNDER AN ERISA PLAN [29 U.S.C. § 1132(a)(3)]

57. Plaintiffs and the class members repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as if fully set forth herein.

58. As alleged herein, Defendants have acted as ERISA fiduciaries with respect to the administration and claims decisions under Anthem plans and, in particular, have acted as ERISA fiduciaries in denying requests for microprocessor controlled knee and foot-ankle prosthesis, as alleged herein.

59. Defendants have improperly denied Plaintiffs' and the class members' requests for microprocessor controlled knee and foot-ankle prostheses in beach of their fiduciary duties, as alleged herein.

60. Pursuant to 29 U.S.C. § 1132(a)(3), Plaintiffs and the class members seek declaratory, equitable and remedial relief as follows:

a. An order declaring that Defendants' denials of requests for microprocessor controlled knee prostheses are wrong and improper;

b. An order declaring that Defendants' denials of requests for microprocessor controlled foot-ankle prostheses are wrong and improper;

c. An injunction requiring Defendants to reevaluate and reprocess Plaintiffs' and class members' requests without the erroneous denial bases under appropriate and valid medical necessity criteria;

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d. An injunction requiring Defendants to provide notice of the reevaluation and reprocessing in the form and manner required by ERISA to all class members;

e. An injunction preluding Defendants from relying on specific reasons or specific policy provisions not recited in their form denial letters.

f. An accounting of any profits made by Defendants from the monies representing the improperly denied claims and disgorgement of any profits;

g. Such other equitable and remedial relief as the Court may deem appropriate; and

h. Attorneys fees in an amount to be proven.

REQUEST FOR RELIEF

Wherefore, Plaintiffs and the class members pray for judgment against Defendants as follows:

1. Benefits denied Plaintiffs in an amount to be proven at trial, including interest;

2. A clarification of rights to future benefits under the plan for all class members;

3. Injunctive and declaratory relief, as described above;

4. An accounting of any profits made and retained through the improper denial of claims and disgorgement of any profits;

5. Attorneys' fees; and

6. Such other equitable and remedial relief as the Court may deem just and proper.

DATED: September 15, 2017

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