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Attorneys for Plaintiff
ANDREW HOWARD, on behalf of himself
and all others similarly situated,

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

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| ANDREW HOWARD, on behalf of himself and all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>AETNA LIFE INSURANCE COMPANY;<br><br>Defendant. | Case No.: 2:22-CV-01505<br><br>**COMPLAINT FOR RECOVERY OF ERISA PLAN BENEFITS; ENFORCEMENT AND CLARIFICATION OF RIGHTS; AND BREACH OF FIDUCIARY DUTY**<br><br>**CLASS COMPLAINT** |

Plaintiff Andrew Howard on behalf of himself and all others similarly situated, set forth herein the allegations of his Complaint against Defendant Aetna Life Insurance Company.

## INTRODUCTION

1. Defendant Aetna Life Insurance Company ("Aetna") is in the business of insuring and/or administering group health plans within the meaning of 29 Code of Federal Regulations § 2560.503-1(m) (both fully insured and self-insured), 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*. Those ERISA-governed group health plans are hereinafter referred to as "Aetna plans."

2. Plaintiff brings this action to address Aetna's repeated violations of ERISA resulting from its systemic practice of denying services for lumbar artificial disc replacement surgery (L-ADR) on the basis that such services are "experimental and investigational." Aetna has developed and used a coverage policy, the Clinical Policy Bulletin "Intervertebral Disc Prostheses," that it uses when deciding claims for L-ADR. That Policy Bulletin provides that lumbar ADR is experimental and investigational and, therefore, excluded in all circumstances. Aetna has systematically denied all requests for L-ADR as experimental and investigational under this Clinical Policy Bulletin. Contrary to Aetna' position, L-ADR has been approved by The United States Food and Drug Administration ("FDA") for over fifteen years and is a safe, effective, and often recommended procedure that has successfully treated the symptoms of lumbar disc disease.

## JURISDICTION AND VENUE

3. This action is brought under 29 U.S.C. §§ 1132(a), (e), (f) and (g) as it involves a claim by Plaintiff for employee benefits under an employee benefit plan 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.

4. The Court has personal jurisdiction over Aetna 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).

5. The claims of Plaintiff and the putative class arise out of policies Aetna issued, administered, and/or implemented in this District. Moreover, Plaintiff Andrew Howard resides 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

6. Plaintiff Andrew Howard was at all relevant times covered under a fully-insured Aetna plan arranged through his employer, Shamrock Capital Advisors, through ADP TotalSource, Inc, a certified professional employer organization. This is an employee welfare benefit plan regulated by ERISA that provides medical, surgical, and other services.

7. Aetna is a corporation with its principal place of business in Hartford, Connecticut. Aetna administers and makes benefit determinations related to ERISA group health care plans around the country.

## SUBSTANTIVE ALLEGATIONS

### A. L-ADR

8. Traditionally, surgeons recommended a spinal fusion to treat degenerative lumbar disc disease. Fusion, however, causes a lack of mobility at the fused disc level and, consequently, more stress on the adjacent disc levels, leading to a greater risk of additional disc herniation/disease.

9. With L-ADR, the diseased disc is replaced with an artificial disc that maintains the integrity of the disc space while providing the flexibility of a natural disc.

10. The FDA has approved various devices for use in L-ADR surgery, beginning with the Charité Artificial Disc in 2004. The ProDisc-L device received

FDA Premarket Approval on August 14, 2006 for use in patients who have single-level degenerative disc disease of the lumbar spine (L3-S1). The activL device received FDA Premarket Approval on June 11, 2015, also for use in patients who have single-level degenerative disc disease of the lumbar spine (L4-L5 or L5-S1).

11. The FDA's Premarket Approval process is rigorous and applies to all Class III medical devices such as the PRODISC-L and the activL. Class III medical devices are devices which, by definition, present significant risks to human health. These devices must therefore meet the FDA's most stringent safety standards before they are approved for commercial sale and distribution. These include sufficient controlled clinical trial evidence to ensure that a given device is safe and effective. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-318, 322-323 (2008).

12. There have been numerous published peer-reviewed articles of controlled clinical trials establishing that L-ADR with an FDA-approved device is safe and effective. L-ADR is widely recognized in the medical community and by providers throughout the nation as a viable, safe and effective treatment for degenerative disc disease. Artificial disc devices have been used in thousands of spinal arthroplasties and have been proven to be safe and effective in the treatment of degenerative disc disease. Medical societies such as the North American Spine Society have endorsed the surgery and it is performed at leading medical centers across the country. All major health insurers other than Aetna (Anthem, United HealthCare, Humana, Cigna) cover the surgery.

**B. Aetna's categorical denial of requests for L-ADR**

13. Aetna plans are either fully insured (i.e., funded by Aetna) or self-insured (funded by the employer). Regardless of which entity funds the plan, Aetna acts as the claims administrator. If the plan is self-funded, Aetna will enter into an administrative services agreement with the plan's employer-sponsor to perform critical claims handling functions, including the functions of adjudicating claims and utilization management

14. Aetna plans cover surgical and hospital services to treat illness and injury, including services for surgery on both an inpatient and outpatient basis.

15. Aetna plans exclude from coverage those medical services that Aetna considers "experimental and investigational."

16. Aetna has developed internal Clinical Policy Bulletins ("CPB"), that is, written directives on coverage positions Aetna takes with respect to certain medical treatments.

17. Aetna's CPB 0591, "Intervertebral Disc Prostheses," sets forth Aetna's coverage position on L-ADR. It provides in pertinent part:

> Aetna considers lumbar prosthetic intervertebral discs (e.g., the activL Artificial Disc, the Charité Artificial Disc, and the ProDisc-L Total Disc Replacement) experimental and investigational for lumbosacral degenerative disc disease and for all other indications.

18. Pursuant to CPB 0591, Aetna has denied all requests for L-ADR on the basis that L-ADR is "experimental and investigational." Aetna denies coverage for L-ADR regardless of the member's medical profile or medical need. Aetna denies coverage for L-ADR upon the initial request for the surgery and on any appeal taken on the identical basis, that L-ADR is experimental and investigational.

**C. Aetna's denial of Plaintiff Andrew Howard's request for L-ADR**

19. At all relevant times, Plaintiff Andrew Howard was covered under an ERISA group health plan, an Aetna Open Access Managed Choice High Deductible Health Plan, offered under ADP Total Source, Inc., a certified professional employer organization, through his employer, Shamrock Capital Advisors ("Howard Aetna Plan").

20. Howard's ERISA group health plan is a fully-insured plan, i.e., insured and administered at all relevant times by Aetna.

21. Like all Aetna plans, the Howard Aetna Plan covers health services to treat illnesses and injuries. It is an ERISA group health plan because it is arranged by his employer for the benefit of its employees and their dependents. It provides payment

for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body.

22. Among other services, the Howard Aetna Plan covers surgical services performed in a surgical center or hospital.

> **Outpatient Surgery**
> **Covered services** include services provided and supplies used in connection with outpatient **surgery** performed in a surgery center or a **hospital's** outpatient department
>
> **Physician Services**
> **Covered services** include services by your **physician** to treat an illness or injury. You can get services:
> - At the **physician's** office
> - In your home
> - In a **hospital**
> - From any other inpatient our outpatient facility
> - By way of **telemedicine**.
>
> **Hospital Care**
> **Covered services** include inpatient and outpatient **hospital** care.

23. The Howard Aetna Plan contains an exclusion for services that are "Experimental or Investigational."

24. Plaintiff suffered from disc disease at the L5-S1 level of his lumbar spine that caused Plaintiff significant pain and immobility. Conservative measures such as medication and corrective exercises did not help to relieve these symptoms or the further degeneration of Plaintiff's spine condition.

25. After confirming Plaintiff's condition on MRI, and conducting a history and physical of Plaintiff, his surgeon, Robert Bray, M.D., recommended that Plaintiff undergo L-ADR. Plaintiff elected to proceed with the procedure.

26. Request was made of Aetna to preauthorize L-ADR for Plaintiff.

27. On November 10, 2021, Aetna advised Plaintiff that it was denying his request for L-ADR because it was experimental and investigational pursuant to CPB 0591. Aetna stated:

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> We reviewed information received about your condition and circumstances. We used the Clinical Policy Bulletin (CPB): Intervertebral Disc Prostheses. Based on CPB criteria and the information we have, we are denying coverage for L5-S1 anterior disk replacement with Active-L. Clinical studies have not proven that this service is effective for treatment of the member's condition.

28. Plaintiff and his physician appealed this decision. On December 2, 2021 2019, Aetna rejected the appeal and affirmed its initial denial of Plaintiff's request for L-ADR surgery pursuant to CPB 0591 on the basis that L-ADR is experimental and investigational.

29. In making its determination on Plaintiff's initial request for L-ADR and its determination of Plaintiff's appeal, the only reason given by Aetna for rejecting the claim was that it deemed L-ADR experimental and investigational under CPB 0591.

30. As a result of Aetna's rejection of his claim, Plaintiff paid for L-ADR out of his own pocket.

**D. *Hendricks v. Aetna Life Insurance Company***

31. In *Hendricks v. Aetna Life Insurance Company*, Case No.: 2:19-cv-06840 CRC (MRWx), a pending federal action venued in the Central District of California, plaintiffs Brian Hendricks and Andrew Sagalongos allege that Aetna violated ERISA by systematically and categorically denying requests for lumbar ADR surgery on the ground it is "experimental and investigational." The *Hendricks* action was filed on August 7, 2019.

32. On June 11, 2021, the court certified a class consisting of Aetna members whose claims are governed by the *abuse of discretion* standard of review under ERISA. The court did not include in the class those Aetna members insureds whose plans are subject to a *de novo* standard of the review on the basis that the Hendricks plaintiffs' claims, subject to an abuse of discretion standard, were not typical of their claims.

33. California Insurance Code section 10110.6 voids discretionary clauses in fully-insured health insurance policies that provide coverage to California

residents, regardless where the plan was issued. Aetna takes that position members of fully-insured plan in states that ban discretionary clauses, such as California, are subject to *de novo* review, and hence, claims for lumbar ADR arising under them fall outside of the *Hendricks* class.

## CLASS ACTION ALLEGATIONS

34. Plaintiff brings this action on behalf of himself 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), Plaintiff seeks certification of a class defined as follows:

> All persons covered under Aetna Plans, governed by ERISA and subject to a *de novo* standard of review, whose requests for lumbar artificial disc replacement surgery were denied at any time within the applicable statute of limitations, or whose requests for that surgery will be denied in the future, on the ground that lumbar artificial disc replacement surgery is experimental or investigational.

35. Plaintiff and the Class 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.

36. 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 there is a well-defined community of interest in the litigation and the proposed class is easily ascertainable.

### A. Numerosity

37. 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, Plaintiff is informed and believes that there are a substantial number of individuals covered under Aetna plans who have been similarly affected.

**B. Commonality**

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

**C. Typicality**

39. The claims of the named Plaintiff are typical of the claims of the proposed class. Plaintiff and all members of the class are similarly affected by Aetna' wrongful conduct.

**D. Adequacy of representation**

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

**E. Superiority of class action**

41. 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.

42. 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. Plaintiff is 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**

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

44. 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.

45. Aetna has 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**
**FOR DENIAL OF PLAN BENEFITS AND FOR CLARIFICATION OF RIGHTS UNDER AN ERISA PLAN [29 U.S.C. § 1132(a)(1)(B)]**

46. Plaintiff and the Class repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as if fully set forth herein.

47. 29 U.S.C. § 1132(a)(1)(B) entitles Plaintiff to recover benefits due and to enforce and clarify their rights to the benefits at issue.

48. As alleged herein, Plaintiff's Aetna plan provide surgical and hospital services to treat illness and injury. L-ADR is a form of spinal surgery that is covered under Plaintiff's Aetna plan. Plaintiff requested that Aetna authorize coverage for L-ADR.

49. As alleged herein, Aetna categorically denies all requests for L-ADR based upon the position set forth in CPB 0591 that L-ADR surgery is "experimental and investigational" and excluded under all Aetna plans.

50. Aetna improperly denied Plaintiff's requests for L-ADR because, it said, L-ADR is experimental and investigational pursuant to CPB 059 and therefore excluded under Plaintiff's Aetna plans. Aetna has applied and continues to apply its internal guideline in a manner which restricts access to L-ADR for individuals with degenerative disc disease, a practice wholly inconsistent with the Aetna plans' promise to provide surgical and hospital services to treat illness and injury. Moreover, L-ADR is not experimental or investigational. As alleged herein, L-ADR is a safe and effective treatment and has been approved by the FDA for over fifteen years.

51. Plaintiff has exhausted his administrative remedies, as alleged herein, and to the extent Aetna asserts that those remedies were exhausted, any such attempts

would have been futile due Aetna's policy that lumbar ADR is experimental and investigational, as determined by the court in *Hendricks*. (*Hendricks*, Dkt. 94 at 13-14.)

52. There is now due and owing to Plaintiff benefits, interest, and attorney fees in an amount to be determined at the time of trial.

53. On behalf of the class, Plaintiff seeks a clarification of rights relating to Aetna's categorical denial of L-ADR as experimental and investigational.

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

54. Plaintiff and the Class repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.

55. Aetna acts as ERISA fiduciary with respect to the administration and claims decisions under Aetna plans, such as the plans at issue, within the meaning of 29 U.S.C. § 1109(a) and 1002(21)(A). With respect to these plans, Aetna exercises discretionary authority or control respecting management of the plans, and exercises authority and control respecting management or disposition of the plans' assets. Aetna has the authority, and actually exercise the authority, to make decisions on claims for benefits and appeals thereof, and to write checks for benefits.

56. As alleged herein, Plaintiff's Aetna plan provides surgical and hospital services to treat illness and injury. L-ADR is a form of spinal surgery that is covered under Plaintiff's Aetna plan. Plaintiff requested that Aetna authorize coverage for L-ADR.

57. As alleged herein, Aetna categorically denies all requests for L-ADR based upon the position set forth in CPB 0591 that L-ADR surgery is "experimental and investigational" and excluded under all Aetna plans.

58. Aetna improperly denied Plaintiff's requests for L-ADR because, it said, L-ADR is experimental and investigational pursuant to CPB 059 and therefore excluded under Plaintiff's Aetna plans. Aetna has applied and continues to apply its internal guideline in a manner which restricts access to L-ADR for individuals with

degenerative disc disease, a practice wholly inconsistent with the Aetna plans' promise to provide surgical and hospital services to treat illness and injury. Moreover, L-ADR is not experimental or investigational. As alleged herein, L-ADR is a safe and effective treatment and has been approved by the FDA for over fifteen years.

59. Pursuant to 29 U.S.C. § 1104(a), Aetna was required to discharge its fiduciary duties with respect to Aetna plans solely in the interest of the participants and beneficiaries and—

(A) for the exclusive purpose of:

(i) providing benefits to participants and their beneficiaries; and

(ii) defraying reasonable expenses of administering the plan;

(B) with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims;

... and

(D) in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III.

60. Aetna violated its duty of loyalty under 29 U.S.C. § 1104(a)(1)(A) by: (a) creating CPB 0591 that erroneously classifies L-ADR surgery as experimental and investigational and excluded under all Aetna plans, in violation of the plans' promise to provide coverage for surgery to treat illness or injury and the terms of the "experimental and investigational" exclusion; (b) instructing claims personnel to implement CPB 0591 for claims for L-ADR and to deny those claims on the basis they are experimental and investigational; and (c) failing to provide or offer to provide an explanation of the scientific or clinical judgment for its "experimental and investigational" denial reason in violation of 29 Code of Federal Regulations § 2560.503-1(g)(1)(v)(B) by providing a knowingly biased and incomplete picture of the

safety and effectiveness of L-ADR in CPB 0591. These actions by Aetna cause the deprivation of benefits under Aetna plans for participants and their beneficiaries and increase the reasonable expenses of administering the plan because they cause a systematic denial of claims for L-ADR resulting in loss of benefits, needless appeals, and other expenses.

61. Aetna violated its duty of due care under 29 U.S.C. § 1104(a)(1)(B) by: (a) creating CPB 0591 that erroneously classifies L-ADR surgery as experimental and investigational and excluded under all Aetna plans, in violation of the plans' promise to provide coverage for surgery to treat illness or injury and the terms of the "experimental and investigational" exclusion; (b) instructing claims personnel to implement CPB 0591 for claims for L-ADR and to deny those claims on the basis they are experimental and investigational; ; and (c) failing to provide or offer to provide an explanation of the scientific or clinical judgment for its "experimental and investigational" denial reason in violation of 29 Code of Federal Regulations § 2560.503-1(g)(1)(v)(B) by providing a knowingly biased and incomplete picture of the safety and effectiveness of L-ADR in CPB 0591.

62. Aetna violated its duty to comply with plan terms under 29 U.S.C. § 1104(a)(1)(D) by: (a) creating CPB 0591 that erroneously classifies L-ADR surgery as experimental and investigational and excluded under all Aetna plans, in violation of the plans' promise to provide coverage for surgery to treat illness or injury and the terms of the "experimental and investigational" exclusion; (b) instructing claims personnel to implement CPB 0591 for claims for L-ADR and to deny those claims on the basis they are experimental and investigational; and (c) failing to provide or offer to provide an explanation of the scientific or clinical judgment for its "experimental and investigational" denial reason in violation of 29 Code of Federal Regulations § 2560.503-1(g)(1)(v)(B) by providing a knowingly biased and incomplete picture of the safety and effectiveness of L-ADR in CPB 0591.

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

a. An order declaring that Aetna's denials of Plaintiff's and the class members' claims for L-ADR were wrong and improper;

b. A class-wide injunction requiring Aetna to retract its CPB 0591 that erroneously classifies claims for L-ADR as experimental and investigational;

c. A class-wide injunction requiring Aetna to reform its claims adjudication process so as to adjudicate future claims without the erroneous "experimental and investigational" denial basis and do so under appropriate and valid medical criteria;

d. A class-wide injunction requiring Aetna to reevaluate and reprocess prior denials without the erroneous "experimental and investigational" denial basis under appropriate and valid medical criteria;

e. An injunction requiring Aetna to provide notice of the reformation of its claims adjudication process for such claims in the form and manner required by ERISA to all class members;

f. Surcharge, including an accounting of any profits made by Aetna 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, Plaintiff and the Class pray for judgment against Aetna as follows:

1. Re-process and payment of the health benefits due to Plaintiff and class members;

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

3. Injunctive and declaratory relief for all class members, as described above;

4. Surcharge, including an accounting of any profits made by Aetna from the monies representing the improperly denied claims and disgorgement of any profits;

5. Pursuant to 29 U.S.C. § 1132(g), payment of all costs and attorney fees incurred in pursuing this action;

6. Payment of prejudgment and post-judgment interest as allowed for under ERISA; and

7. For such other and further relief as the Court deems just and proper.

DATED: March 4, 2022

GIANELLI & MORRIS

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