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1 2 3 4 5 6 7 8	Alex R. Straus (SBN 321366) MILBERG COLEMAN BRYSON PHILLIPS GROSSMAN, PLLC 280 S. Beverly Drive, PH Suite Beverly Hills, CA 90212 Tel: (917) 471-1894 Fax: (310) 496-3176 astraus@milberg.com <i>Attorneys for Plaintiffs and the Proposed Class</i> <i>Additional Attorneys on Signature Page</i> UNITED STATES DIST	RICT COI	U RT
9	FOR THE NORTHERN DISTRI	CT OF CA	LIFORNIA
10			
11	MSP RECOVERY CLAIMS, SERIES LLC, a) Ca	se No.: 3:2	2-cv-07604
12	Delaware series limited liability company; MSPA)		TON COMPLAINT
13			
14	Recovery Claims PROV. Series LLC, a Delaware)	EMAND FO	OR JURY TRIAL
15	series limited liability company; on behalf of)		
16	Plaintiffs,		
17			
18	V.) ACTELION PHARACELITICALS US INC 2)		
19 20	19ACTELION PHARACEUTICALS US, INC., a)Delaware corporation; CARING VOICE)20COALITION, INC. an Idaho non-profit)		
21	corporation; and ADIRA FOUNDATION, a) Virginia non-profit corporation,)		
22	Defendant(s).		
23)		
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	-1-		
	CLASS ACTION COMPLAINT	- 3:22-cv-(07604

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1 Plaintiffs, MSP Recovery Claims, Series LLC ("MSPRC"); MSPA Claims 1, LLC 2 ("MSPA"); MSP Recovery Claims Series 44, LLC ("Series 44"); MSP Recovery Claims PROV, 3 Series LLC ("Claims PROV"); MSP Recovery Claims CAID, Series LLC ("Claims CAID") 4 (hereinafter all plaintiffs collectively referred to as, "Plaintiffs"), on behalf of themselves and other Medicare Advantage health plans¹ and Medicaid health plans² (collectively, "Class Members"),³ 5 6 sue Actelion Pharmaceuticals US, Inc. ("Actelion"), Caring Voice Coalition, Inc. ("CVC") and 7 Adira Foundation f/k/a Facilitating Patient Health ("Adira") (hereinafter all defendants collectively 8 referred to as "Defendants"), allege:

9

NATURE OF ACTION

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 This case arises out of Actelion's conspiratorial schemes to increase the unit price and quantity dispensed of Tracleer, Opsumit, Veletri, and Ventavis ("Subject Drugs" or "Actelion Drugs") which is used to treat pulmonary arterial hypertension ("PAH"). As a result of these schemes, Plaintiffs' Assignors ("Assignors") and the Class Members paid supra-competitive prices for Actelion Drugs and for artificially inflated quantities of dispensed Actelion Drugs on behalf of beneficiaries enrolled in their health plans ("Enrollees").

- RICO Defendants created a scheme to circumvent Congressionally mandated co payment requirements (referred to as "Co-Payment Scheme" or "Scheme") designed to reduce
 sensitivity to the ever-increasing drug prices and increased dispensing of Actelion Drugs.⁴
- 20

 2ϵ ³ The full class is defined *infra*, Section V.

²⁶⁴ When Medicare beneficiaries, including those covered by Medicare Advantage health plans, obtain a prescription drug, the beneficiaries need to make a co-payment. Congress included copayment requirements in the Medicare structure, in part, to encourage market forces to serve as a check on health care costs, specifically including the prices that pharmaceutical companies can

demand for their drugs. Austin Frerick, A., *The Cloak of Social Responsibility: Pharmaceutical*

 ¹ "Medicare Advantage health plans" is defined as Medicare Advantage entities such as Medicare Advantage organizations ("MAOs"), Independent Practice Associations ("IPAs"), Management Service organizations ("MSOs"), Health Maintenance organizations ("HMOs"), Part D Sponsors, and other Medicare first tier, downstream, and related entities. Throughout the Complaint, "MA Plan" is used as a shorthand for all such Medicare Advantage health plan entities.

 ^{24 &}lt;sup>2</sup> "Medicaid health plans" is defined to include Medicaid Managed Care Organizations ("MCO") and other Medicaid first tier, downstream, and related entities. Throughout the Complaint,
 25 "Medicaid Plans" is used as a shorthand for all such Medicaid health plan entities.

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3. Defendants executed their Scheme, engaging in numerous overt acts that both
 effectively eliminated price sensitivity, allowing Actelion to raise their prices to supra-competitive
 levels, without concern of their product not being dispensed due to patient financial restrictions
 which caused the over-dispensing of supra-competitively priced drugs. This resulted in cognizable
 economic damages as Assignors and Class Members lost money or property they otherwise would
 still have but-for the Co-Payment Scheme.

Actelion and CVC colluded and agreed that CVC would act as an illegal conduit,
disguised as an independent charity, by which Actelion could funnel kickbacks to pharmacies
through CVC's disease funds. Actelion and CVC agreed that CVC would create a PAH Fund that
would exclusively, or nearly so, cater to patients taking the Subject Actelion Drugs and that
Actelion would be the sole donor to CVC's PAH Fund.

12 5. Actelion bribed CVC to serve as Actelion's conduit and funnel kickbacks to13 pharmacies.

6. As part of this Scheme, Actelion routinely obtained data from CVC detailing how
many patients taking each Subject Drug CVC had assisted, how much CVC had spent on those
patients, and how much CVC expected to spend on those patients in the future. This information
was used to ensure that CVC used the purported "donations" for Actelion Drugs only, and allowed
Actelion to perform return on investment calculations.

19 7. Actelion and CVC routinely exchanged information to ensure Actelion possessed
20 sufficient data to maximize profits from its "donations" to CVC.

8. Defendants also funneled MA Plan and Medicaid Plan patients away from Actelion's
free drug program. Defendants excluded individuals from participating in Actelion's free drug
program because the individuals were eligible for participation in the federal health programs. In
other words, Defendants treated customers differently based on eligibility for participation in the
federal health programs.

26

27

CLASS ACTION COMPLAINT - 3:22-cv-07604

²⁸ Corporate Charity, TAX NOTES, Vol. 153, No. 9, Nov. 28, 2016. [hereinafter Cloak of Social Responsibility].

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1 9. Actelion's bribes to CVC and Defendants' illegal renumerations to federal healthcare 2 program beneficiaries constituted violations of the federal Anti-Kickback Statute ("AKS"), thereby 3 rendering each claim unpayable by federal healthcare programs and disqualifying Actelion from receiving any payment from such programs for the Subject Drugs during the course of the Scheme. 4

5

10. Actelion ensured that the large sums of money continuously paid to CVC improperly influenced CVC's practices. Likewise, Defendants ensured that the co-payment assistance grants-6 7 paid for and facilitated by Actelion, and distributed by CVC-improperly influenced patients 8 receiving and/or pharmacies dispensing Actelion Drugs.

9 In doing so, Defendants eliminated the effects of price sensitivity—because the 11. 10 patients (i.e., consumers) were no longer incurring any cost-thereby elimination price considerations, thus artificially increasing the quantity dispensed by pharmacies, and the amount of 11 claims paid by Assignors and Class Members for Actelion Drugs. Accordingly, with price 12 13 sensitivity eliminated, the Co-Payment Scheme allowed Actelion to circumvent congressional 14 safeguards and artificially increase the price of Actelion Drugs for all prescriptions to supra-15 competitive levels.

16 12. As a result, the Assignors and Class Members were forced to pay artificially 17 increased prices for Actelion Drugs prescriptions and for an increased quantity of claims for 18 Actelion Drugs. This resulted in cognizable economic damages as the Assignors and Class 19 Members paid substantially more than they otherwise would have-but for the Co-Payment 20Scheme.

21 13. Actelion, a sophisticated pharmaceutical manufacturer, knew that the intended 22 victims of the Scheme were the health plans Plaintiffs seek to represent. Indeed, after a patient's 23 cost sharing obligation is paid, health plans such as the Assignors and Class Members must then pay 24 for Actelion Drugs. To be clear, if a patient does not provide their cost sharing obligations (e.g., co-25 pay), a prescription will not be dispensed from a pharmacy.

26 14. On December 5, 2018, Actelion paid \$360 million to settle the United States' claims 27 that Actelion violated the AKS and False Claims Act ("FCA"). Actelion entered into a Settlement 28 Agreement with the United States of America ("Actelion Settlement"), with the United States

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Department of Justice ("DOJ") and on behalf of the Office of Inspector General ("OIG") of the
 Department of Health and Human Services related to the general conduct at issue in this lawsuit.
 See Actelion Settlement Agreement, attached as **Exhibit A**; *See also* DOJ Settlement Agreement
 Press Release, attached as **Exhibit B**.

5 15. The Actelion Settlement did not address or settle damages sustained by the
6 Assignors and Class Members. The terms of the Actelion Settlement did not address the claims
7 Plaintiffs set forth in the action.

8 16. Additionally, CVC made several fraudulent and voidable transfers to Adira, in
9 violation of Va. Code Ann. §§ 55.1-400 *et seq*.

10 17. Adira is the de facto successor of CVC. Adira was created by and has always been operated by the very same people who operated CVC-including, but not limited to Greg Smiley, 11 James Rock, and Bruce Packett. Adira received the remainder of CVC's assets, including cash, 12 13 investments, and valuable personal property. Adira received and continues to maintain all of CVC's 14 data including taking ownership and control of what CVC described as its "home-grown patient 15 portal for monitoring patient and grant data-known in shorthand by previous leadership as PAMS 16 [which] was [CVC's] largest and most significant of assets." As CVC's successor, Adira is liable for CVC's debts and liabilities. 17

18 18. Additionally, and upon information and belief, after CVC allegedly ceased
operations, CVC and Adira contacted Actelion and agreed to transfer millions of dollars of illicit
funds to Adira, where both Adira and Actelion continued taking overt acts in furtherance of their
scheme to defraud third-party payors. As a coconspirator to the scheme to defraud, Adira is jointly
and severally liable for the harm caused by CVC's and Actelion's conduct.

23

19. Indeed, each Defendant is jointly and severally liable for the conduct of the others.

24 20. Plaintiffs bring this lawsuit to redress the damages sustained by Assignors and Class
25 Members as a result of Defendants' unlawful Scheme to increase the prices and dispensed quantities
26 of Actelion Drugs.

27 21. The improper actions alleged here have allowed Actelion to maintain supra28 competitive prices by eliminating price sensitivity that would have directly benefited consumers and

- 4 -

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the public at large. Price sensitivity counterbalances Actelion's desire to inflate prices for medically 1 necessary drugs-which is why Congress relies on price sensitivity as a vital mechanism for 2 3 combating supra-competitive pricing for Government payors. CVC's co-payment assistance program allowed Actelion to increase the price of the Actelion Drugs regardless of the relevant 4 5 market conditions by insulating Actelion from the realities of patients' inability to afford high copayment obligations-obligations that would have had to have been capped at a reasonable amount 6 7 but-for the unlawful Scheme alleged herein. Not only did this allow Actelion to charge supracompetitive prices, but also resulted in the artificially increased volume of dispensed Actelion 8 9 Drugs.

22. Defendants used mail and wires in furtherance of their racketeering Scheme.
Actelion used the wires to transmit their "donations" to CVC, which, in reality, were bribes to CVC.
CVC would then transmit data using the mail and wires, allowing Actelion to perform what
amounted to return on investments ("ROI") calculations on their "donations." Defendants would
also use the mail and wire to communicate with pharmacies regarding, among other things, copayments for patients prescribed Actelion Drugs. This resulted in the further use of mail and wires
by pharmacies submitting claims for payment to Plaintiffs and Assignors.

17 23. RICO Defendants' conduct violated the AKS, 42 U.S.C. § 1320a-7b, the Travel Act,
18 U.S.C. § 1952 ("Travel Act"), Mail Fraud, 18 U.S.C. § 1341, and Wire Fraud, 18 U.S.C. § 1343.

19

20

21

PARTIES, JURISDICTION, AND VENUE

|| Plaintiffs

I.

24. Plaintiffs are companies that obtained assignments from their Assignors to recover
reimbursement or payment from Defendants. The Assignors provide health insurance coverage,
pursuant to Medicare Part C and Part D and Medicaid on behalf of their Enrollees. Specifically, the
Assignors made payments on behalf of, or otherwise became financially responsible for the cost of
the illegally inflated and excessively dispensed Actelion Drugs as a result of the Scheme.

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28

25. Each and every cause of action identified in this Complaint was expressly assigned to the named Plaintiffs.

- 5 -

<u>MSPRC</u>

1

2 26. MSPRC is a Delaware series limited liability company with its principal place of
3 business located in Coral Gables, Florida. MSPRC's limited liability company agreement provides
4 for the establishment of one or more designated Series.

5 27. MSPRC has established various designated series pursuant to Delaware law to maintain various claims recovery assignments separate from other Company assets, and to account 6 7 for and associate certain assets with certain particular series. Pursuant to MSPRC's limited liability 8 agreement, all designated series form a part of MSPRC. MSPRC may receive assignments in the 9 name of MSPRC and further associate such assignments with a particular series or may have claims 10 assigned directly to a particular series. In either event, MSPRC will maintain the right to sue on behalf of each series and pursue any and all rights, benefits, and causes of action arising from 11 12 assignments to a series. Any claim or suit may be brought by MSPRC in its own name, or it may 13 elect to bring suit in the name of its designated series, under its bylaws. MSPRC's limited liability 14 agreement provides that any rights and benefits arising from assignments to its series shall belong to 15 MSPRC. MSPRC's assignments, samples of which are alleged in detail in the Appendix to this 16 Complaint, are valid and binding contracts.

17 28. Each and every cause of action identified in this Complaint was expressly assigned18 to MSPRC.

19

<u>MSPA</u>

20 29. MSPA is a limited liability company that is duly organized, validly existing, and in 21 good standing under the laws of Florida, with its principal place of business in Coral Gables, 22 Florida. One or more health plans irrevocably assigned to MSPA the right to assert the causes of 23 action alleged in this Complaint. As a result of said assignments, MSPA is authorized and 24 empowered to obtain the relief sought herein. MSPA's assignments, samples of which are alleged in 25 detail in the Appendix to this Complaint, are valid and binding contracts.

26 30. Each and every cause of action identified in this Complaint was expressly assigned
27 to MSPA.

28

Series 44

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31. Series 44 is a duly organized and existing Delaware series limited liability company
with its principal place of business located in Coral Gables, Florida. Series 44's limited liability
company operating agreement provides for the establishment of one or more designated series as
permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Series 44 established
various designated series to serve as units of the company for the purpose of maintaining various
claims recovery assignments separate from other company assets, and to account for and associate
certain assets with certain particular series.

8 32. Series 44 has enumerated rights relating to its designated series pursuant to its 9 limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-10 (c). Specifically, all rights and benefits arising from assignments to its series shall belong to Series 44. Series 44 may receive assignments in the name of Series 44 and further associate such 11 12 assignments with a particular series or may have claims assigned directly to a particular series. In 13 either event, Series 44 and the designated series are authorized to pursue or assert any claim or suit 14 capable of being asserted by any designated series arising from, or by virtue of, an assignment to a 15 designated series. Series 44 retains the legal right to sue on behalf of each designated series and 16 pursue all rights, benefits, and causes of action arising from assignments to a series in its own name 17 or in the name of the designated series. Series 44's assignments, samples of which are alleged in 18 detail in the Appendix to this Complaint, are valid and binding contracts.

19 33. Each and every cause of action identified in this Complaint was expressly assigned
20 to Series 44.

21

<u>Claims PROV</u>

34. Claims PROV is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Claims PROV's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware Law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Claims PROV established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series.

- 7 -

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35. 1 Claims PROV has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-2 3 (c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims PROV. Claims PROV may receive assignments in the name of Claims PROV and further associate 4 5 such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Claims PROV and the designated series are authorized to pursue or assert any claim 6 7 or suit capable of being asserted by any designated series arising from, or by virtue of, an 8 assignment to a designated series. Claims PROV retains the legal right to sue on behalf of each 9 designated series and pursue all rights, benefits, and causes of action arising from assignments to a 10 series in its own name or in the name of the designated series. One or more Health Plans irrevocably assigned to certain series of Claims PROV the right to assert the causes of action alleged in this 11 12 Complaint. As a result of said assignments, Claims PROV, through its operating agreement, is 13 authorized and empowered to obtain the relief sought herein. Claims PROV's assignments, samples 14 of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

15 36. Each and every cause of action identified in this Complaint was expressly assigned
16 to Claims PROV.

<u>C</u>

17

<u>Claims CAID</u>

18 37. Claims CAID is a duly organized and existing Delaware series limited liability 19 company with its principal place of business located in Coral Gables, Florida. Claims CAID's 20 limited liability company operating agreement provides for the establishment of one or more 21 designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, 22 Claims CAID established various designated series to serve as units of the company for the purpose 23 of maintaining various assignments separate from other company assets, and in order to account for 24 and associate certain assets with certain particular series.

38. Claims CAID has enumerated rights relating to its designated series pursuant to its
limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims
CAID. Claims CAID may receive assignments in the name of Claims CAID and further associate

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such assignments with a particular series or may have claims assigned directly to a particular series. 1 2 In either event, Claims CAID and the designated series are authorized to pursue or assert any claim 3 or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Claims CAID retains the legal right to sue on behalf of each 4 5 designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plan irrevocably 6 7 assigned to certain series of Claims CAID the right to assert the causes of action alleged in this 8 Complaint. As a result of said assignments, Claims CAID, through its operating agreement, is 9 authorized and empowered to obtain the relief sought herein. Claims CAID's assignments, samples 10 of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

39. Defendants' Co-Payment Scheme triggered payment obligations of the Assignors
and Class Members. These actions caused the Assignors and Class Members to pay artificially
inflated prices and purchase artificially inflated quantities of Actelion Drugs. This illegal conduct
directly harmed Assignors and the Class Members.

40. Each and every cause of action identified in this Complaint was expressly assigned
to Claims CAID.

17 Defendants

41. Actelion is a Delaware corporation with principal executive offices located in South
San Francisco, California. Actelion manufacturers and markets pharmaceutical products that are
approved for pulmonary arterial hypertension. At all relative times, Actelion advertised, marketed,
and sold pharmaceutical products, including the Subject Drugs, throughout all states and territories
in the United States, including California. Actelion derived substantial revenue related to the
Subject Drugs from its business throughout each of the states and territories of the United States,
including California.⁵

26

18

<u>Actelion</u>

See, Exhibit 3 – Actelion 1999 Financial Reports; Exhibit 4 – Actelion 2000 Financial Reports;
 Exhibit 5 – Actelion 2001 Financial Reports; Exhibit 6 – Actelion 2002 Financial Reports; Exhibit 7 – Actelion 2003 Financial Reports; Exhibit 8 – Actelion 2004 Financial Reports; Exhibit 9 – Actelion 2005 Financial Reports; Exhibit 10 – Actelion 2006 Financial Reports; Exhibit 11 – -9-

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42. This Court has personal jurisdiction over Actelion because Actelion's principal
 executive offices are located within the state of California and therefore Actelion is at home in the
 state.

 \underline{CVC}

4

43. CVC is an Idaho corporation claiming 501(c)(3) status for tax purposes. CVC's
principal place of business during the duration of the Scheme was located at 6606 West Broad
Street, Suite 403, Richmond, Virginia 23230, however, pursuant to a filing with the Commonwealth
of Virginia, on July 31, 2019, CVC, changed their principal place of business to P.O. Box 28955,
Henrico, VA 23228. CVC was established in 2003 and operates disease funds, including the PAH
Fund, to pay the co-payments of certain patients, including Medicare and Medicaid patients.
Exhibit 22 – CVC & Adira Business Records

12 44. This Court has personal jurisdiction over CVC because CVC's conduct as a member 13 of the Co-Payment Circumvention Enterprise (defined below) constitutes "certain minimum 14 contacts with the forum such that the maintenance of the suit does not offend traditional conceptions of fair play and substantial justice" therefore satisfying California's Long Arm Statute. 15 16 International Shoe Co. v. State of Washington, 326 U.S. 310, (1945); Cal. Civ. Proc. Code § 410.10. 17 CVC transacts its affairs in the State of California. CVC further engaged in the substantial and not 18 isolated activity throughout the State of California. As a result of the Co-Payment Scheme, the 19 Assignors and Class Members sustained financial and economic injuries in the State of California. 20 CVC maintains systematic and continuous contacts in the State of California, and regularly 21 transacts business in the State of California. CVC purposefully availed itself of the privilege of 22 conducting activities in the State of California, thus benefiting from the protections and benefits of 23 the law and conducting its affairs in the State of California. Furthermore, at all relevant times 24 herein, CVC contracted with Actelion.

25

Actelion 2007 Financial Reports; Exhibit 12 – Actelion 2008 Financial Reports; Exhibit 13 – Actelion 2009 Financial Reports; Exhibit 14 – Actelion 2010 Financial Reports; Exhibit 15 – Actelion 2011 Financial Reports; Exhibit 16 – Actelion 2012 Financial Reports; Exhibit 17 – Actelion 2013 Financial Reports; Exhibit 18 – Actelion 2014 Financial Reports; Exhibit 19 – Actelion 2015 Financial Reports; Exhibit 20 – Actelion 2016 Financial Reports; Exhibit 21 – Actelion 2017 Financial Reports

1

<u>Adira</u>

45. Adira is a Virginia corporation claiming 501(c)(3) status for tax purposes. Adira's
principal office is located at 7330 Staples Mill Road #288, Henrico, VA, 23228-4122. Adira,
originally incorporated under the name Facilitating Patient Health, was established in 2019 and
operates disease funds to pay the co-payments of certain patients, including Medicare and Medicaid
patients. Exhibit 22 – CVC & Adira Business Records.

7 46. This Court has jurisdiction over Adira because Adira is a successor company of
8 CVC, and as noted above, this Court has personal jurisdiction over CVC. *Successor Agency to*9 *Former Emeryville Redevelopment Agency v. Swagelok Co.*, 364 F. Supp. 3d 1061, 1074 (N.D. Cal.
10 2019); International Shoe Co., 326 U.S. at 316; Cal. Civ. Proc. Code § 410.10.

47. This Court has federal question jurisdiction pursuant to 28 U.S.C. § 1331. The causes
of action alleged in this Complaint arise under federal law.

48. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a), because
Plaintiffs are completely diverse from Defendants and the amount in controversy exceeds
\$75,000.00, exclusive of interest and costs.

49. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d), because at least
one member of the Class is a citizen of a state different from Defendants and the amount in
controversy exceeds \$5,000,000.00, exclusive of interest and costs.

19 50. This Court also has supplemental jurisdiction under to 28 U.S.C. § 1367, as the state
20 law claims are so related to the federal claims as to form part of the same case or controversy.

51. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)(2) because a
substantial part of the events that gave rise to this lawsuit occurred in California. Venue is also
proper in this district under 18 U.S.C. § 1965(a) because Defendants transact their affairs in
California.

25 DIV

DIVISIONAL ASSIGNMENT

52. This action is properly assigned to the San Francisco/Oakland Division of this
District pursuant to N.D. Cal. L.R. 3-2, because Defendant Actelion's principal place of business is
in San Francisco County, which is served by the San Francisco Division. Moreover, Defendant

- 11 -

Actelion conducts substantial business in San Francisco County, which is served by this Division.

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II.

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STANDING

53. The Assignors provide health care benefits to their Enrollees under either (i) contractual agreements, such as participation and network agreements with capitation and risk sharing arrangements; or (ii) state and federal laws that provide for the reimbursement of payments made by the assignor health plans.

54. The assignment agreements between Assignors and Plaintiffs are valid and binding
 contracts, expressly empowering Plaintiffs to bring and recover on the claims asserted in this
 lawsuit.

55. Plaintiffs seek recovery on behalf of each of their Assignors who paid for or reimbursed the cost of Actelion Drugs at supra-competitive prices and paid for inflated quantities of Actelion Drugs. An explanation of the representative assignment for each named Plaintiff is provided in the Appendix.

- 56. Plaintiffs seek recovery on behalf of each of their Assignors who paid for or reimbursed claims relating to Actelion Drugs tainted by Defendants' violations of the AKS.
- 57. At all material times hereto, one or more Assignor(s) provided Medicare benefits to MA Plan beneficiaries and one or more Assignor(s) provided Medicaid benefits to Medicaid Plan beneficiaries. The Assignors paid supra-competitive prices for Actelion Drugs and paid for artificially inflated dispensed quantities of Actelion Drugs as a result of Defendants' Scheme. The Assignors also paid claims for Actelion Drugs tainted by Defendants' AKS violations.
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58. Defendants' Scheme triggered payment obligations for Actelion Drugs at inflated prices and induced the artificially increased dispensing of Actelion Drugs over cheaper and therapeutically equivalent generic or alternative treatments.

Assignors paid approximately \$31 million in claims on behalf of covered patients
 receiving the Actelion Drugs from at least January 1, 2014, through present.

28

60.

Assignors provided payment for Actelion Drugs throughout the United States.

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1

III. REGULATORY BACKGROUND

2 61. In 1965, Congress amended the Social Security Act to create the Medicare Act under 3 Title XVIII of the U.S. Code. The Medicare Act created a federally funded health insurance program for the nation's elderly and disabled. The Medicare Act consists of five parts—Parts A, B, 4 5 C, D and E. Part A and Part B create, describe, and regulate traditional fee-for-service, governmentadministered Medicare. Part C outlines the Medicare Advantage program and provides that 6 7 Medicare beneficiaries may elect for private insurers to deliver their Medicare benefits. Part D 8 provides for prescription drug coverage to Medicare beneficiaries. Part E includes "Miscellaneous 9 Provisions." Plaintiffs' Assignors provide Medicare benefits under Parts C and D.

62. Medicare Part D coverage is a voluntary prescription drug benefit program for
Medicare beneficiaries established in 2003. Medicare Part D took full effect in 2006. A beneficiary
may enroll in Part D if he or she lives in the service area of a Part D plan and is entitled to Medicare
benefits under Part A or enrolled under Part B.

14 63. Unlike Parts A and B, yet much like Medicare Part C, Medicare Part D is based on a
15 private-market model, where Medicare contracts with private entities, known as Part D "sponsors."
16 These sponsors administer prescription drug plans, and plan sponsors must provide qualified
17 prescription drug coverage.

18 64. A Part D sponsor submits a bid the year before it is to deliver Part D benefits. The
19 bid contains a per member, per month cost estimate for providing Part D benefits to an average
20 Medicare beneficiary in the geographic area.

65. If the Part D plan sponsor's bid exceeds the benchmark, the enrolled beneficiary may
have to pay the difference as part of a monthly premium. Centers for Medicare and Medicaid
Services ("CMS") then provides each Part D plan sponsor with advance monthly payments equal to
the Part D plan sponsor's standardized bid. Part D plans are required to include some cost sharing
obligations that the beneficiary must satisfy.

66. All providers and suppliers of medical services and items—including drug
manufacturers who supply covered medications indirectly—must enroll with Medicare to be
eligible to receive any payment under Medicare. 42 CFR § 424.505. To enroll in Medicare, all

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providers and suppliers must submit an enrollment application to CMS and must "attests that the
 information submitted is accurate and that the provider or supplier is aware of, and abides by, all
 applicable statutes, regulations, and program instructions." 42 CFR § 424.510(d)(3).

67. The application forms used by all providers and suppliers to enroll in Medicare
includes the following attestation: "I agree to abide by the Medicare laws, regulations and program
instructions that apply to me or to the organization listed in . . . this application. . . . I understand
that payment of a claim by Medicare *is conditioned upon* the claim and the underlying transaction
complying with such laws, regulations and program instructions (including, but not limited to, the
Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b))."⁶ (emphasis added).

10 68. In addition, "in order for coverage to be available under Medicare Part D for applicable drugs of a manufacturer, the manufacturer must," among other things, enter "into and 11 have in effect an agreement described in § 423.2315(b)." 42 CFR § 423.2310(a). This manufacturer 12 13 agreement requires that "[e]ach manufacturer . . . must comply with the requirements imposed by CMS . . . for purposes of administering the program." 42 CFR § 423.2315. Congress has 14 15 unequivocally instructed that "compliance with federal health care laws, including the [AKS], is a 16 condition of payment by the Medicare program." McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1260 (11th Cir. 2005). 17

18 69. Likewise, MA Plans are required to certify compliance with the AKS and are
19 prohibited from paying for claims that are tainted by an AKS violation or are rendered unpayable
20 due to disqualifying conduct by the underlying provider or supplier. 42 CFR § 422.504(h)(1). Every
21 subcontract that the MA Plan enters into must also contain this certification of compliance. 42 CFR
22 § 422.504(i).

70. MA Plans and other Part C entities play an important role in the American healthcare
landscape. They provide thousands of Americans with not only health insurance, but with the
freedom to go into the marketplace and select the health insurance that best meets their needs.

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⁶ Medicare Enrollment Application, CMS Form 855i, Available at: 28 <u>https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf</u>. See also https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Enrollment-Applications - 14 -

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Indeed, "Congress's goal in creating the Medicare Advantage program was to harness the power of
 private sector competition to stimulate experimentation and innovation."⁷ In 2017, 33% of
 Medicare-eligible individuals received their health insurance from MA Plans.

71. Similarly, while Medicaid is jointly funded by state and federal governments, it is
largely administered by private MCOs. When administered directly by the state, Medicaid operates
as a fee-for-service plan—similar to Medicare Parts A & B. As of 2016, over two-thirds of all
Medicaid beneficiaries receive their care in risk-bearing MCO plans. A co-pay assistance grant can
easily influence these beneficiaries—even if their cost sharing obligation is already low—because
Medicaid is specifically designed for individuals and families near or below the poverty line.

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IV.

<u>FACTUAL ALLEGATIONS</u>

12 "Part D enrollees with high drug costs can have difficulty affording their medications
 when they are in the deductible phase [and] when they reach the coverage gap—theperiod in which
 they are required to pay a larger share of total drug costs."⁸ Legitimate patient assistance programs
 ("PAPs") aim to help financially needy patients afford necessary medications during this difficult
 period.

There are two ways that pharmaceutical companies give to PAPs. First,
manufacturers can establish their own PAPs. "Under this option, pharmaceutical companies give
drugs directly to patients who cannot afford them or donate the drugs to a foundation that then gives
them to patients. The second option is through independent charity PAPs (herein referred to as "co-payment charities")." *See The Cloak of Social Responsibility.*

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74. At all relevant times herein, CVC and Adira represented to government agencies, third-party payors, health care providers, and the public at large, that they operated legitimate independent charity PAPs, or co-payment charities.

Pharmaceutical companies donate money to the co-payment charities, purportedly to

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⁷ In re Avandia Mktg. Sales Practices & Prods. Liab. Litig., 685 F.3d 353, 363 (3rd Cir. 2012).

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^{28 &}lt;sup>8</sup> Congressional Research Service, *Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)*, June 15, 2017.

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help patients who cannot afford their drugs. These patients often have health insurance (usually
 Medicare or Medicaid) but apply to these charities to help cover all, or a portion of, their co payment obligations.

4 76. There are two key differences between these two giving options. "First, companies 5 donate drugs in option 1 and money in option 2. Second, pharmaceutical companies receive no 6 money besides a [tax] deduction in option 1, *but under option 2 they receive a [tax]* deduction and 7 money from the insurer paying the other portion of the drug costs. Thus, assistance provided by 8 option 2 reduces out-of-pocket costs to insured patients but do[es] not reduce the price of 9 prescription drugs to the healthcare payer. These are one-sided discounts." *Id*. (emphasis added).

10 77. Small donations to a co-payment charity may substantially increase revenue received
11 by a given pharmaceutical company from MA Plans and Medicaid Plans, such as the Assignors.⁹

78. As pharmaceutical drug company "giving" to co-payment charities rises, the copayment charity benefits as well. In fact, executives at co-payment charities are among some of the *highest paid executives* in the United States.

- 15 79. Thus, in this context, pharmaceutical companies and co-payment charities have a 16 mutually beneficial purpose—to receive donations, establish additional disease funds to cover co-17 payments of the pharmaceutical company's expensive specialty drugs, and ensure federal healthcare 18 programs bear the cost of these drugs. Together, the co-payment charity can show "results" for the 19 pharmaceutical company and justify increased donations.
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80. Often these charities receive bribes from pharmaceutical companies to assist certain

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See Michael Banigan, A Guide to Patient Assistance Programs: What You Need to Know to 23 Promote Patient Advocacy and Maximize Charitable Contributions." Chronic Disease Fund Inc. (2016) (providing that pharmaceutical companies can calculate their profitability, or "charitable 24 margin," as a result of their donations to co-payment charities and can stand to earn 220 percent 25 charitable margins); see also Cloak of Social Responsibility (explaining that example of "charitable margin" can yield a "charitable margin of 220 percent"); Citi Research, The Straw that Could Break 26 the Camel's Back: DOJ/OIG Action on Foundation Funding Could Severely Impede Industry *Returns*, May 16, 2017 [hereinafter *Citi Research*] (explaining that "[e]ach \$1m industry donation 27 to a charitable foundation to enable Medicare patients Xtandi access or similar high priced drugs 28 has the potential to generate up to \$21m for the sponsor company, *funded by the US Government*") (emphasis added).

1 patients with enrolling in Medicare and Medicaid programs.

81. Given these shared economic incentives, it is no surprise that charitable assistance
from co-payment charities increased from \$11 million in 2004 to nearly \$868 million in 2014. See *Cloak of Social Responsibility* (noting that from 2007 to 2009, during the Great Recession,

6 pharmaceutical giving increased by nearly \$1.5 billion, while overall corporate giving decreased by
7 \$1.2 billion). The chart below details total giving for certain co-payment charities, including CVC,
8 from 2001 to 2014.

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0 0	Table A-L To	atal Giving in I	Dollars for Indepe	ndent Charity Pa	tient Assistance P	mgrams (PAPs),	2001-2014
1		atient Access Network Foundation*	Chronic Disease Fund/ Good Days ^b	Caring Voice Coalition®	He althwell Foundation ^d	Patient Services	Subtotal: Independent Charity PAPs
2001		_		—	_	\$2,328,611	\$2,328,611
2 2002		_	_	—	_	\$3,296,181	\$3,296,181
2003		_	_	—	_	\$5,118,345	\$5,118,345
2004		_	_	\$80,383	-	\$6,932,842	\$11,301,748
2005		\$7,557,312	\$5,597,689	\$5,257,808	\$15,856,798	\$15,719,269	\$49,988,866
2006		\$18,652,834	\$66,279,917	\$9,850,206	\$47,289,619	\$15,333,700	\$157,406,276
2007		\$24,880,629	\$63,551,700	\$15,816,549	\$59,391,157	\$21,467,030	\$185,107,065
2008		\$32,825,596	\$82,133,885	\$27,943,050	\$57,521,456	\$35,269,942	\$235,693,929
2009		\$37,323,252	\$136,713,152	\$37,530,533	\$71,425,660	\$29,594,995	\$312,587,592
2010		\$37,562,665	\$172,488,043	\$38,166,963	\$84,233,714	\$37,440,434	\$369,891,819
2011		\$28,379,485	\$195,647,202	\$46,827,156	\$49,521,777	\$39,983,874	\$360,359,494
2012		\$108,460,641	\$182,365,638	\$58,221,721	\$36,995,288	\$50,332,148	\$436,375,436
2013		\$174,340,174	\$194,448,004	\$67,435,466	\$31,135,498	\$60,897,475	\$528,256,617
2014		\$496,427,781	\$170,628,203	\$98,027,589	\$29,039,150	\$73,735,080	\$867,857,753
Source:		Nonprofit Explo		ot≲″on Borm 990.:	although for some	entities before 200	, the totals com
from li	ne 23, part II.		s an initial return.				·, ·- ···
^b Excluse Exclusion	ded 2004 retur led 2002 retur	m because it wa m because it wa	s an initial return.	and their reporting	; years run July t o J	ure.	

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82. The rise of co-payment charities and pharmaceutical corporate giving to such
charities (with the economic incentives detailed above) is tied to the enactment of public insurance
programs expanding the number of Americans with prescription drug coverage, the growth of
specialty drugs, and the federal anti-kickback law.

83. First, this increased giving to co-payment charities occurred during a period in which
there was a surge in the number of Americans with prescription drug coverage as a result of the
enactment of Medicare Part D and, subsequently, the passing of the Affordable Care Act in 2010
("ACA"), which expanded prescription drug benefits. "Before these public insurance expansions,

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federal government spending on prescription drugs was 25 percent of total spending in 2005. In
 2014 it was 41 percent." *See Cloak of Social Responsibility*.

84. Specialty drug prices are set by drug manufacturers with an intimate knowledge of
the drug market. This knowledge enables manufacturers to set supra-competitive drug prices by
using PAPs to circumvent beneficiary co-payment obligations, thus eliminating price sensitivity.

85. Second, along with these public insurance programs, specialty drugs (i.e., generally
defined as expensive prescriptions requiring extra handling or administration in treating complex
diseases) have contributed to the growth of co-payment charities. "In recent years, spending for
specialty drugs has grown faster than spending for other pharmaceuticals. Although specialty
medications account for only one percent of prescriptions, they account for almost a third of U.S.
prescription spending. For Medicare Part D, specialty drugs accounted for a quarter of a percent of
prescriptions in 2013 but eleven percent of total drug cost." *Id.*

13 86. Co-payment charities allow pharmaceutical companies to manage price sensitivity
14 for these more expensive specialty drugs. The OIG noted that PAPs "may steer patients toward and
15 lock them into a particular manufacturer's product, even when other equally effective and less
16 costly alternatives are available." *Id*.

17 87. Moreover, the rise of co-payment charities stemmed from federal anti-kickback law.
18 The AKS made the receipt of kickbacks, bribes, or rebates in connection with items or services
19 covered by the Medicare and Medicaid programs a crime. The AKS makes it a crime to knowingly
20 and willfully offer, pay, solicit, or receive any renumeration to induce a person to purchase or
21 recommend any good, service, or item covered under a federal health care program. *See* 42 U.S.C. §
22 1320a-7b(b).

88. As it relates to PAPs, the OIG has stated that the AKS could be violated "if a
donation is made to a PAP to induce the PAP to recommend or arrange for the purchase of the
donor's federally reimbursable items," as well as if a PAP's grant of financial assistance to a patient
is made "to influence the patient to purchase (or induce the patient's physician to prescribe) certain
items." *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*,
79 Fed. Reg. 31120, 31121 (May 30, 2014), attached as Exhibit 24.

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89. Congress has determined that any Medicare or Medicaid claim "that includes items
 or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" for
 purposes of the FCA. *See* 42 U.S.C. § 1320a-7b(g).

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A. OIG Guidance for Co-Payment Charities

90. The OIG has provided guidance to co-payment charities regarding compliance with applicable laws and regulations, including the AKS and FCA. In this guidance, the OIG made clear that such charities will violate those laws and regulations if they do not follow specified rules. Those rules ensure that a pharmaceutical manufacturer cannot control a co-payment charity, or receive information from such a charity, that would allow the manufacturer to link the amount it donates to additional profits from the sale of a particular drug.

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91. In 2005, the OIG issued a special advisory bulletin on PAPs ("2005 Bulletin"). The 2005 Bulletin provided that certain cost-sharing subsidies provided by bona fide, independent PAPs unaffiliated with drug manufacturers do not raise AKS concerns, even if the PAPs receive manufacturer contributions. *See OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70623 (Nov. 22, 2005), attached as **Exhibit 25**. The 2005 Bulletin also set forth factors that the OIG considers to be "fundamental" to a properly structured, independent, bona fide PAP, including the following:

- a. No drug manufacturer or donor exerts any direct or indirect influence or control over the PAP;
- b. The PAP awards assistance in a truly independent manner that severs any link between the drug manufacturer donors funding and the beneficiary;
- c. The PAP awards assistance without regard to the drug manufacturer's interests, or the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan;
 - d. The PAP provides assistance based upon a reasonable verifiable, and uniform measure of financial need applied in a consistent manner; and
- e. the drug manufacturer does not solicit or receive data from the PAP that would allow the manufacturer to substantiate the amount of its donations with the number of subsidized prescriptions for its products. *Id.* at 70626-27 ("Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries drug choices.")

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1	92. In 2014, the OIG issued an updated bulletin raising concerns about the conduct of			
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2	co-payment charities and intensifying its scrutiny of arrangements between pharmaceutical			
3	companies and co-payment charities ("2014 Bulletin"). See Supplemental Special Advisory Bulletin:			
4	Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014), attached as			
5	Exhibit 24. In the 2014 Bulletin, the OIG stated that although PAPs can provide an important			
6	safety net to financially needy patients, these programs also present a risk of fraud, waste, and abuse			
7	with respect to federal health care programs if they are not independent from donors. <i>Id.</i>			
8	93. The OIG noted three more areas of concern related to disease funds, eligible			
9	recipients, and the conduct of donors, and required co-payment charities to certify to the OIG that:			
10	a. The co-payment charity will not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a			
11	particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states;			
12	b. The co-payment charity will not maintain any disease fund that provides co-payment			
13	assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates; and			
14	c. The co-payment charity will not limit its assistance to high-cost or specialty drugs.			
15 16	Instead, the co-payment charity will make assistance available for all products, including generic or bioequivalent drugs covered by Medicare or other insurers, when prescribed for the treatment of the disease state(s) covered by the fund. <i>Id.</i>			
17	94. As for the "conduct of donors," the 2014 Bulletin reiterated its prior focus (from the			
18	2005 Special Advisory Bulletin) on co-payment charities not giving a "donor any information that			
	would enable a donor to correlate the amount or frequency of its donations with the number of aid			
	recipients who use its products or services or the volume of those products supported by the PAP."			
21	<i>Id.</i> Notably, the OIG warned that:			
22	[t]he procedures described in these certifications are a critical safeguard and a material fact upon which we have relied in issuing favorable advisory opinions			
23	regarding Independent Charity PAPs. These opinions do not address actions by donors to correlate their funding of PAPs with support for their own products. Such			
24	actions may be indicative of a donor's intent to channel its financial support to co- payments of its own products, which would implicate the antikickback statute.			
25	Id.			
26	10.			
27	B. CVC's Growth and OIG's Communications			
28	95. "In 2003 Congress passed the Medicare Prescription Drug, Improvement, and			
	- 20 -			
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1 Modernization Act of 2003, which created Medicare Part D, 'an optional prescription drug benefit ... which went into effect in 2006."¹⁰ 2

3 96. With the enactment of Part D, Congress implemented co-pay requirements as a 4 "safety-valve" against supra-competitive pricing.

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97. That same year, in 2003, CVC registered for status as a national 501(c)(3) non-profit, 6 charitable organization aimed at providing co-payment assistance for patients with certain chronic or life-threatening diseases. CVC established certain disease funds, including the PAH fund, which 7 8 were funded by donors, including Actelion.

9 98. CVC grew from receiving \$80,383 from donors in 2004 to receiving over \$131 10 million from donors in 2015.

11 99. With the increase in CVC donations, came corresponding increases in reported personal compensation and benefits for CVC's executives. Exhibit 26 – CVC's Form 990 Filings. 12

13 100. The personal compensation and benefits reportedly received by CVC's directors, 14 executives, and managers, directly correlated with the amounts of donations CVC received from 15 pharmaceutical manufacturers, including Actelion.

16 101. CVC violated one of the most basic rules that separates legitimate co-payment 17 charities from illegal ones-it explicitly coordinated with Actelion to steer patients towards 18 Actelion Drugs and provided information to Actelion so that Actelion could correlate its donations 19 with its increased profits on the sale of Actelion Drugs-CVC then repeatedly and continuously lied 20 about this conduct to the OIG.

21 In 2006, CVC certified to the OIG that it would comply with the requirements 102. 22 outlined above in the OIG's 2005 Special Advisory Bulletin. CVC subsequently requested an 23 advisory opinion from the OIG asking whether its "Proposed Arrangement" as a nonprofit, taxexempt, charitable corporation's proposal to provide financially needy Medicare beneficiaries with 24 25 assistance and cost-sharing obligations under Medicare Part B, Medicare Part D, Medigap, and

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²⁷ ¹⁰ Patient Servs., Inc. v. United States, No. 3:18CV16, 2019 WL 267872, at *4 (E.D. Va. Jan. 18, 2019) (quoting Centers for Medicare & Medicaid Services, History, CMS.gov (last accessed Oct. 28 17, 2018), https://www.cms.gov/About-CMS/Agency-Information/History/index.html).

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Medicare Advantage would constitute grounds for sanctions under certain federal laws, including 1 2 the AKS. In response, on April 20, 2006, the OIG issued an Advisory Opinion to CVC. See OIG, 3 Adv. Op. 06-04 (April 20, 2006), attached as Exhibit 27. The 2006 CVC Advisory Opinion noted CVC's certification that, among other requirements, no donor had exerted or will exert "any direct 4 5 or indirect influence or control" over CVC. Id. ("[CVC] has certified that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer shareholder, or contractor 6 7 (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) has 8 exerted or will exert any direct or indirect influence or control over [CVC] or any of [CVC]'s 9 programs.").

10 103. The 2006 CVC Advisory Opinion provided that upon request and as a courtesy, donors will be informed monthly of the aggregate number of patients who qualify for assistance in a 11 category, but highlighted CVC's certification that "the monthly data will not contain any 12 13 information that enable a donor to correlate the amount or frequency of its donation with the 14 number of subsidized prescriptions or orders for its products or the volume or medical condition of 15 patients choosing its services." Id. ("No individual patient information will be conveyed to donor, 16 nor will any data related to the identity, amount, or nature of products or services subsidized under 17 the Proposed Arrangement.").

18 104. The OIG concluded, in part, that "*[b]ased on the facts certified in [CVC's] request* 19 for an advisory opinion and supplemental submissions . . . [and subject to various limitations set 20 forth by the OIG] while the Proposed Arrangement could potentially generate prohibited 21 remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of 22 Federal health care program business were present, the OIG would not impose administrative 23 sanctions on [CVC] under [federal laws regarding civil monetary penalties] in connection with the 24 Proposed Arrangement." *Id*.

In December 2015, the OIG published a Modified Advisory Opinion to CVC
following the OIG's request that CVC certify compliance with the other factors outlined in the 2014
Bulletin ("2015 CVC Modified Advisory Opinion"), attached as Exhibit 28. See OIG, Adv. Op. 0604 (Dec. 23, 2015). The 2015 CVC Modified Advisory Opinion stated that CVC had certified

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compliance to each additional factor, and further that CVC had proposed additional modifications to
 its current operations. *Id*.

3	106. CVC was admittedly on notice of the OIG's guidance, cautionary language, and the			
4	certification requirements set forth in the 2005 and 2014 Bulletins, as wellas the Advisory Opinions			
5	OIG provided specifically to CVC. In fact, one of the tactics used by CVC to mislead the OIG (the			
6	public, third-party payors, patients, and healthcare providers) was through the creation of a fake			
7	"Compliance Program" "to assist CVC in preventing, detecting and responding to illegal, improper			
8	and unethical conduct [and to] serve as a procedural framework for enhancing and monitoring			
9	compliance with applicable law, regulation, the CVC Code of Conduct and organizational policies			
10	and procedures. <u>The Compliance Program is based on applicable [OIG] guidance.</u> " (See			
11	Summary of the CVC Compliance Program, attached at Exhibit 29 (emphasis added). In turn,			
12	CVC's "Code of Conduct" purports to "describe[] the commitment that [CVC] expects of itself			
13	to maintain the highest ethical standards of honesty and integrity as well as to comply with all laws			
14	and legal requirements applicable to [CVC], including [OIG] guidance for charitable patient			
15	assistance programs and CVC's OIG Advisory Opinion 06-04, as modified, and industry guidance,			
16	including the Independent Charitable Patient Assistance Program Code of Ethics ('IPAP Code of			
17	Ethics')." (See CVC's Code of Conduct, attached at Exhibit 30).			
18	107. CVC used the wire and mail to falsely represent to the OIG, the public, healthcare			
19	providers, and third-party payors, that it was "dedicated to the following values/ethical principles			
20	. [among others]":			
21	a. Act with honesty, integrity and objectivity, and in a manner that will merit the continued trust and confidence of patients and stakeholders.			
22	b. Operate independently free from the influence of CVC donors.			
23	c. Comply with all federal, state, and local laws, regulations, and legal requirements			
24	applicable to CVC, including OIG guidance for charitable patient assistance programs and CVC's OIG Advisory Opinion 06-04, as modified.			
25	d. Be vigilant in the detection and prevention of potential fraud, waste, or abuse.			
26	e. Promptly investigate and address potential violations of applicable law, regulation,			
27	OIG guidance, CVC's Advisory Opinion, IPAP Code of Ethics, this Code, or Company policies and procedures. <i>Id.</i>			
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108. The referenced IPAP Code of Ethics that CVC falsely represented that it would 1 comply with similarly provides that co-payment charities "[o]perate under the auspices of an 2 3 ongoing compliance with an organization-specific [OIG] Advisory Opinion," and "[o]perate independently, free from the influence of donors," which included "[r]efrain[ing] from providing 4 5 donors or other entities with information that could permit the correlation of the amount or frequency of donations with the number of patients assisted by the [co-payment charity] who use a 6 7 donor's products or services or the volume of those products supported by the [co-payment 8 charity]." (See IPAP Code of Ethics, attached as Exhibit 31).

9 109. CVC also publicly advertised its services to healthcare providers, patients, third10 party payors, and the general public, representing that it operated a legitimate 501(c)(3),
11 independent charity, when in reality, it was serving as a conduit to funnel kickbacks for Actelion.

12 110. CVC also publicly represented that it was comply with OIG regulations, when it was
13 not, and it knew it was not.

14 111. Indeed, CVC shared with Actelion the very information it promised it wouldn't share
15 and steered patients in violation of the OIG's general guidance, the OIG's specific guidance to
16 CVC, CVC's certifications to the OIG, CVC's internal "compliance" policies, the FCA, and the
17 AKS.

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112. CVC knew that its conduct violated OIG regulations.

19 113. In November 2017, the OIG rescinded its prior advisory opinions issued to CVC
20 ("2017 CVC Rescission Letter"). *See* OIG, Adv. Op. 06-04 (Nov. 28, 2017), attached as Exhibit 32.
21 The 2017 CVC Rescission Letter was based on CVC's "failure to fully, completely, and accurately
22 disclose all material facts to OIG," and CVC's failure to comply with certain factual certifications
23 made to the OIG. *Id.*

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114. The Recission Letter stated,

Specifically, we have determined that, in contravention of the certifications
[CVC] made, [CVC]: (i) provided patient-specific datato one or more donors that
would enable the donor(s) to correlate the amount and frequency of their
donations with the number of subsidized prescriptions or orders for their
products, and (ii) allowed donors to directly or indirectly influence the
identification or delineation of [CVC's] disease categories."

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Id.

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115. The 2017 CVC Rescission Letter concluded that:

[CVC]'s failure to comply with these certifications materially increased the risk that CVC served as a conduit for financial assistance from a drug manufacturer donor to a patient, and thus increased the risk that the patients who sought assistance from [CVC] would be steered to federally reimbursable drugs that the manufacturer donor sold. This type of steering can harm patients and the Federal health care programs, because, for example, patients may be urged to seek, and physicians may be more likely to prescribe, a more expensive drug if copayment assistance is available for that drug but not for less expensive but therapeutically equivalent alternatives. *In these circumstances, manufacturers may have greater ability to raise the prices of their drugs while insulating patients from the immediate out-of-pocket effects of price increases, leaving <u>Federal healthcare programs like Medicare (and the taxpayers who fund those programs) to bear the cost.</u>*

Id. (emphasis added).

12 116. Shortly thereafter, CVC announced that in light of the 2017 CVC Rescission Letter it
 13 would not open financial assistance for any disease fund in 2018. Exhibit 33 – CVC December
 14 2018 Announcement.¹¹

- 15 117. Instead, in February of 2018, the President of CVC, Greg Smiley, incorporated a new
 501(c)(3) charity (Defendant Adira) where CVC began fraudulently conveying CVC's assets and
 records, as well as Actelion's funds, to the new charity, as further discussed below. Exhibit 23 –
 Adira Business Records.
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C. The Scheme Permitted Actelion to Charge Supra-Competitive Prices For and Artificially Inflate the Quantity of Actelion Drugs Dispensed

118. As part of the Scheme, Defendants artificially increased the quantity of claims the
Assignors and Class Members paid for Actelion Drugs by pushing patients away from Actelion's
free drug program "which was open to other financially needy patients, even if those Medicare
patients could not afford their copays for Subject Actelion Drugs. Instead, in order to generate
revenue from Medicare and to induce purchases of Subject Actelion Drugs, Actelion referred such
Medicare patients to the foundation, which allowed the patients' copays to be paid and resulted in

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¹¹ <u>http://www.caringvoice.org/decision-2018-financial-assistance</u>

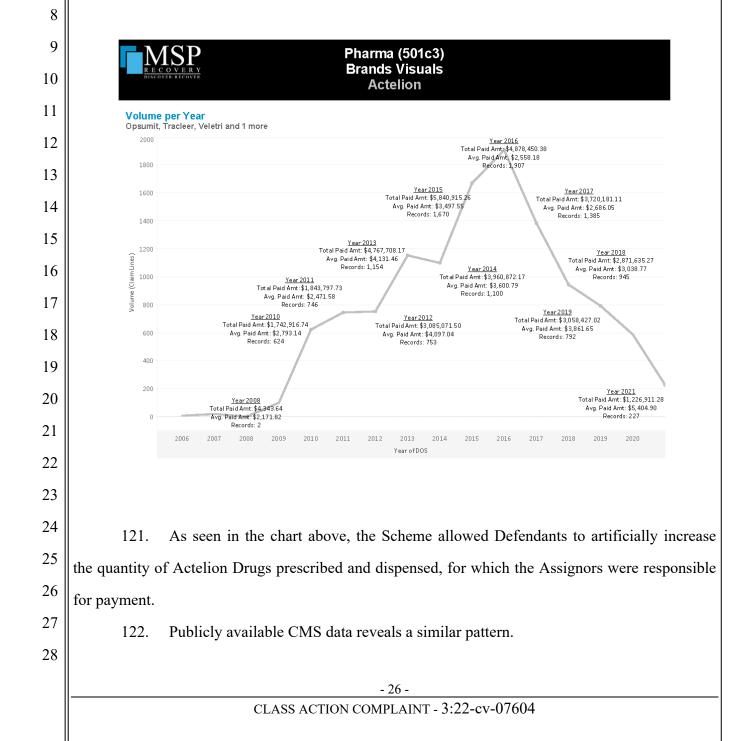
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claims to Medicare for the remaining cost." *See* Exhibit 2 DOJ Settlement Agreement Press
 Release. These claims, and all claims for Actelion Drugs during the Scheme, forced the Assignors
 and Class Members to pay for Actelion Drugs at artificially supra-competitive prices.

4 119. In and around 2016, the DOJ began issuing subpoenas to Defendants regarding their
5 business practices, donations, and co-payment programs.

6 120. At that same time, the volume (or quantity) of Actelion Drugs prescribed, dispensed,
7 and paid for by Assignors plummeted, as seen in the chart below.



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1 123. For example, according to CMS data, in 2015, Medicare and Medicaid programs
 2 reportedly paid more than \$63.2 million for Ventavis. In 2016, Medicare and Medicaid programs
 3 reportedly paid \$49.3 million, and continued to decline year over year. By 2020, Medicare and
 4 Medicaid programs paid at least \$13.6 million for Ventavis, a substantial decline since the DOJ first
 5 began investigating Defendants' Scheme.

6 124. Similarly, for Tracleer, in 2015, Medicare and Medicaid programs reportedly paid
7 more than \$402.1 million. In 2016, Medicare and Medicaid programs reportedly paid \$354 million,
8 and continued to decline year over year. By 2020, Medicare and Medicaid programs paid at least
9 \$61.9 million for Tracleer, a substantial decline since the DOJ first began investigating Defendants'
10 Scheme.

11 125. As seen in Defendants' Financial Reports (*See*, Exhibits 3 through 21), during all
 12 relevant times, Medicare and Medicaid programs accounted for a substantial proportion of
 13 Actelion's total global sales.

14 126. Further, because Defendants' Scheme violated the AKS, *all claims* for the Subject
15 Drugs generated or submitted during the Scheme were unpayable by the Assignors and Class
16 Members pursuant to federal law.

17

<u>Tracleer</u>

18 127. Tracleer is used to treat high blood pressure in the lungs (pulmonary arterial19 hypertension).

20 128. During the period covered by the DOJ Settlement, Actelion raised the price of its
21 main PAH drug, Tracleer, by nearly <u>30 times</u> the rate of overall inflation in the United States. This
22 trend continued to increase year over year until at least 2020

23 129. Medicaid's spending per dosage unit of Tracleer increased approximately 53%
24 between 2012 and 2016. This trend continued to increase year over year until at least 2020

130. The change in average spending by Medicaid per dosage unit of Tracleer increased
by 12.4% from 2015-2016 with the annual growth rate in average spending per dosage unit from
2012-2016 increasing by 11.2%. The average spending per dosage unit in 2012 was \$99.35, with an
average spending per claim totaling \$5,578.92. By 2016, the average spending per dosage unit

- 27 -

jumped to \$152.02, with an average spending per claim totaling \$7,253.49. This trend continued to
 increase year over year until at least 2020

3 131. Tracleer Medicare Part D also witnessed a significant rise in cost. Between 2012 and
4 2016, the average price per dose jumped approximately 37%, resulting in the average spending per
5 beneficiary costing approximately 44% more. This trend continued to increase year over year until
6 at least 2020.

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132. Assignors' data for their covered beneficiaries yields similar findings.

Opsumit

9 133. Opsumit is used to treat high blood pressure in the lungs (pulmonary arterial 10 hypertension).

11 134. Medicare Part D also witnessed a staggering jump in price during a mere four-year
12 period. From 2013 to 2017, the average spending per beneficiary increased by over ten times. The
13 average spending per beneficiary in 2013 was \$7,089 and in 2017, it was \$72,616. This trend
14 continued to increase year over year until at least 2020

15 135. Assignors' data for their covered beneficiaries yields similar findings. Assignors'
16 total amount paid for Opsumit increased from \$100,000 in 2013 to \$3 million in 2015.

17 <u>Veletri</u>

18 136. Veletri is used to treat high blood pressure in the lungs (pulmonary arterial19 hypertension).

20 137. Between the years 2016 and 2017, the average Medicare Part D spending per
21 Beneficiary jumped nearly 22%. This trend continued to increase year over year until at least 2020.

138. Assignors' data for their covered beneficiaries yields similar findings. Assignors'
total amount paid for Veletri increased from under \$100 in 2013 to \$74,000 in 2015.

<u>Ventavis</u>

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25 139. Ventavis is used to treat high blood pressure in the lungs (pulmonary arterial26 hypertension).

27 140. Medicaid's spending per dosage unit of Ventavis increased by over 100% between
28 2012 and 2016. Additionally, the average spending per claim increased by approximately 58%

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1 during that same period. This trend continued to increase year over year until at least 2020

141. Medicaid spending per dosage unit of Ventavis was \$58.30 in 2012, and \$120.54 in
2016. The average spending per claim of Ventavis was \$11,173 in 2012, and \$17,737 in 2016. This
trend continued to increase year over year until at least 2020

5 142. Assignors' data for their covered beneficiaries yields similar findings. Assignors'
6 total amount paid for Ventavis increased from approximately \$100,000 in 2013 to nearly \$250,000
7 in 2015.

8 143. Actelion's ability to exponentially increase the prices and quantity dispensed of
9 Actelion Drugs year over year would not have been possible but for the illegal Co-Payment
10 Scheme.

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D. The DOJ Settlement

13 144. The DOJ prosecuted Actelion and CVC for their roles in the Scheme, which also14 defrauded the federal government.

15 145. This resulted in a settlement in which Actelion agreed to pay \$360 million to the
16 United States after the DOJ alleged that Actelion's use of CVC as a conduit violated the AKS and
17 FCA.

18 146. The DOJ investigation into the Scheme represents one part of a much larger ongoing 19 investigation by the DOJ and OIG, along with the U.S. Attorney's Office for the District of 20 Massachusetts, into schemes by various drug manufacturers and co-payment charities that violated 21 the AKS and FCA.¹² As recognized by pharmaceutical-industry financial analysts, these 22

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¹² Other recent results involving the resolution of AKS and FCA claims brought by the United States against drug manufacturers participating in improper schemes with co-payment charities include: (i) Jazz Pharmaceuticals PLC ("Jazz") agreeing in May 2018 to pay the United States \$57 million related to claims involving Jazz's relationship with CVC to fund co-payment for Jazz's narcolepsy drug Xyrem; (ii) United Therapeutics agreed to pay the United States \$210 million to resolve the United States' AKS and FCA claims on behalf of Medicare based on United Therapeutics' relationship with CVC; and (iii) Lundbeck LLC agreeing in April 2019 to pay the United States \$52.6 million related to claims involving Lundbeck's relationship with CVC to fund co-payment for Lundbeck's Huntington Disease drug, Xenazine.

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1 investigations "impede industry returns."¹³

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147. The Actelion Settlement with the United States was based on the DOJ's claims that

3 Actelion's conduct violated the AKS and FCA, thereby leaving Federal healthcare programs (in that

4 case, Medicare Parts A & B) "bear[ing] the cost."

148. The DOJ found that from *at least* January 1, 2014, through *at least* August 2015,¹⁴

Actelion used a foundation (CVC) as an illegal conduit to pay the copay obligations 6 of thousands of Medicare patients taking the Subject Drugs and to induce those 7 patients to purchase them, because they knew that the prices Actelion set for the Subject Drugs could otherwise pose a barrier to those purchases. Actelion made 8 donations to the foundation, which, in turn, used those donations to pay copays of patients prescribed the Subject Drugs. Actelion routinely obtained data from the 9 foundation detailing how much the foundation had spent for patients on each Subject 10 Drug; it then used this information to decide how much to donate to the foundation and to confirm that its contributions were sufficient to cover the copays of only 11 patients taking the Subject Drugs. Actelion had a policy of not permitting Medicare patients to participate in its free drug program, which was open to other financially 12 needy patients, even if those Medicare patients could not afford their copays for the Subject Drugs. 13

- 14 (See Exhibit 1– Actelion Settlement)
- 15 149. The DOJ further found:

16 [A]ctelion routinely obtained data from CVC detailing how many patients on each Subject Drug CVC had assisted, how much CVC had spent on those patients, and 17 how much CVC expected to spend on those patients in the future. Actelion received this information through funding requests, telephone calls, and written reports. 18 Actelion used this information to budget for future payments to CVC on a drug-19 specific basis and to confirm that its contribution amount to CVC were sufficient to cover the copays of patients taking the Subject Drugs, but not of patients taking other 20manufacturer's PAH drugs. Actelion had a policy of not permitting Medicare patients to participate in its free drug program, which was open to other financially 21 needy patients, even if those Medicare patients could not afford their copays for Actelion drugs. Instead, in order to generate revenue from Medicare and to induce 22 purchases of the Subject Drugs, Actelion referred Medicare patients prescribed the 23 Subject Drugs to CVC, which resulted in claims to federal healthcare programs to

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 ¹³ See Citi Research ("[t]he ongoing multiple DOJ/OIG investigations into financial donations by pharmaceutical companies to independent foundations has the potential to severely limit future revenues for several high-priced blockbuster Medicare Part D drugs through (i) lowered overall

²⁷ funding for patient out-of-pocket assistance (ii) lesser ability for individual pharmaceutical donors to guide their funding towards specific drugs.").

 ¹⁴ Although the Actelion Settlement discussed conduct that occurred through August 2015, Plaintiffs have evidence suggesting that the Scheme continued up until, and after, the execution of the Actelion Settlement in December of 2018.

cover the cost of the drugs.

(*See* Exhibit 2 – DOJ Settlement Agreement Press Release)

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150. The Actelion Settlement did not redress the harm that Defendants' Scheme caused to the Assignors and Class Members or settle any claims that the Assignors and Class Members have against Defendants.

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151. The Actelion Settlement does not represent the full time span of Defendant's Scheme.

10 152. Defendants' misconduct caused economic injury to Assignors and the Class Members.

153. Actelion bribed CVC to act as a conduit to illegally pay the co-payment obligations
 of MA Plan and Medicaid patients taking Actelion Drugs.

154. Defendants' conduct eliminated price sensitivity of patients allowing pharmacies to dispense Actelion Drugs, which in turn enabled Actelion to raise the price of Actelion Drugs to supra-competitive levels, quickly and outside of ordinary market conditions. Assignors and Class Members were left to bear the cost, while CVC was able to show "results" to Actelion Drugs—if Actelion "donated" money to CVC, it would make money, not only off the new "customers" but also by its ability to raise prices, and ensure that the drugs were still prescribed, dispensed, and reimbursed.

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155. RICO Defendants' conduct caused MA Plan and Medicaid Plan patients to purchase the Actelion Drugs;

- a. Actelion routinely obtained data from CVC detailing how many patients, including MA Plan and Medicaid Plan patients, CVC had assisted and how much CVC had spent on those patients for Actelion Drugs;
- b. In deciding whether and how much to donate to CVC, Actelion considered the revenue it would receive from prescriptions for MA Plan patients who received assistance from CVC to cover their co-payments for Actelion Drugs;
- c. Actelion used data from CVC to confirm that Actelion's revenue exceeded the amount of Actelion's "donations" to CVC;

d. Actelion ensured that MA Plans and Medicaid Plans bore the cost of Actelion Drugs by employing a policy of not permitting MA Plan and Medicaid Plan patients to participate in Actelion's free drug program (i.e., where government funds are not implicated), which was open to other financially needy patients, even if those MA Plan and Medicaid Plan patients could not afford their co-payments for Actelion Drugs; and

e. Actelion funneled MA Plan and Medicaid Plan patients prescribed Subject Actelion Drugs to CVC, which upon CVC providing coverage of patients' co-payments, triggered Assignors' obligations reimburse for Actelion Drugs.

7 156. Defendants' Scheme violated the AKS prohibitions on illegal renumeration by 8 Actelion bribing CVC to both (a) illegally funnel funds to certain pharmacies to induce Government 9 payors (such as Assignors and Class Members) to pay for over-priced Actelion Drugs; and (b) to 10 illegally refer, recommend, and arrange for federal healthcare program beneficiaries to receive the 11 Actelion Drugs. 42 U.S.C. § 1320a–7b(b)

- 12 157. Defendants also violated the AKS prohibitions on making and causing to be made 13 false statements and representations by Actelion breaching its certifications to comply with the 14 AKS, by causing the prescribing physicians and dispensing pharmacies to submit per se false claims 15 to Assignors and Class Members, and by concealing and failing to disclose the illegal renumerations 16 that rendered these claims false while also receiving payment for such claims. 42 U.S.C. § 1320a-17 7b(a)
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158. Therefore, all claims for the Actelion Drugs generated or submitted during the 19 course of the Scheme were disqualified from being paid for by Assignors and Class Members.

20 159. But-for Defendants' conduct, Assignors and Class Members would not and could not 21 have paid for any Actelion Drugs.

22 160. Because of Defendants' Scheme, Assignors and Class Members paid for 23 prescriptions they would not have otherwise paid and there was a direct relationship between the 24 misconduct at issue here and the payments Assignors and Class Members made for Enrollees. Such 25 payments involved reimbursement of illegal and unpayable claims, artificially increased quantities 26 of prescribed and/or dispensed Actelion Drugs, and supra-competitive prices on all Actelion Drugs 27 prescriptions.

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1 161. RICO Defendants knew and intended that their Scheme would generate disqualified
 2 claims and artificially inflate the quantities of prescribed and/or dispensed Actelion Drugs and allow
 3 Actelion to raise the prices of Actelion Drugs to supra-competitive levels.

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162. At relevant times herein, Defendants (their agents and conspirators) actively and falsely marketed to and misled health care providers, third-party payors, governmental agencies, and the public, regarding the legitimacy of their Co-Payment Scheme, tainting any and all claims for Actelion Drugs submitted during the course of the Scheme.

8 163. Assignors and Class Members were the primary and intended victims of Defendants'
9 Scheme. The injury to the Assignors was a foreseeable and natural consequence of the Scheme
10 because Actelion knew that third-party payers such as the MA Plans and the Medicaid Plans would
11 pay for or reimburse the cost of Actelion Drugs.

12 164. Assignors and Class Members suffered direct economic injury as a direct and
13 proximate cause of Defendants' Scheme and are therefore best suited to advance and pursue the
14 recovery of the claims asserted in this Complaint.

15 165. In fact, Assignors and Class Members are likely the only entities harmed by
16 Defendants' Scheme.

17 166. Indeed, wholesale distributors, specialty distributors, and/or pharmacies actually
18 benefit from the scheme as their sales increase *because the rate of abandonment decreases*, their *co-*19 *payment revenue increases*, as well as revenue from service fees, some of which are based on a
20 percentage of the Wholesale Acquisition Cost ("WAC").^{15, 16}

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 ¹⁵ Prescription abandonment—when a prescription is transmitted to the pharmacy but never filled—is a major concern for both providers and drug manufacturers. Prescription abandonment is multifaceted, but it is widely understood that high co-payments are a leading cause and lowering co-payments significantly reduces abandonment for highly effective chronic treatments. Dana P.

Goldman et al., Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health. 298.1 Jama 61, 61-69 (2007). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6375697/

 ²⁶
 ¹⁶ Prescription abandonment causes an estimated 125,000 avoidable deaths in the U.S. annually.
 ²⁷
 ²⁸ Regardless of whether patients and doctors are induced by PAP funds at the prescription stage, the

data is clear that patients are induced by co-payment assistance at the dispensing stage. Hayden B.

²⁸ Bosworth et al., *Medication Adherence: A Call for Action*. 162.3 Am Heart J. 412 (2011). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947508/

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1 167. Actelion knows or has reason to know that prescription abandonment and low
 2 medication adherence (i.e., taking the prescription as prescribed) are serious issues in treating
 3 PAH.^{17, 18} High co-pay costs for patients is a major contributing factor to both abandonment and
 4 low adherence.¹⁹ Instead of lowering the cost of its PAH medication or allowing federal healthcare
 5 program beneficiaries to access its free drug program, Actelion chose to run an illegal and lucrative
 6 scheme to force Assignors and Class Members to shoulder the burden of its greed.

7 Defendants had the shared goal of, among other illicit objectives, maximizing the 168. 8 amount of sales for Actelion Drugs and growing Actelion's co-payment assistance fund, thereby 9 enabling CVC's directors and officers to use the non-profit charities increased funds to justify a surge in their own compensation and luxurious lifestyle. The Co-payment Scheme increased the 10 number of MA Plan and Medicaid Plan patients (among all healthcare programs) who were 11 receiving co-payment assistance for Actelion Drugs from Actelion's co-payment fund, triggering 12 13 the Assignors' and Class Members' coverage obligations for these Enrollees, eliminating price 14 sensitivity to Actelion, and allowing Actelion to increase its revenues and profits related to Actelion 15 Drugs sales.

16 169. For Defendants, this collusive bribery Scheme was a "win-win" arrangement.
17 Actelion systematically blocked MA Plan and Medicaid Plan beneficiaries from accessing
18 Actelion's free drug program. Instead, Actelion referred those beneficiaries to CVC. Actelion
19 directed its bribes to CVC with the intent to increase MA Plan and Medicaid Plan reimbursements.
20 Part of those bribes were made to CVC in order for CVC to enroll patients in state and federal

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28 Available at <u>https://doi.org/10.1371/journal.pone.0217798</u> ¹⁹ See footnotes 16 and 17, *supra*.

 ¹⁷ Stephen Mathai et al., Low Utilization of Prostacyclin Therapy Prior to Death Among Medicare Patients with Pulmonary Arterial Hypertension, Vol. 158 Chest J. 4 (2020). Available at https://journal.chestnet.org/article/S0012-3692(20)34047-2/fulltext

¹⁸ Duncan Grady et al. Medication and patient factors associated with adherence to pulmonary 25 hypertension targeted therapies. 2018 Pulm Circ. (2018).Available 8(1), at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5731720/. Over 6% of the study sample was below 26 80% adherence over a two-year period, resulting in a significant increase in reported adverse events. Nisha B. Shah et al. High rates of medication adherence in patients with pulmonary arterial 27 hypertension: An integrated specialty pharmacy approach, PLOS ONE 14(6): e0217798, (2019).

health care plans, while other parts were made to CVC in order for CVC to provide quarterly 1 2 reports to Actelion regarding the Actelion Drugs.

3 170. As CVC illegally provided data and information to Actelion related to the profitability of Actelion's "donations" to CVC, Actelion would couple their use of CVC with price 4 5 increases of Actelion Drugs. Actelion's bribes to CVC resulted in more MA Plan and Medicaid Plan patients receiving co-payment assistance. This in turn eliminated price sensitivity for Actelion 6 7 Drugs, resulting in supra-competitive pricing and artificially inflated quantities of dispensed 8 Actelion Drugs, which together increased profits for all Defendants and their executives. And all 9 along the way, as Actelion's drug prices increased and utilization of CVC increased to mask the 10 effects of the price increases, donations to CVC continued to rise, and Defendants' executives continued to pocket more and more illicitly generated profits for themselves. See, Exhibits 3 11 12 through 21; Exhibit 26.

13 171. Data from CMS and Assignors show how Defendants' Scheme eliminated price 14 sensitivity of patients purchasing, physicians prescribing, and pharmacies dispensing Actelion 15 Drugs and resulted in federal healthcare programs bearing the increased costs. This data reflects that 16 Actelion charged supra-competitive prices and increased the quantity of Actelion Drugs paid for by 17 federal programs while the Co-Payment Circumvention Enterprise pursued such goals through 18 unlawful means, as described herein.

19 172. Assignors paid approximately \$31 million in claims for Actelion Drugs from January 20 1, 2014, until present. Information in the exclusive control of Defendants will show that a 21 significant portion of the co-payments paid on behalf of the beneficiaries of the Assignors and Class 22 Members were made by CVC as a result of Defendants' Co-payment Scheme.

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173. Assignors were not privy to which patients' co-payments were related to Actelion's 24 bribes to CVC. Assignors' obligations to cover claims for Actelion Drugs only arose after CVC 25 unlawfully funneled Actelion funds to certain pharmacies.

26 174. Evidence suggests that most, if not all, of the pharmacies that dispensed the Actelion 27 Drugs during the relevant time period, were aware of, participated in, and/or recklessly disregarded 28 the fact that Actelion used CVC as a conduit in violation of the AKS, resulting in millions of co-

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1 payment revenue paid by Actelion through CVC to the pharmacies. 2 As a result of Defendants' fraudulent concealment of their Scheme, Assignors did 175. not and could not have known that their reimbursement obligations, or the supra-competitively 3 4 priced drugs, were caused by Defendants' misconduct. 5 176. Defendants' documents and disclosures clearly show that they possess information to 6 show exactly which patients received co-payment assistance. 7 For example. CVC's Form 990 Tax Filings state in Supplemental Information to 177. 8 Schedule I, Part I, Line 2: 9 Financial grants are given when an individual specifies he/she has adisease supported by Caring Voice and he/she meets stated income guidelines. Individuals fill out an 10 11

- applicating voice and neosite meets stated meetine guidennes. Individuals information of a medical application for financial assistance which must be accompanied by a medical certification from their physician documenting their diagnosis. Grant funds are paid to third party pharmacies or insurance companies after proof is received that the patient has incurred therapy costs associated with the specific diagnosis. Caring Voice monitors the use of grant funds for individuals using proprietary database software. The database maintains all records to substantiate the amount of an individual's grant, the grantee's eligibility and payments made on the grant.^[20]
- 15 178.

16 states that CVC will:

- Maintain accurate and complete books and records, including accounting and financial data, and retain such books and records in accordance with applicable federal, state and local laws and regulations, Company's record retention policies and procedures and Company instructions.²¹
- 19

179. As noted above, RICO Defendants' Scheme benefited CVC and its executives.

CVC's Code of Conduct (adopted by CVC's Board of Directors on July 22, 2017)

In addition, Actelion intentionally concealed the Scheme, covering up the true nature of its payments and relationship with charities. The payments were in fact bribes and for the purpose of using the foundations as conduits to effectuate its goals of artificially and deceptively inflating the drug prices and increasing the use of the drugs to increase profits at the expense of healthcare payors like Assignors and Class Members. Actelion's concealment prevented Plaintiffs from reasonably discovering the facts underlying Defendants' Scheme which caused Assignors' and prevented Plaintiffs

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 ^{28 &}lt;sup>20</sup> See CVC's Form 990 Tax Filings, attached as Exhibit 26.
 ²¹ See CVC's Code of Conduct, attached as Exhibit 30.
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the Class Members' injuries. In other words, Actelion's concealment lulled Plaintiffs into inaction,
 resulting in substantial damages to Plaintiffs' property and business over the course of the illegal
 scheme.

4 181. Defendants' Scheme caused pharmacies to seek reimbursement from federal health 5 care programs for their purchases of Actelion Drugs. Not only are physicians and pharmacies 6 required to explicitly certify compliance with the AKS, but the act of submitting claims for 7 reimbursement carries with it an implied certification of compliance with governing federal rules 8 that are a precondition of or material to payment. Pharmacies submitting claims for reimbursement 9 therefore certified compliance with federal law, including the AKS. Defendants thus caused 10 pharmacies to provide false certifications.

11 182. Upon information and belief, some pharmacies involved in the Scheme knowingly
12 provided false certification to Assignors and Class Members.

13 183. Upon information and belief, discovery will likely reveal that certain pharmacies
14 conspired with Defendants to achieve the objectives of the Co-Payment Scheme, thereby
15 contributing to the billions of dollars in yearly "co-payment revenue" received by those pharmacies.

16 184. As Actelion used CVC as a conduit, CVC did not act as an independent charity.
17 Instead, Defendants' conduct violated the AKS, OIG regulations, and state and federal laws,
18 rendering any certification relating to the Actelion Drugs as false, and any claim for reimbursement
19 unpayable by Medicare and Medicaid programs (such as Assignors and Class Members).

20 185. As a result of Actelion's collusion with and unlawful use of CVC as a conduit, the
21 Assignors and Class Members were harmed by paying for claims that were unpayable, which they
22 would not have paid but for RICO Defendants' concealment of their scheme.

23 186. As a direct result of the Co-payment Scheme, Assignors and Class Members also
24 paid for an increased number of Actelion Drugs prescriptions throughout the United States.

25 187. As a direct result of the Co-Payment Scheme, Assignors and Class Members also
26 paid supra-competitive prices for the Actelion Drugs. Such prices would not have been possible but27 for Defendants' Scheme.

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188. Following CVC's announcement in 2018 that it was discontinuing operations, CVC

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1 contacted Actelion to transfer approximately \$10 million to Adira.

2 189. By then, Johnson and Johnson owned Actelion. Exhibit 34 – J&J 2017 10-K;
3 Exhibit 35 – J&J 2018 10-K; Exhibit 36 – J&J 2019 10-K; Exhibit 37 – J&J 2020 10-K; Exhibit
4 38 – J&J 2021 10-K.

5 190. Upon information and believe, starting in 2019, Adira joined the Co-Payment
6 Circumvention Enterprise, assumed the role of conduit from CVC, partnered with Actelion, and
7 engaged in overt acts in furtherance of the scheme to defraud Assignors and Class Members

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E. CVC's Fraudulent Transfers to Adira

10 191. As stated above, in or around November of 2017, the OIG issued the 2017 CVC Rescission Letter.

12 192. On February 20, 2018 (just months after the 2017 CVC Rescission Letter), CVC's 13 President and Chairman together incorporated a new 501(c)(3) charity—Facilitating Patient Health, 14 which was later renamed to Adira—to continue using the same fraudulent funds in furtherance of 15 the Scheme.

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 193. During this time, CVC was aware of, and involved in, several DOJ investigations
 and settlements for fraudulent and illegal acts at issue in this Complaint.

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194. On December 6, 2018, the DOJ announced that it had entered into a settlement
agreement with Actelion regarding its fraudulent conduct with CVC. Exhibit 2.

195. That same month, CVC publicly announced that it was discontinuing operations,
 which was false. Exhibit 33.

196. Instead, CVC's management simply transferred millions in assets to themselves, through Adira, and then publicly claimed to be defunct. *See* Exhibit 22 – CVC Articles of Dissolution.

197. In fact, between at least 2011 and 2017 Greg Smiley served as treasurer of CVC.
Starting sometime in 2016 or 2017, Greg Smiley became the President and CEO of CVC and held
that position until the end of CVC's disillusionment. Exhibit 22, 26 - CVC Form 990s.

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198. Similarly, in 2014, James Rock became a director and member of the executive team

at CVC. Starting in 2016, James Rock was elevated to Chairman of CVC and held that position
 until the end of CVC's disillusionment. Exhibit 22, 26 - CVC Business Records & Form 990s.

3 199. On February 23, 2018, (just months after the 2017 CVC Rescission Letter), CVC's
4 President Greg Smiley and Chairman James Rock together incorporated a new purported 501(c)(3)
5 charity—Facilitating Patient Health ("FPH"), which was later renamed to Adira—to continue
6 operating some of the same disease funds that CVC was forced to close. James Rock and Greg
7 Smiley were named as two of the three founding directors. *See* Exhibit 22, 23 – Adira Business
8 Records & Form 990s.

9 200. FPH's 2019 Annual Report (submitted February 9, 2019) names James Rock as
10 Director and Greg Smiley as Director and Chief Executive Officer.

201. On March 15, 2019, CVC entered into a Grant Agreement with FPH. ("CVC-FPH
Agreement"). Greg Smiley—who was President of both CVC and FPH at the time—signed on
behalf of CVC, while James Rock—who was Chairman of both CVC and FPH at the time—signed
on behalf of FPH.

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202. The CVC-FPH Agreement provided that CVC would provide \$3,000,000 to FPH.

16 203. On May 6, 2019, FPH amended its articles of incorporation (signed by Greg Smiley)
17 to change the organization's name to "Adira Foundation."

204. On May 31, 2019, CVC entered into a "Records Transfer Agreement" with Adira,
where CVC would "transfer title and custody of all electronic patient records . . . as well as certain
other records" to CVC. The Records Transfer Agreement contains an attached "Bill of Sale" which
purports that, in consideration of the agreement, Adira paid CVC \$10.

205. Greg Smiley signed the Records Transfer Agreement on behalf of *both* CVC *and*Adira. No other signatures appear on the Records Transfer Agreement. In addition to Greg Smiley
and James Rock, several CVC employees—including other senior management personnel—began
working for Adira at the same time as the transfers. For example, Lauren Ruiz was Director of
Patient Services at CVC from November 2011, until joining Adira in April 2019 as a Programs
Manager. Additionally, Bruce Packett, who served as a director at CVC for several years, including
from 2017-2020, has now also served on Adira's Board of Directors since 2018.

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206. CVC and Adira even used the same accounting firm, Meadows Urquhart Acree & 1 2 Cook LLP, to file their respective 2019 990 forms.

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Plaintiffs are in possession of further evidence of CVC fraudulently conveying its 207. 4 assets to Adira, and Adira taking overt acts in furtherance of the Scheme.

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208. In fact, in July of 2019, CVC continued communicating with Actelion, informing 6 Actelion that it was continuing operations and Adira, and requesting Actelion's consent to transfer 7 approximately \$10 million of Acetlion's funds to Adira.

8 Adira then began using the mail and wires to correspond with Actelion, in 209. 9 furtherance of the Scheme.

10 210. Additionally, an internal CVC document titled "CVC Board Slides 202004" reveals that CVC transferred all non-restricted and unobligated funds to Adira, noting that "\$4.0 million 11 12 Total Will be transferred to Adira on or before 6/30/2020." In addition, this same document 13 instructs that CVC will transfer to Adira both cash and "safe assets earning 5+%."

14 211. Further, several additional internal CVC documents instruct that an extensive list of 15 personal property was (or would be) given to Adira, including laptops, computer servers, software 16 licensees, office equipment, etc.

17 Greg Smiley's salary from CVC in 2018 was \$190,309. In 2019, Greg Smiley's 2019 212. 18 CVC salary was \$256,066 and \$192,865 in 2020. See Exhibit 26 - CVC Form 990. In addition to 19 his CVC salary, Greg Smiley was paid, by Adira, \$192,865 in 2019 and \$234,248 in 2020. See Exhibit 23 – Adira Form 990s. 20

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V.

CLASS ACTION ALLEGATIONS

At all material times, Actelion Drugs-manufactured and sold by Actelion-were 213. 23 shipped across state lines and sold to customers located both within and outside its state of 24 manufacture. 25

214. During the relevant time period, in connection with the purchase and sale of Actelion 26 Drugs, monies, as well as contracts, bills, and other forms of business communication and 27 transactions, were transmitted in continuous and uninterrupted flow across state lines.

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1 215. During the relevant time period, various methods of communication were used to 2 effectuate the illegal acts alleged here, including the United States mail, interstate and foreign 3 travel, and interstate and foreign telephone commerce. The activities of Defendants, as alleged in 4 this Complaint, were within the flow of, and have substantially affected, interstate commerce.

5 6 216. Plaintiffs bring this action on behalf of themselves and the following Class Members:

7 Federal RICO / State RICO / State Consumer Protection Statute Class 1:

8 All Medicare Advantage Organizations, Medicaid Managed Care Organizations, and at-risk, first-tier, and downstream entities in the United States and its territories that 9 from at least January 1, 2014 through present, pursuant to Medicare and/or Medicaid contracts offering Medicare and Medicaid benefits, provided services, purchased 10 Subject Actelion Drugs, provided reimbursement, or possess the recovery rights to reimbursement for some or all of the purchase price of the Actelion Drugs resulting 11 from CVC's or Adira's co-payment assistance. This class excludes: (a) RICO Defendants, their officers, directors, management, employees, subsidiaries, and 12 affiliates; (b) the federal government; and (c) any judges or justices involved in this 13 action and any members of their immediate families.

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- Federal RICO / State RICO / State Consumer Protection Statute Class 2:
- All self-funded, third-party payors and related entities in the United States and its territories that from at least January 1, 2014 through present, provided services, purchased the subject pharmaceuticals, provided reimbursement, or possess the recovery rights to reimbursement for some or all of the purchase price of Actelion Drugs resulting from CVC's or Adira's co-payment assistance. This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) the federal government; and (c) any judges or justices involved in this action and any members of their immediate families.
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217. Plaintiffs bring this action pursuant to Federal Rule of Civil Procedure 23 both individually and on behalf of a national damages class.

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As discussed in this Complaint, Defendants' Scheme resulted in increased sales of
 the Actelion Drugs, the cost of which were borne by Assignors and Class Members. All members of
 the class are subject to the same AKS compliance requirements and are all prohibited from paying
 for or reimbursing claims that are unpayable due to AKS violations. The damages suffered by
 Plaintiffs apply to all individual Class Members (and Plaintiffs as the rightful assignees of those

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1 organizations that assigned their rights to Plaintiffs). Class action law has long recognized that, 2 when companies engage in conduct that has uniformly harmed a large number of claimants such as 3 Plaintiffs and other third-party payers, class resolution is an effective tool to redress the harm.

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219. Assignors and Class Members have been deprived of money as a result of their 5 obligation to pay for prescribed the Actelion Drugs at artificially inflated quantities and supra-6 competitive prices, and because of RICO Defendants' improper shifting of patients from Actelion's 7 free drug program to the co-payment charity. But for the Scheme, Assignors and Class Members 8 would have paid far less for the Actelion Drugs.

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220. The Classes, defined above, are properly brought and should be maintained as a nationwide class action under Rule 23(a), satisfying the class action prerequisites of numerosity, 10 11 commonality, typicality, and adequacy:

12 Numerosity: The Class Members are so numerous that joinder is impracticable. Plaintiffs believe the Class includes thousands of third-party payors that paid for 13 hundreds of thousands, if not millions, of prescriptions. There are thousands of entities (including the organizations that assigned their rights to Plaintiffs) 14 throughout the United States that sustained damages as a result of their payment for the Actelion Drugs caused by Defendants' Scheme. Thus, the numerosity element for 15 class certification is met.

- Commonality: Defendants' misconduct was directed at all Class Members. 17 Questions of law or fact are common to all Class Members. Defendants' co- payment assistance conspiracy Scheme and racketeering activity carried out by their 18 enterprise have a common, adverse effect on all Class Members. Thus, common questions of law or fact are prevalent throughout the class, such as whether Defendants 19 engaged in a pattern of racketeering activity and conspired to induce Class Members' 20payment for the Actelion Drugs prescriptions. Each Class Member shares the same needed remedy-namely reimbursement for unlawfully paid bills and lost money or 21 disgorgement of Defendants' profits as a result of Defendants' Scheme and racketeering activity that caused Assignors and Class Members to pay supra-22 competitive prices for artificially inflated quantities of the Actelion Drugs.
- Typicality: Plaintiffs' claims are typical of the claims of the Class Members because 24 their claims arise from the same course of conduct by Defendants, namely Defendants' formation of their co-payment Scheme and racketeering activity 25 unlawfully causing Class Members to reimburse pharmacies for the over-prescription and over-dispensing of the Actelion Drugs at supra- competitive prices and actual 26 payment that would otherwise not have been made but for Defendants' conduct. Plaintiffs' claims are, therefore, typical of the Class Members. 27
- 28 Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of

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the Class Members. Plaintiffs' interests in vindicating these claims are shared with all of the Class Members. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation and have particular experience with class action consumer protection and RICO litigation in the pharmaceutical industry.

5 221. The Class is properly brought and should be maintained as a class action under Rule 6 23(b) because a class action is the superior method for resolving these claims. Pursuant to Rule 7 23(b)(3), common issues of law and fact predominate over any questions affecting only individual 8 members of the Classes. Defendants deliberately conspired to cause Assignors to pay for the 9 Actelion Drugs through the formation of the Scheme that subsequently resulted in the submission 10 and payment of supra-competitive prices for the Actelion Drugs by Assignors and the Class 11 Members that otherwise would not have been paid.

- 12 222. Assignors and Class Members paid for prescriptions of the Actelion Drugs that they
 13 otherwise would not have paid but for Defendants' Co-payment Scheme and racketeering activity.
- 14 223. Additional questions of law and fact common to some or all the Classes include, but15 are not limited to:
- a. Whether Defendants engaged in a bribery and/or kickback scheme and thereby violated the AKS, the Travel Act, and/or mail and wire fraud statutes;
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 - b. The effect of such bribery and/or kickback scheme on the quantities dispensed and prices of the Actelion Drugs; and
- 18 19

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c. The quantum of overcharges paid by Assignors and Class Members in the aggregate.

224. Class action treatment is a superior method for the fair and efficient adjudication of 20 the controversy in that, among other things, such treatment will permit a large number of similarly 21 situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and 22 without the unnecessary duplication of evidence, effort, and expense that numerous individual 23 actions would engender. The benefits of proceeding through the class mechanism, including 24 providing injured persons or entities with a method for obtaining redress on claims that might not be 25 practicable to pursue individually, substantially outweigh any difficulties that may arise in 26 management of this class action. 27

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225. Plaintiffs know of no difficulty to be encountered in this action that would preclude

TOLLING OF THE STATUTE OF LIMITATIONS

its maintenance as a class action.

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VI.

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226. The claims asserted in this Complaint have been tolled as a matter of law as Defendants took affirmative steps to conceal the wrongful conduct alleged herein including, inter alia, Actelion utilizing CVC as a conduit and concealing such use under the guise of "donations" to an "independent" co-payment assistance charity.

Fraudulent Concealment Tolling

227. The claims asserted in this Complaint have been tolled as a matter of law as CVC 9 took affirmative steps to conceal the wrongful conduct alleged herein by misleading the OIG, DOJ, 10health care providers, certain pharmacies, beneficiaries, third-party payors, and the general public, 11 into believing it was operating a legitimate, legal, and independent 501(c)(3) charitable 12 organization, when in reality, it was serving as an illegal conduit for certain manufacturers, 13 including Actelion. 14

228. The claims asserted in this Complaint have been tolled as a matter of law as CVC 15 and Adira took affirmative steps to conceal the wrongful conduct alleged herein including, inter 16 alia, CVC's fraudulent transfers to Adira and concealing such transfers as bona fide transactions. 17

18

Continuing Violation Doctrine

229. The Complaint alleges a continuing course of conduct, and Defendants' unlawful 19 conduct has inflicted continuing and accumulating harm. Defendants' unlawful conduct and the 20 accumulating harm to the Assignors did not end alongside the DOJ Settlement Agreements. 21 Accordingly, Plaintiffs can recover for damages that they suffered during any applicable limitations 22 period.

Discovery Rule Tolling

Assignors did not know, and had no reasonable way of discovering, Defendants' 230. alleged Scheme until it became public knowledge.

231. Within the applicable statutes of limitation, Assignors could not have discovered 27 through the exercise of reasonable diligence that Defendants were concealing the conduct alleged

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1 herein.

2 232. Assignors did not discover, and did not know of, facts that would have caused a 3 reasonable person to suspect that Defendants were engaged in the alleged Scheme, nor would a reasonable diligent investigation have disclosed the true facts. 4

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233. Assignors did not know, and had no reasonable way of discovering, CVC's and Adira's fraudulent and/or voidable transfers. 6

7 234. Within the applicable statutes of limitation, Assignors could not have discovered 8 through the exercise of reasonable diligence that CVC and Adira were concealing their conduct 9 alleged herein. The Assignors did not discover, and did not know of, facts that would have caused a 10 reasonable person to suspect that CVC and Adira were fraudulently transferring assets, nor would a reasonable diligent investigation have disclosed the true facts. 11

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Equitable Tolling

13 235. Defendants were under a continuous duty to disclose to Assignors and Class 14 Members the existence and true nature of the Co-payment Circumvention Enterprise, including the 15 subsequent obligations for payment triggered by Defendant's misconduct.

16 236. The existence of Defendants' co-payment assistance scheme was a material fact, and 17 Defendants concealed its existence and instead falsely represented that they were in compliance 18 with federal regulations including the FCA and AKS. When Defendants made these 19 misrepresentations and concealed their co-payment assistance conspiracy scheme, they had 20 knowledge of the facts surrounding the scheme's existence. Defendants concealed the co-payment 21 assistance conspiracy scheme and made misrepresentations about it with the intention that 22 Assignors and Class Members would rely on said misrepresentations and would pay for the 23 Actelion Drugs. Defendants' concealment induced Assignors and Class Members to reasonably rely 24 and act upon these misrepresentations and were misled into paying for the Actelion Drugs Drugs. 25 See Safe Env't of Am., Inc. v. Emps. Ins. of Wausau, 278 F. Supp. 2d 121, 126–27 (D. Mass. 2003).

26 Based on the foregoing, Defendants are estopped from relying on any statutes of 237. 27 limitations in defense of this action and all equitable principles of tolling should apply

28

VII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF Violations of Racketeering Influenced Corrupt Organization Act ("RICO") 18 U.S.C. § 1962(c) Through the Use of Co-Payment Charity Scheme

Against All Defendants

5 238. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint
6 as if fully set forth herein.

7 239. At all relevant times, RICO Defendants have been "persons" under 18 U.S.C.
8 § 1961(3) who conducted the affairs of the enterprise through the pattern of racketeering activity
9 detailed throughout this Complaint in violation of 18 U.S.C. § 1962(c).

240. Section 1962(c) makes it "unlawful for any person employed by or associated with
 any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to
 conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a
 pattern of racketeering activity." 18 U.S.C. § 1962(c).

241. Section 1964(c) provides that "any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee." The elements of a RICO claim under § 1964(c) pursuant to a violation of § 1962(c) are: (i) conduct; (ii) of an enterprise; (iii) through a pattern of; (iv) racketeering activity.

20

Description of the Co-payment Circumvention Enterprise

242. RICO defines an enterprise as "any individual, partnership, corporation, association,
or other legal entity, and any union or group of individuals associated in fact although not a legal
entity." 18 U.S.C. § 1961(4).

24 243. Under 18 U.S.C. § 1961(4), a RICO "enterprise" may be an association-in-fact that,
although it has no formal structure, has (i) a common purpose, (ii) relationships among those
associated with the enterprise, and (iii) longevity sufficient to pursue the enterprises' purpose.

27 244. The Co-payment Circumvention Enterprise is an association-in-fact enterprise within
28 the meaning of 18 U.S.C. § 1961(4), consisting of RICO Defendants Actelion, CVC, and Adira,

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1 || including their employees and agents.

2 245. The Co-payment Circumvention Enterprise functioned as an ongoing and continuing
3 unit. The Co-payment Circumvention Enterprise was created and/or used as a tool to effectuate a
4 pattern of racketeering activity. Each of the Enterprise participants is a "person" distinct from the
5 Enterprise.

6 246. The Co-Payment Circumvention Enterprise had a common purpose that united its
7 members. One purpose was to steal funds from the Medicare Trust Fund. Another purpose was to
8 generate personal profits for Defendants' executives from unlawful bribes and kickbacks.

9 Defendants' common purposes were accomplished by, among other things, (1) 247. growing CVC's fund and CVC's executive compensation; (2) eliminating price sensitivity for 10 patients and health care providers; (3) misleading government agencies, third-party payors, health 11 care providers, and beneficiaries regarding the legitimacy of CVC's operations and its conduct; (4) 12 13 funneling patients towards and then away from Actelion's free drug program; (5) applying to 14 Medicare and Medicaid programs on behalf of beneficiaries; and (6) violating OIG regulations and providing data to allow Actelion to conduct continuous ROI calculations, all of which resulted in 15 16 the unlawful depletion of state and federal dollars, increased the number of patients who had their 17 drugs purchased by Assignors and Class Members, and increased the personal gains received by 18 Defendants' executives through the payment of AKS-tainted claims and drugs at supra-competitive 19 prices.

248. By funneling and steering people into CVC's fund, and applying for and obtaining
state and federal coverage for individuals, the Co-payment Circumvention Enterprise increased
Actelion's number of covered "customers," thereby triggering the Assignors' and Class Members'
coverage obligations for their Enrollees and eliminating price sensitivity to the Actelion Drugs.

24 249. Defendants each received substantial revenue from participating in the Co- Payment
25 Scheme. Such revenue was exponentially greater than it would have been in the absence of such
26 Scheme.

27 250. Each portion of the Co-payment Circumvention Enterprise benefitted from the28 existence of the other parts.

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251. The Co-payment Circumvention Enterprise has a systemic linkage because there are
 contractual relationships, financial ties, and continuing coordination of activities between each
 Defendant.

252. There were interpersonal relationships between those associated with the Co-4 5 payment Circumvention Enterprise. This includes relationships: (1) among CVC's officers, agent, and directors and relationships among Actelion's officers, directors, principals, and agents; (2) 6 among CVC and Actelion; (3) among CVC's officers, agents, and directors and Adira's officers, 7 8 agents, and directors; and (4) among Actelion's officers, directors, principals, and agents, and 9 Adira's officers, agents, and directors. This is evidenced by, among other things, the routine 10 communications (through the U.S. Mail and Wire) between Defendants to enable execution of the Scheme. For example, by sharing data with Actelion (in exchange for bribes), CVC enabled 11 Actelion to track and monitor its "donations" to ensure that its payments achieved their proper 12 13 purpose of paying co-pays only for patients receiving the Actelion Drugs, thereby substantially 14 depleting state and federal funds and increasing profits for Actelion.

15 253. The OIG explicitly warned CVC not to send pharmaceutical manufacturers this 16 information because doing so would violate the AKS and FCA, and CVC certified its understanding 17 and compliance with the OIG's warnings. But Defendants participated in this conduct anyway. 18 Actelion settled the DOJ's AKS and FCA claims for \$360 million for them harm this Scheme 19 caused the DOJ.

20 254. The Co-payment Circumvention Enterprise had the longevity sufficient to permitits
21 associates to pursue the enterprise's purpose. It lasted for years, during which time its purposes
22 were pursued. CVC grew its fund for the Actelion Drugs as Actelion increased its annual
23 "donations" to CVC. And Defendants' officers and directors increased their annual compensation,
24 year over year. *See* Exhibits 15 through 23, 26.

25 255. Actelion carried out its business activities both with and without CVC. Similarly,
26 CVC operated other funds without Actelion. The Scheme thus did not involve parallel conduct
27 because Defendants participate in transactions with co-payment charities that do not result in
28 violations of the AKS, FCA, RICO, Consumer Protection Laws, OIG regulations, or other state and

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federal laws.

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Conduct of the Enterprise's Affairs

3 256. Each Defendant conducted or participated in, either directly or indirectly, the conduct of the Co-payment Circumvention Enterprise's affairs. Each Defendant was part of the Co-4 5 payment Circumvention Enterprise and each operated and managed the Co-payment Circumvention Enterprise. Such participation included, but is not limited to: (1) CVC managing, collecting, and 6 sharing data (through the U.S. mail and wire facilities) with Actelion so that Actelion could 7 effectively conduct ROI analyses on the amounts of "donations" to CVC's PAH Fund; (2) Actelion 8 9 providing bribes and kickbacks, disguised as donations, to CVC so the payment obligations of the 10 Assignors and Class Members would be triggered; (3) CVC and Actelion steered and funneled theActelion Drugs patients to CVC's PAH Fund; and (4) Adira assuming CVC's role and enabling 11 the continuation of the Scheme after CVC's fraudulent operations were covered by the DOJ, 12 13 stripping CVC of its ability to continue operating as a 501(c)(3) charity.

14 257. At all relevant times, each Defendant was aware of the Co-Payment Circumvention
15 Enterprise's conduct and was a knowing and willing participant in the racketeering conduct of the
16 Enterprise.

17

Defendants' Pattern of Racketeering Activity

18 258. To carry out their illegal and collusive bribery Scheme Defendants knowingly
19 conducted or participated, directly or indirectly, in the affairs of the Co-payment Circumvention
20 Enterprise through a pattern of racketeering activity within the meaning of 18U.S.C. §§ 1961(1),
21 1961(5), and 1962(c), and employed the use of the mail and wire facilities, in interstate commerce,
22 to promote, manage, establish, and carry out the Co-Payment Circumvention Enterprise in violation
23 of 18 U.S.C. § 1952 (Travel Act), § 1341 (Mail Fraud), and § 1343 (Wire Fraud).

24 259. Defendants' pattern of racketeering likely involved thousands, if not hundreds of
25 thousands, of separate instances of use of the U.S. mail or interstate wire facilities to further the Co26 Payment Circumvention Enterprise. Each of these mailings and interstate wire transmissions
27 constitutes an instance of "racketeering activity" under 18 U.S.C. § 1961(1)(B) by violating the
28 underlying predicate acts of § 1952, § 1341, and § 1343. Collectively, these violations constitute a

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"pattern of racketeering activity," under 18 U.S.C. § 1961(5), to advance Defendants' intentional
 and illegal Scheme.

3	260.	Defendants engaged in a scheme to illegally profit at the direct expense of third-party	
4	payors, including the Assignors and Class Members. Defendants steered patients into CVC's funds		
5	for the Actelion Drugs, knowing third-party payors such as Assignors and Class Members would		
6	ultimately bear the cost for the Actelion Drugs. Defendants knew their Scheme to funnel, steer, and		
7	refer patients and funds were violations of federal and state laws including, but not limited to, the		
8	AKS and the FCA and that they were transmitting false and illegal information through mail and		
9	wire communications.		
10	261.	Defendants' use of the mails and wires to perpetuate their Scheme involved	
11	thousands of communications which included, among others, the following:		
12	a.	Communications from Actelion and CVC to patients, steering them to Actelion's co-payment assistance program using CVC;	
13	b.	Transmittal of bribes, disguised as donations, by Actelion to CVC;	
14 15	c.	Transmittal of kickbacks, disguised as donations, by Actelion to CVC and pharmacies;	
16	d.	Submission of certifications by Actelion and CVC in which they claimed to be in compliance with federal law, including the AKS and FCA;	
17 18	e.	Submissions of data from CVC to Actelion so that Actelion could determine how much money it was making from its "donations" to CVC and how much more money it could make by increasing its "donations";	
19 20 21	f.	Certifications by CVC that it would determine the eligibility according to a "uniform measure of financial need that is applied in a consistent manner" when in fact CVC emphasized patients taking the Actelion Drugs based on Actelion bribes, not financial need; ²²	
22	g.	Causing false claims, in violation of the FCA and AKS, to be submitted by	
23		complicit, and non-complicit, pharmacies to Assignors and Class Members; and	
24	h.	Using the mail and wire to mislead the government agencies (i.e., the OIG,	
25		IRS, DOJ and state departments of record) through false certifications and misrepresentations; and	
26	i.	Fraudulently conveying ill-gotten gains to Adira and then using the mail and wire to advertise and market Adira's services; and	
27	j.	Misleading third-party payors, health care providers, investors, government	
28	²² See CVC's Form 990 Filing, attached as Exhibit 26 .		
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agencies, and the general public into believing the legitimacy of Defendants' Scheme.

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262. Defendants violated the Travel Act by using the mail and wire facilities to commit,
promote, manage, establish, and carry on their bribery and/or kickback scheme in violation of the
laws of the United States, namely, the AKS. Defendants further used the mail and wire facilities to
distribute the proceeds of their bribery and/or kickback scheme.

7 263. The predicate acts violating the Travel Act, as well as mail and wire fraud, had the
8 same purpose: to make money by growing CVC's funds as large as possible so that CVC's officers
9 and directors could pay themselves millions, and so that Actelion could get as many "customers" as
10 possible for the Actelion Drugs at the expense of the Assignors and Class Members.

264. All of the predicate acts detailed above, including the certifications made by Actelion
and CVC, as well as the wire communications in furtherance of their Scheme, were in done
willingly, and in furtherance of the purpose of the Scheme.

14 If the certifications by Actelion to CMS had not been made, Assignors would not 265. have purchased Actelion's products. If CVC's certifications had not been made, CVC would not 15 16 have been permitted to administer its PAH Fund and the Assignors and Class Members would not 17 have paid for the claims resulting from the unlawful conduct. If the Scheme did not exist, 18 pharmacies would have received substantially less co-pay revenues, and the pharmacies would not 19 have submitted AKS-tainted claims to Assignors and Class Members. If the Scheme did not exist, 20 Actelion would not have been able to continuously increase the prices of Actelion Drugs and still 21 remain profitable to the extent that it was.

22 266. These predicate acts allowed the continuance of the Scheme to increase the quantity
23 of the Actelion Drugs and maintain supra-competitive prices. As a result of the Scheme, Assignors
24 and Class Members paid supra-competitive prices for Subject Actelion Drugs at artificially inflated
25 volumes.

26 267. Defendants, including officers, directors, agents, and principals of both
27 organizations, participated in all of the predicate acts. These individuals sent or caused to be sent
28 false certifications through the mail and wire facilities. These individuals repeatedly, and

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1 continuously, used the mail and wires in furtherance of the Scheme.

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268. The intended and direct victims of the Scheme were Assignors and Class Members.

269. The violations of the Travel Act and Mail and Wire Fraud included transmission of
false claims and the unlawful transmission of data and communications to further the racketeering
Scheme over a period of at least five years involving harm to multiple parties.

6 270. CVC was involved in similar fraudulent schemes with other drug manufacturers. It 7 was engaged in similar schemes with Jazz, United Therapeutics, and Lundbeck, each of which 8 resulted in settlements with the United States for violations of the AKS and FCA in 2018. 9 Specifically, Jazz settled for \$57 million, United Therapeutics settled for \$230 million, and 10 Lundbeck settled for \$52.6 million. CVC's multi-faceted fraud involved multiple victims and 11 predicate acts and is the type of broad and persistent racketeering activity that RICO was intended 12 to stop.

13 271. As CVC's successor, Adira is liable for CVC's conduct and is also independently
14 liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of
15 the Scheme.

16 272. The Co-payment Circumvention Enterprise and the predicate acts proximately 17 caused injury to Assignors' and Class Members' business and property by, among other ways, 18 triggering the Assignors' and Class Members' duty to purchase the Actelion Drugs and by driving 19 up the cost of the Actelion Drugs. Defendants' scheme rendered the claims for the Actelion Drugs 20 unpayable and Assignors and Class Members would not have (and could not have) paid if 21 Defendants had not concealed their Scheme.

22 273. Accordingly, Defendants' violations of 18 U.S.C. §1962(c) directly and proximately
23 caused injuries and damages to Assignors and Class Members, entitling Plaintiffs to bring this
24 action for three times their actual damages, as well as injunctive/equitable relief, costs, and
25 reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

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SECOND CLAIM FOR RELIEF Violations of 18 U.S.C. § 1962(d) Through the Use of the Co-Payment Charity Scheme Against All Defendants

3 274. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint
4 as if fully set forth herein.

5 275. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section
6 1962(c), among other provisions.

7 276. Defendants violated § 1962(d) by conspiring to violate § 1962(c). The object of this
 8 conspiracy was to conduct or participate in, directly or indirectly, the conduct of the affairs of the
 9 Co-payment Circumvention Enterprise described previously through a pattern of racketeering
 10 activity.

11 277. Defendants knowingly agreed that Actelion would perform services that would 12 facilitate the illicit activities of the Co-payment Scheme. Actelion steered the Actelion Drugs 13 patients away from its manufacturer-sponsored free-drug fund and into CVC's PAH Fund. Actelion 14 also provided CVC with "donations" so that CVC could pay the co-payments of Actelion's 15 "customers" in CVC's funds. Actelion also sent certifications over the interstate mails and wires 16 claiming it was in compliance with federal law, including the AKS and FCA. Actelion also used the 17 data CVC sent it, in violation of the AKS and FCA, to determine how much money it was making 18 from its "donations" to CVC and how much more money it could make by increasing its 19 "donations."

20 278. Indeed, Actelion and CVC were not engaged in parallel conduct but were working
21 together and had a meeting of the minds that they could both profit from the Co-payment
22 Circumvention Enterprise. The shared data showed how much money Actelion made the prior year
23 before from its "donations" to CVC and how much more it could make by increasing its
24 "donations." It thus set out a roadmap of illegal activities and profits.

25 279. Further, Defendants knowingly agreed that CVC would perform services that would
 26 facilitate the activities of the Co-payment Circumvention Enterprise and those who were running it
 27 in an illegal manner. Some of the services that CVC performed were steering people into its funds,

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and helping to enroll patients into Medicare and Medicaid Programs. Actelion would then pay CVC
 agreed-upon bribes for each patient CVC successfully enrolled in Medicare and Medicaid Programs
 for the Actelion Drugs.

4 280. CVC also sent certifications over the interstate mails and wires claiming it was in 5 compliance with federal law, including the AKS and FCA. CVC also sent Actelion data, in 6 violation of the AKS and FCA, so Actelion could see how much money it was making from its 7 "donations" to CVC and how much *more* money it could make by increasing its "donations." 8 Indeed, this sharing of data shows that Actelion and CVC were not engaged in parallel conduct but 9 were working together and had a meeting of the minds that they could both profit from the Co-10 payment Scheme. CVC knew that the more money it accepted in "donations" from Actelion, the more money would go into the pockets of CVC's officers and directors. By illegally giving 11 12 Actelion this data, CVC was soliciting greater contributions.

13 281. Further, Actelion and CVC knowingly agreed to perform services that would 14 facilitate the activities of the Co-Payment Circumvention Enterprise and those who were running it 15 in an illegal manner. Actelion steered people towards CVC's co-payment assistance funds by using 16 CVC data to ensure Actelion could verify that its "donations" provided co-pays for the Actelion 17 Drugs. Actelion and CVC caused false certifications to be sent over the interstate mail and wire 18 facilities claiming they were in compliance with federal law, including the AKS and FCA. CVC 19 sent Actelion data, in violation of the AKS and FCA, so that Actelion could see how much money it 20 was making from its "donations" to CVC, and how much more money it could make by increasing 21 its "donations." Indeed, this conduct shows that Defendants did not engage in parallel conduct but 22 worked together and had a meeting of the minds that they could each profit from the Co-payment 23 Scheme. Actelion knew that if it provided more "donations," CVC would provide more co-pay 24 assistance, thereby increasing Actelion's profits. Thus, by illegally providing data to Actelion, CVC 25 managed to increase its own profits—as well as Actelion's profits.

26 282. Defendants knowingly agreed that one or all of them would commit at least two
27 instances of Travel Act violations or mail and wire fraud (or cause an innocent third-party to send
28 false statements over the mails and wires). Defendants had actual or constructive knowledge that

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1 CVC had certified to HHS that it would not share data with manufacturers, allow manufactures to exert influence over it, steer people to particular drugs, or serve as a conduit for drug manufacturers. 2 3 In short, Defendants knew that CVC had certified that it would abide by the AKS and FCA. Defendants knew that the Scheme they were engaged in or were going to engage in was going to 4 5 make all these certifications false. They also knew that each time a pharmacy filled a prescription for someone in CVC's funds, any certifications the pharmacist made that he or she would abide by 6 7 federal law would be false. Actelion also knew that any certifications it made to HHS or the 8 Government about its compliance with federal law would be false.

9 283. Defendants knew that any communications they had over the telephone, e-mail, or
10 text message in furtherance of the Scheme would be predicate acts.

11 284. Defendants agreed to pursue the same objective of profiting illegally from the Co-12 payment Scheme. They agreed to divide the work of accomplishing this objective. Actelion would 13 make the "donations"; CVC would provide data; and they would both steer clients and make false 14 certifications. Defendants intended to further this endeavor, which, as described above, when 15 completed, amounted to a violation of 18 U.S.C. § 1962(c) that proximately and directly caused 16 injury to the Assignors and Class Members.

17 285. As CVC's successor, Adira is liable for CVC's conduct and is also independently
18 liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of
19 the Scheme.

20 286. Plaintiffs bring this action for three times their actual damages, as well as 21 injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

> THIRD CLAIM FOR RELIEF Violations of State Consumer Protection Laws

> > Against All Defendants

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- 24

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287. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint as if fully set forth herein.

26 288. Defendants engaged in unfair, false, unconscionable, or deceptive acts or practices in
27 violation of various state consumer protection laws, as set forth below.

28

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289. Defendants directly misrepresented to Assignors and the Class Members that they
 were complying with federal and state laws, including laws against bribery, kickbacks, and false
 claims to the government.

4 290. Defendants utilized the Scheme to eliminate price sensitivity in order to raise prices
5 for the Actelion Drugs to supra-competitive levels.

6 291. Defendants intended for payers such as Assignors and Class Members to rely on 7 these certifications. The intention may be inferred by the very nature of the representation, whose 8 sole purpose was to procure payment for the Actelion Drugs. These representations and 9 certifications were made in an effort by Defendants to have the consuming public use the CVC fund 10 and were addressed to the market generally by having improper and unnecessary prescriptions for the Actelion Drugs paid for by Medicare, Assignors, and the Class Members. The ultimate 11 12 consequence of this conduct is a significant injury to the consuming public by, among other things, 13 imposing additional costs on the taxpaying public for Medicare.

14 292. Assignors and the Class Members relied on these misrepresentations to their
15 detriment, which were material to their decision to pay for the Actelion Drugs.

16 293. As CVC's successor, Adira is liable for CVC's conduct and is also independently
17 liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of
18 the Scheme.

19 294. Assignors and the Class Members were directly and proximately injured by
20 Defendants' conduct suffered an injury in fact, and suffered actual, ascertainable damages.

21 295. Assignors and the Class Members would not have reimbursed for nearly as much of
22 the Actelion Drugs as they did, had Defendants refrained from engineering the false representations
23 or otherwise disclosed its schemes. Likewise, Assignors and the Class Members would not have
24 paid nearly as much for each prescription of the Actelion Drugs as they did, had Defendants not
25 eliminated price sensitivity through the Co-payment Scheme.

26 296. Accordingly, Plaintiffs and the Class Members in each of the below jurisdictions,
27 seek damages (including statutory damages where applicable), to be trebled or otherwise increased
28 as permitted by a jurisdiction's consumer protection law, and cost of suit, including reasonable

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1 attorneys' fees, to the extent permitted by the below state laws.

2

California Unfair Competition Law (Cal. Bus. Code §§ 17000, et seq.)

3 297. Defendants' conduct occurred in "trade" or "commerce" within the meaning of Cal.
4 Bus. Code Article 2 §§ 17020-17031.

5 298. The California UCL provides that "Any person who engages, has engaged, or 6 proposes to engage in unfair competition shall be liable for a civil penalty." Cal. Bus. Code 7 §17206(a).

8 299. Defendants' conduct constitutes "unfair or deceptive" acts in violation of the
9 California UCL.

10

300. Defendants' illegal conduct substantially affected California trade and consumers.

301. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and
actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and
omissions and/or misrepresentations, at a minimum, in the form of increased payments for the
Actelion Drugs here.

15 302. Defendants' conduct alleged in this Complaint occurred throughout the United
16 States, including the State of California.

17 303. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the
18 Actelion Drugs in the State of California.

19 304. Plaintiffs are entitled to recover their actual damages.

20 305. Plaintiffs also seek punitive damages, attorney fees, and any other just and proper
21 relief under the California UCL.

22

Connecticut Unfair Trade Practices Act (Conn. Gen. Stat. §§ 42-110a et seq.)

23 306. Defendants' conduct occurred in "trade" or "commerce" within the meaning of
24 Conn. Gen. Stat. § 42-110a(4) ("Connecticut UTPA").

307. The Connecticut UTPA provides that "no person shall engage in unfair methods of
competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."
Conn. Gen. Stat. § 42-110b(a).

28

308. Defendants' conduct constitutes "unfair or deceptive" acts in violation of the

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1 Connecticut UTPA.

2 309. Defendants' illegal conduct substantially affected Connecticut commerce and
3 consumers.

4 310. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and 5 actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and 6 omissions and/or misrepresentations, at a minimum, in the form of increased payments for the 7 Actelion Drugs herein.

8 311. Defendants' conduct alleged in this Complaint occurred throughout the United
9 States, including in the State of Connecticut.

10 312. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the
11 Actelion Drugs in the State of Connecticut.

313. Simultaneously with the filing of this Complaint, Plaintiffs served a copy on the
Attorney General and Commissioner of Consumer Protection pursuant to Conn. Gen. Stat.
§ 42-110g.

15 314. Plaintiffs are entitled to recover their actual damages, punitive damages, and
16 attorneys' fees pursuant to Conn. Gen. Stat. § 42-110g.

17

Florida Deceptive & Unfair Trade Practices Act (Fla. Stat. §§ 501.201 et seq.)

18 315. Plaintiffs, Assignors, and the Class Members are "interested persons" and
19 "consumers" within the meaning of the Florida Deceptive and Unfair Trade Practices Act
20 ("FDUTPA"). Fla. Stat. § 501.203(6)-(7).

21 316. Defendants are engaged in "trade or commerce" within the meaning of Fla. Stat. §
22 501.203(8).

317. FDUTPA prohibits "[u]nfair methods of competition, unconscionable acts or
practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce[.]" Fla.
Sta. § 501.204(1).

26 318. Defendants' conduct constitutes "unconscionable acts or practices, and unfair or
27 deceptive acts or practices" under FDUTPA.

28

319. Defendants knew or should have known that their conduct was in violation of

1 FDUTPA.

2 320. Defendants' illegal conduct substantially affected Florida commerce and consumers. 3 321. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and 4 5 omissions and/or misrepresentations, at a minimum, in the form of increased number and size of payments for the Actelion Drugs described herein. 6 7 Defendants' conduct alleged in this Complaint occurred throughout the United 322. 8 States, including in the State of Florida. 9 323. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the 10 Actelion Drugs in the State of Florida. 11 324. Plaintiffs seek to recover against each Defendant the amount of their actual damages, attorneys' fees, and costs pursuant to Fla. Stat. §§ 501.211(2) and 501.2105(1). 12 13 Illinois Consumer Fraud & Deceptive Business Practices Act (815 Ill. Comp. Stat. 505/1 et seq.) 14 15 325. Defendants' conduct occurred in "trade" or "commerce" within the meaning of the 16 Illinois Consumer Fraud and Deceptive Business Practices Act ("Illinois CFDBPA"). 815 Ill. 17 Comp. Stat 505/1(f). 18 326. Defendants are "persons" within the meaning of the Illinois CFDBPA. 815 Ill. 19 Comp. Stat. 505/1(c). 20 Assignors and the Class Members are "consumers" within the meaning of the Illinois 327. 21 CFDBPA. 815 Ill. Comp. Stat. 505/1(e). 22 328. The Illinois CFDBPA provides that "Unfair methods of competition and unfair or 23 deceptive acts or practices... are hereby declared unlawful whether any person has in fact been 24 misled, deceived or damaged thereby." 815 Ill. Comp. Stat. 505/2. 25 329. Defendants' conduct constitutes "unfair or deceptive" acts or practices in violation of 26 the Illinois CFDBPA. 27 330. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and 28 actual damages as a direct and proximate result of RICO Defendants' unfair and deceptive practices - 59 -CLASS ACTION COMPLAINT - 3:22-cv-07604

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and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the
 Actelion Drugs herein.

3 331. Defendants' conduct alleged in this Complaint occurred throughout the United
4 States, including the State of Illinois.

5 332. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the
6 Actelion Drugs in the State of Illinois.

333. Simultaneously with the filing of this Complaint, Plaintiffs served a copy on the
8 Illinois Attorney General pursuant to 815 Ill. Comp. Stat. 505/10(d).

9 334. Plaintiffs are entitled to recover three (3) times the amount of actual damages
10 resulting from Defendants' violation together with costs and reasonable attorney's fees. 815 Ill.
11 Comp. Stat. 505/2W.

12

<u>Massachusetts Regulation of Business Practice & Consumer Protection Act</u> (Mass. Gen. Laws ch. 93A, <u>§§</u> 1 et seq.)

13

14 335. Assignors, the Class Members, and Defendants are "persons" within the meaning of
15 the Massachusetts Regulation of Business Practice & Consumer Protection Act ("Massachusetts
16 CPA"). Mass. Gen. Laws ch. 93A, § 1(a).

17 336. Defendants are engaged in "trade or commerce" within the meaning of Mass. Gen.
18 Laws ch. 93A, § 1(b).

19 337. Defendants' conduct, and Plaintiffs' injury occurred primarily and substantially
20 which the Commonwealth of Massachusetts.

338. The Massachusetts CPA makes unfair methods of competition and unfair or
deceptive acts or practices in the conduct of any trade or commerce unlawful. Mass. Gen. Laws ch.
93A, § 2(a).

24 339. Defendants' conduct constitutes "unfair or deceptive acts or practices" under
25 Massachusetts CPA.

26 340. Defendants knew or should have known that their conduct was in violation of27 Massachusetts CPA.

28

341. Defendants' illegal conduct substantially affected Massachusetts commerce and

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1 consumers.

2 Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and 342. 3 actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the 4 5 Actelion Drugs described herein.

6

343. Defendants' conduct alleged in this Complaint occurred throughout the United 7 States, including in the State of Massachusetts.

8 Plaintiffs' analysis of its Assignors' data identified one or more purchases of the 344. 9 Actelion Drugs in the State of Massachusetts.

10 Plaintiffs seek monetary relief against Defendants measured as the greater of (a) 345. actual damages in an amount to be determined at trial and (b) statutory damages in the amount of 11 12 \$25 for each Plaintiff. Because Defendants' conduct was committed willfully and knowingly, 13 Plaintiffs are entitled to recover up to three times actual damages, but no less than two times actual 14 damages pursuant to Mass. Gen. Laws ch. 93A, §§ 9 and 11.

15 Plaintiffs also seek punitive damages, and attorneys' fees, costs, and any other just 346. 16 and proper relief available under the Massachusetts CPA.

17

Michigan Consumer Protection Act (Mich. Comp. Laws §§ 445.901 et seq.)

18 347. Defendants' conduct occurred in "trade" or "commerce" within the meaning of 19 Michigan Consumer Protection Act ("Michigan CPA"). Mich. Comp. Laws § 445.902(g).

20 348. Defendants are "persons" within the meaning of Michigan CPA. Mich. Comp. Laws 21 § 445.902(d).

22 349. The Michigan CPA provides that "Unfair, unconscionable, or deceptive methods, 23 acts, or practices in conduct of trade or commerce are unlawful." Mich. Comp. Laws § 445.903(1).

24 350. Defendants' conduct constitutes "unfair, unconscionable, or deceptive" methods, 25 acts, or practices under the Michigan CPA.

26 351. Defendants' conduct includes, but is not limited to, several categories defined in the 27 Michigan Consumer Protection Act. See Mich. Comp. Laws § 445.903(1)(a), (c), (s), (u), (w), and 28 (z).

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1352. Defendants' conduct substantially affected Michigan trade or commerce, and2consumers.

3 353. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair, unconscionable, or deceptive 4 5 practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the Actelion Drugs herein. 6 7 354. Defendants' conduct alleged in this Complaint occurred throughout the United 8 States, including the State of Michigan. 9 355. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the 10 Actelion Drugs in the State of Michigan. 11 356. Plaintiffs are entitled to recover their actual damages and reasonable attorney fees 12 pursuant to Mich. Comp. Laws \S 445.911(2)-(3). 13 New York General Business Law (N.Y. Gen. Bus. Law §§ 349 et seq.) 14 15 357. The New York General Business Laws ("New York GBL") makes unlawful 16 "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law § 349. 17 18 358. Defendants' conduct constitutes "deceptive acts" in violation of the New York GBL. 19 359. Defendants' conduct was consumer oriented. 20 360. Defendants' conduct eliminated price sensitivity and raised prices in the relevant 21 markets for the Actelion Drugs, which necessarily impacted consumers at large. 22 361. Defendants' conduct was consumer oriented since it was necessarily directed at 23 Plaintiffs, consumers and/or other similarly situated entities. 24 362. Defendants' illegal conduct substantially affected New York commerce and consumers. 25 26 363. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and 27 actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and 28 omissions and/or misrepresentations, at a minimum, in the form of increased payments for the - 62 -CLASS ACTION COMPLAINT - 3:22-cv-07604

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Actelion Drugs described herein.

2 Defendants' conduct alleged in this Complaint occurred throughout the United 364. 3 States, including in the State of New York.

4 365. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the 5 Actelion Drugs in the State of New York.

6

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366. As a result of the foregoing willful, knowing, and wrongful conduct of Defendants, 7 Plaintiffs have been damaged in an amount to be proven at trial, and seek all just and proper 8 remedies, including but not limited to actual damages or \$50, whichever is greater, treble damages 9 up to \$1,000, punitive damages to the extent available under the law, reasonable attorneys' fees and 10 costs, an order enjoining Defendants' deceptive and unfair conduct, and all other just and appropriate relief available pursuant to N.Y. Gen. Bus. Law § 349. 11

12

13

- **Ohio Consumer Protections Laws** (Ohio Rev. Code Ann. §§ 1345 et seq.; §§ 4165 et seq.)
- 14 367. Defendants, Assignors, and the Class Members are "persons" within the meaning of the Ohio Consumer Sales Practice Act Ohio Rev. Code Ann. §§ 1345.01 ("Ohio CSPA") and the 15 16 Ohio Deceptive Trade Practices Act Ohio Rev. Code Ann. §§ 4165.01. ("Ohio DTPA").

17 368. Defendants are "suppliers" within the meaning of the Ohio CSPA. Ohio Rev. Code 18 Ann. § 1345.01

19 369. Defendants engaged in trade or commerce within the meaning of the Ohio CSPA and Ohio DTPA. 20

21 370. The Ohio CSPA specifies "No supplier shall commit an unfair or deceptive act or 22 practice." Ohio Rev. Code Ann. § 1345.02.

23 371. The Ohio DTPA declares it unlawful for any person to engage in a deceptive practice 24 in the course of the person's business, vocation, or occupation. Ohio Rev. Code Ann. § 4165.02.

25 372. Defendants' conduct constituted "unfair, deceptive acts or practices" in violation of 26 the Ohio CSPA and Ohio DTPA.

27 373. Defendants knew or should have known that their conduct was in violation of **both** 28 the Ohio CSPA and Ohio DTPA.

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374. Defendants' illegal conduct substantially affected Ohio commerce and consumers.

2 Members relied 375. Assignors and the Class upon Defendants' material 3 misrepresentations regarding the certifications, their compliance with federal and state laws, including laws against bribery, kickbacks, and false claims to the government. 4

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376. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and 6 7 omissions and/or misrepresentations, at a minimum, in the form of increased payments for the 8 Actelion Drugs described herein.

9 377. Defendants' conduct alleged in this Complaint occurred throughout the United 10 States, including in the State of Ohio.

11 378. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of Ohio. 12

13 379. Plaintiffs seek actual economic losses, punitive damages, attorney's fees, and any 14 other just and proper relief available pursuant to the Ohio CSPA and Ohio DTPA.

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- 16

<u>Puerto Rico Regulation of Commerce (P.R. Laws Ann. tit. 10, §§ 251 et seq.;</u> P.R. Laws Ann. Tit. 31, §§ 5141 et seq)

17 380. Assignors, the Class Members, and Defendants are "persons" within the meaning of 18 P.R. Laws Ann. tit. 10, §§ 251 et seq.

19 381. Defendants engaged in trade or commerce within the meaning of P.R. Laws Ann. tit. 10, §§ 251 et seq. 20

21 The Puerto Rico Regulation of Commerce states "[u]nfair competition, and unfair or 382. 22 deceptive acts or practices in trade or commerce are hereby decaled unlawful." P.R. Laws Ann. tit. 23 10, §§ 251 et seq.

24 383. Defendants' conduct constituted "unfair competition, and unfair or deceptive acts or 25 practices" in violation of P.R. Laws Ann. tit. 10, §§ 251 et seq.

26 384. Defendants knew or should have known that their conduct was in violation of the 27 P.R. Laws Ann. tit. 10, §§ 251 et seq.

28

Under P.R. Law Ann tit. 31, § 5141, "a person who by an act or omission causes 385.

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1 damage to another through fault or negligence shall be obliged to repair the damage so done.

2 386. Defendants' unfair, unconscionable, deceptive practices or acts violated P.R. Law 3 Ann tit. 31, §§ 5141 et seq.

4 387. In an effort to conceal the Scheme, Defendants regularly omitted information and/or 5 made false or misleading statements causing third parties to submit false certifications for payment of claims otherwise prohibited by federal law. 6

7 388. Defendants utilized the Scheme to raise prices of the Subject Actelion Drugs to 8 supra-competitive prices, as explained above.

9 389. Plaintiffs suffered harm by paying and/or reimbursing AKS tainted claims at supra-10 competitive prices.

11 390. Defendants' illegal conduct substantially affected Puerto Rico commerce and 12 consumers.

13 391. Assignors and the Class Members relied on Defendants' material misrepresentations 14 about their certifications of compliance with federal and state laws, including laws against bribery, 15 kickbacks, and false claims to the government.

16 392. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and 17 actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and 18 omissions and misrepresentations, at a minimum, in the form of increased payments for the 19 Actelion Drugs.

20 393. Defendants' conduct alleged in this Complaint occurred throughout the United 21 States, including in Puerto Rico.

22 Plaintiffs' analysis of its Assignors' data identified one or more purchases the 394. 23 Actelion Drugs in Puerto Rico.

24 395. Plaintiffs seek damages, punitive damages, and attorneys' fees, costs, and any other 25 just and proper relief available under P.R. Laws Ann. tit. 10, §§ 251 et seq; P.R. Laws Ann. tit. 31, 26 §§5141 *et seq*.

27

Rhode Island Deceptive Trade Practices Act (6 R.I. Gen. Laws §§ 6-13.1 et seq.)

28

Assignors and Class members are "persons" as defined by the Rhode Island 396.

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1 Deceptive Trade Practices Act ("Rhode Island DTPA").

2 397. Defendants engaged in an unfair or deceptive act or practice with the intent to injure
3 consumers through supra-competitive profits.

4

398. Defendants' conduct was unfair or deceptive within the conduct of commerce within
the State of Rhode Island.

6 399. Defendants' conduct amounted to an unfair or deceptive act or practice committed
7 by a supplier in connection with a consumer transaction.

8 400. Defendants' unlawful conduct substantially affected Rhode Island's trade and
9 commerce.

10

401. Defendants' conduct was willful.

402. Defendants deliberately failed to disclose material facts to Assignors and Class
Members concerning the Defendants' unlawful activities, including the unlawful bribes Actelion
provided to CVC as part of the Co-Payment Circumvention Enterprise.

403. Defendants' deception, including their affirmative misrepresentations and/or
omissions concerning the price of the Actelion Drugs, constitutes information necessary to
Assignors and Class Members to the cost of the Actelion Drugs.

17 404. The Actelion Drugs were purchased primarily for personal, family or household18 purposes.

19 405. Plaintiffs seek damages, court costs, and attorneys' fees under R.I. §§ 6-13.1, *et seq*,
20 and any other just and proper relief available under the Rhode Island DTPA.

21

24

Wisconsin Deceptive Trade Practices Act (Wis. Stat. §§ 100.18 et seq.)

406. Assignors and the Class Members are part of "the public" under the Wisconsin
Deceptive Trade Practices Act ("Wisconsin DTPA"). Wis. Stat. § 100.18(1).

407. Assignors and the Class Members are "persons" under Wis. Stat. § 100.18(1).

408. Defendants are each a "person, firm, corporation or association" under Wis. Stat. §
100.18(1).

409. The Wisconsin DTPA makes unlawful any "representation or statement of fact,
which is untrue, deceptive or misleading." Wis. Stat. § 100.18(1).

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410. Defendants' conduct constitutes "representation[s] or statement[s] of fact which
 [were] untrue, deceptive or misleading" in violation of the Wisconsin DTPA.

3 411. Defendants knew or should have known that their conduct violated the Wisconsin
4 DTPA.

5 412. Defendants' illegal conduct substantially affected Wisconsin commerce and
6 consumers.

413. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and
actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and
omissions and misrepresentations, at a minimum, in the form of increased payments for the
Actelion Drugs.

414. Defendants' conduct alleged in this Complaint occurred throughout the United
States, including in the State of Wisconsin.

13 415. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the
14 Actelion Drugs in the State of Wisconsin.

416. No business relationship, contractual or otherwise, existed or exists between
Assignors, the Class Members, and Defendants.

17 417. Plaintiffs seek damages, court costs, and attorneys' fees under Wis. Stat.
18 \$100.18(11)(b)(2), and any other just and proper relief available under the Wisconsin DTPA.

19

20 21

FOURTH CLAIM FOR RELIEF Unjust Enrichment Under State Law Against Defendants

418. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint
as though set forth at length above.

4 419. Defendants have benefitted from artificially inflated profits on the sale of the
Actelion Drugs resulting from the unlawful and inequitable acts alleged in this Complaint.

420. Defendants' financial benefit resulting from its unlawful and inequitable acts is
 traceable to overpayments for direct and indirect purchases of the Actelion Drugs by the Assignors

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1 and Class Members.

421. The Assignors and Class Members afforded Defendants an economic benefit in the
form of profits, and other forms of compensation from unlawful overcharges and monopoly profits
to the economic detriment of the Assignors and Class Members.

5 422. Plaintiffs' analysis of its Assignors' data identified one or more purchases of Subject
6 Actelion Drugs in each of these States and Territories:

- 7 a. Connecticut; 8 b. Florida; 9 Illinois; c. 10 Massachusetts; d. 11 12 Michigan; e. 13 New York; f. 14 d. Ohio; 15 Puerto Rico; g. 16 17 Rhode Island; and h. 18 Wisconsin. i. 19 423. Defendants' conduct directly resulted in the unjust enrichment of the Defendants 20 through the sale of the Actelion Drugs in each of the States and Territory mentioned above. 21 424. It would be futile for the Assignors and Class Members to seek a remedy from any 22 party with whom they have privity of contract with for its direct or indirect purchases of the 23 Actelion Drugs. 24 It would be futile for the Assignors and Class Members to seek to exhaust any 425. 25 remedy against the immediate intermediary in the chain of distribution from which the Assignors 26 and Class Members purchased the Actelion Drugs, as they are not liable and would not compensate 27 the Assignors and Class Members for unlawful conduct caused by Defendants.
- 28

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426. The economic benefit of overcharges and artificially inflated volumes of
 prescriptions derived by Defendants through charging supra-competitive and artificially inflated
 prices for the Actelion Drugs is a direct and proximate result of Defendants' unlawful conduct.

4 427. The economic benefits derived by Defendants rightfully belong to the Assignors and
5 Class Members, as they paid anticompetitive and monopolistic prices beginning in at least January
6 1, 2014, and continuing through the present, and they will continue to do so until the effects of
7 Defendants' illegal conduct cease.

8 428. It would be inequitable under unjust enrichment principles under the law of the
9 District of Columbia and the laws of all states and territories in the United States for Defendants to
10 be permitted to retain any of the overcharges for the Actelion Drugs derived from Defendants'
11 unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

12 429. Defendants are aware of and appreciates the benefits bestowed upon it by the13 Assignors and the Class Members.

14 430. Defendants should be compelled to disgorge all unlawful or inequitable proceeds15 received in a common fund for Plaintiffs' benefit.

431. A constructive trust should be imposed on all unlawful or inequitable sums received
by Defendants traceable to the Assignors and Class Members.

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21 22

FIFTH CLAIM FOR RELIEF Violations of the Florida Civil Remedies for Criminal Practices Act (Fla. Stat. § 772.101 et seq.) Against All Defendants

432. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint
as if fully set forth herein.

433. At all times, as set forth above, Defendants' actions were unlawful under Fla. Stat. §
772.103(3), as they were all "employed by, or associated with, any enterprise through a pattern of
criminal activity."

- 28 434. Defendants violated Fla. Stat. § 772.101 *et seq.*, by participating in or conducting the
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affairs of the Co-Payment Circumvention Enterprise (as described more fully above) through a
 pattern of racketeering activity.

3 435. Plaintiffs, Assignors, and the Class Members are "persons" as defined in Fla. Stat. §
4 1.01, injured in their business or property, through Defendants' racketeering violations.

5

6

Description of the Co-Payment Circumvention Enterprise

436. RICO Defendants are "persons" under Fla. Stat. § 1.01.

7 437. Actelion, CVC, and Adira, are members of and constitute an "association in-fact
8 enterprise."

9 438. The Co-Payment Circumvention Enterprise is an association-in-fact of individuals
10 and corporate entities under Fla. Stat. § 772.101, and consists of "persons" associated for a common
11 purpose.

439. The purpose of the Co-Payment Circumvention Enterprise was to maximize
Actelion's profits and CVC's executive compensation.

440. The Co-Payment Circumvention Enterprise had an ongoing organization with an
ascertainable structure and functioned as a continuing unit with separate roles and responsibilities.
Actelion is the source of the schemes alleged, including providing kickbacks to subsidize payments
for Actelion Drugs whose co-payments were provided by CVC.

18 441. For CVC's part, CVC accepted Actelion's bribes or kickbacks and provided19 unlawful payments for the Actelion Drugs.

20 442. Actelion and CVC, individually and collectively, fulfilled their roles in the Co21 Payment Circumvention Enterprise.

443. Actelion and CVC were distinct legal entities with distinct purposes. Actelion is the
architect of the Co-Payment Circumvention Enterprise, with the sole purpose to make as much
money off the Actelion Drugs as possible before generic competition entered the market. For CVC,
it was to raise the amount of money in the funds to justify paying higher salaries to their executives.

444. The Co-Payment Circumvention Enterprise had an existence that was distinct from
the pattern of racketeering in which Actelion and CVC engaged. Actelion and CVC conspired with
each other to minimize and/or conceal the amount of information Assignors received about the

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1 claims for payment of the Actelion Drugs, materially resulting in Assignors' reimbursement of the 2 purchase price of the Actelion Drugs that they would not have otherwise paid for. See Fla. Stat. § 3 817.234 ("A person commits insurance fraud punishable as provided in subsection (11) if that person, with the intent to injure, defraud, or deceive any insurer: 1. Presents or causes to be 4 5 presented any written or oral statement, as part of, or in support of, a claim for payment or other benefit pursuant to an insurance policy or a health maintenance organization subscriber or provider 6 7 contract, knowing that such statement contains any false, incomplete, or misleading information 8 concerning any fact or thing material to such claims[.]").

9 445. At all relevant times, Defendants operated, controlled, and managed the Co-Payment
10 Circumvention Enterprise, through a variety of actions. First, CVC falsely represented the level of
11 control that Actelion had over CVC in the PAP to the OIG on numerous occasions. Second,
12 Defendants failed to disclose a material fact about the existence of the kickbacks and/or bribes in
13 violation of Fla. Stat. § 817.234, (i.e., causing pharmacies to submit false submissions of payments
14 to the Assignors and the Class Members.).

15 Defendants' participation in the Co-Payment Circumvention Enterprise was 446. 16 necessary for the successful operation of the schemes. The members of the Co-Payment 17 Circumvention Enterprise all served a common purpose, which was to increase the fund to an 18 enormous size while knowing each payment was a kickback, while minimizing the amount of 19 information the Assignors, Class Members, and allegedly innocent third-party pharmacies, knew 20 about the program. These affirmative acts and strategic omissions were material to the Assignors' 21 and Class Members' decision to issue payment for the Actelion Drugs. The Co-Payment 22 Circumvention Enterprise's actions maximized the revenue and profitability of the Enterprises' 23 members by knowingly causing payments for the Actelion Drugs.

447. Fla. Stat. § 772.102 provides that criminal activity is any activity chargeable by
indictment or information by among other statutes Fla. Stat. § 817.234. Section 817.234
criminalizes situations where health care companies, such as the Assignors and Class Members, are
provided incomplete or misleading information about any fact or thing material to a claim for
payment. Actelion and CVC violated Fla. Stat. § 817.234 by providing incomplete or misleading

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information material to the Assignors' and Class Members' decision to issue payment for the
 Actelion Drugs.

3 448. Defendants committed numerous acts of racketeering by providing incomplete or
4 misleading information related to the Actelion Drugs. Actelion and CVC knew or had reason to
5 know that they were providing incomplete or misleading information about these claims.

6 449. Defendants knew or had reason to know that they were not providing complete or
7 non-misleading information under Fla. Stat. § 817.234. Despite knowledge of these facts, they
8 induced the Assignors and Class Members to make payment for claims that they otherwise would
9 not have paid. Instead, Defendants knowingly provided incomplete information to enrich their
10 bottom line.

450. Based on these omissions, the Assignors and Class Members provided payments for
the Actelion Drugs throughout the United States, including Florida, based on half-truths, inaccurate
information, and deliberate omissions. Defendants' omissions were material to the payment of the
Actelion Drugs that the Assignors and Class Members provided payment for. Had the Assignors
and Class Members known of the Co-Payment Scheme, they would not have submitted payment for
the Actelion Drugs.

17 451. The Assignors and Class Members were the primary and intended victims of
18 Defendants' unlawful scheme. The Assignors paid for the Actelion Drugs throughout the United
19 States, including Florida, based on Defendants' omissions of material information under pursuant
20 under to Fla. Stat. § 817.234,.

452. As part of this Scheme, Defendants caused pharmacies to submit false certifications
and misled the Assignors and Class Members into reimbursing prescriptions of the Actelion Drugs.
Actelion, CVC, and Adira, conducted or participated, directly or indirectly, in the Co-Payment
Circumvention Scheme through a pattern of unlawful activity.

453. As CVC's successor, Adira is liable for CVC's conduct and is also independently
liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of
the Scheme.

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454. By reason of and as a result of Defendants' conduct, the Assignors and Class

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1 Members were injured in their business or property.

455. Defendants' violations have directly and proximately caused injuries and damages to
Assignors, Plaintiffs, and the Class Members. The Assignors, Plaintiffs, and Class Members have a
right to bring this action for these damages.

5 456. Under Fla. Stat. § 772.11, Plaintiffs, and the Class Members seek their reasonable
6 attorneys' fees and costs associated with prosecution of this action.

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7

SIXTH CLAIM FOR RELIEF

Violation of Va. Code Ann. § 55.1-400 et seq. (formerly § 55-80 et seq.) Against CVC and Adira

457. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint
as if fully set forth herein.

458. As detailed above, during CVC's dissolution process, all (or nearly all) of CVC's
unrestricted and unobligated assets were given, assigned, and/or transferred to Adira—including
some transfers when Adira was still known as FPH—including millions of dollars in cash, an
unknown amount of investment assets, and a long list of office equipment and other valuable
personal property.

¹⁷ 459. During the Co-Payment Scheme, Plaintiffs became bona fide creditors under Va.
¹⁸ Code Ann. § 55.1-400 *et seq.* as victims of the Co-Payment Scheme.

¹⁹460. All or nearly all of CVC's gifts, transfers, conveyances, and assignments to Adira
²⁰and FPH are voided as a matter of law as voluntary and/or fraudulent conveyances pursuant to Va.
²¹Code Ann. § 55.1-400. The millions of dollars, investment assets, and set of personal property that
²²CVC transferred to Adira and FPH was not upon consideration deemed valuable in law.

461. When CVC completed these transfers, CVC was in the process of completing its
disillusionment. As CVC's transferred all of its remaining unrestricted and unobligated assets to
Adira, this transfer had the effect of rendering CVC insolvent.

462. At the time that CVC transferred its assets to Adira, Adira intended to continue
CVC's business by using its assets for its gain and to the detriment of Plaintiffs and the Class

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1 Members.

2 463. The aforementioned transfers were made with an actual intent to hinder, delay and defraud Plaintiffs. 3

4 464. The aforementioned transfers were made in reckless disregard for the Plaintiffs' 5 rights and were made to leave CVC insolvent without the ability to pay its liabilities as they came 6 due.

7 465. If any consideration was received by Adira in exchange for the asset transfers, such consideration was a sham, nominal consideration, inadequate and far less than a reasonably 8 9 equivalent value for such assets.

10 At the time the transfers were made, Adira knew or should have known that the 466. consideration for the transfers was nonexistent, a sham, nominal consideration, inadequate, and/or 11 12 far less than a reasonably equivalent value for such assets.

13 467. Adira's transfers were not made in good faith. Because Adira had the knowledge 14 aforesaid, it is not a bona fide purchaser.

468. The transfers discussed are fraudulent transfers under Va. Code Ann. § 55.1-400.

16 469. Plaintiffs and Class Members request that this Honorable Court enter an Order under 17 Va. Code Ann § 55.1-400 et seq. to void, as voluntary and/or fraudulent, the transfers set forth here 18 and that it order CVC and Adira, jointly and severally, to immediately turnover such assets, and that 19 it enter a money judgment for the value of such assets in an amount to be determined at trial of this 20 action.

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<u>SEVENTH CLAIM FOR RELIEF</u> Successor Liability as to Adira

470. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint 23 as if fully set forth herein. 24

471. During CVC's wind-up in 2019, Greg Smiley was the controlling or de facto 25 President of both CVC and Adira. 26

CVC and Adira were both co-payment assistance charities that operated out of 472. 27 Virginia, Adira and CVC shared board members, transferred data, monies, and office equipment-28

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all without any or adequate consideration, between the two charities while Smiley was acting as
President of both charities and James Rock was chairman for both charities. Additionally, several
CVC employees—including other senior management personal—began working for Adira at the
same time as the transfers. For example, Lauren Ruiz was Director of Patient Services at CVC from
November 2011, until joining Adira in April 2019 as a Programs Manager. Additionally, Bruce
Packett, who served as a director at CVC for several years, including from 2017-2020, has now also
served on Adira's Board of Directors since 2018.

8 473. CVC and Adira even used the same accounting firm, Meadows Urquhart Acree &
9 Cook LLP, to file their respective 2019 990 forms.

474. Adira is the successor corporation of CVC because, through the substantial contacts
between Adira and CVC alleged herein, Adira impliedly agreed to assume the liabilities of CVC;
the transactions and/or transfers between Adira and CVC resulted in a de facto merger; Adira is a
mere continuation of CVC; and the transactions and/or transfers were fraudulent.

14475. As a successor, Adira is jointly and severally liable to Plaintiffs and the class
members for CVC's involvement in the Co-Payment Scheme.15

16 **DEMAND FOR JUDGMENT**

WHEREFORE, Plaintiffs and the Class Members demand judgment against RICO
Defendants as follows:

19 1. Awarding Plaintiffs and the Class Members actual, consequential, compensatory,
20 statutory, treble, punitive, and other damages, in an amount to be proven at trial, including pre- and
21 post- judgment interest at the statutory rates;

22 2. Awarding Plaintiffs and the Class Members equitable relief in the nature of
23 disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust
24 enrichment;

25 3. Declaring the alleged acts to be unlawful under the state statutes set forth above, and
26 the common law of unjust enrichment of the states and territories set forth above;

27
4. Determining that this action is a proper class action, designating Plaintiffs as class
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representatives under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as

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1	Class Counsel;		
1		d the Class Marchan their measurable casts and environces	
2		nd the Class Members their reasonable costs and expenses,	
3	including attorneys' fees; and		
4	6. Awarding such other le	egal or equitable relief as the Court deems just and proper.	
5			
6	JURY DEMAND		
7	Plaintiffs and the Class Memb	pers demand a jury trial on all claims so triable under Federal	
8	Rule of Civil Procedure Rule 38.		
9			
10	Dated: December 2, 2022	Respectfully Submitted,	
11		<u>/s/ Alex R. Straus</u> Alex R. Straus (#321366)	
12		MILBERG COLEMAN BRYSON	
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10		MSP RECOVERY LAW FIRM 2701 S. LeJune Road, 10 th Floor	
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18		Tel: (305) 614-2222 mmena@msprecoverylawfirm.com	
19		jcleary@msprecoverylawfirm.com	
20			
21			
22		Shereef H. Akeel* (MI Bar No. 54345) Adam S. Akeel* (MI Bar No. 81328)	
23		Sam R. Simkins* (MI Bar No. 81210)	
24		Daniel W. Cermak* (MI Bar No. 84460) Hayden E. Pendergrass (DC Bar No. P1646086)	
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27		shereef@akeelvalentine.com adam@akeelvalentine.com	
28		sam@akeelvalentine.com daniel@akeelvalentine.com	
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1	hayden@akeelvalentine.com
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3	Attorneys for Plaintiffs
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APPENDIX

Plaintiff MSPRC's Assignment to Demonstrate Standing

3 1. Certain series of MSPRC executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These 4 5 assignments authorize the designated series, and in turn MSPRC through its LLC Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and 6 7 benefits. MSPRC alleges the below assignment to demonstrate standing. 8 2. On May 12, 2017, SummaCare, Inc. ("SMCR") irrevocably assigned to MSP 9 Recovery, LLC all its rights to recover against any liable third party (including RICO Defendants) 10 for payments made on behalf of its Enrollees ("SMCR Assignment"). Specifically, the SMCR Assignment states the following: 11 [SMCR] hereby irrevocably assigns, transfers, conveys, sets over and delivers to 12 MSP Recovery, and any of its successors and assigns, any and all of [SMCR]'s right, 13 title, ownership and interests in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not 14 limited to, subrogation) to pursue and/or recover monies for [SMCR] that [SMCR] had, may have had, or has asserted against any party in connection with the Claims 15 and all rights and claims against primary payers and/or third parties that may be liable to [SMCR] arising from or relating to the Claims, including claims under 16 consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims[.]" 17 18 3. On June 12, 2017, MSP Recovery, LLC irrevocably assigned all rights acquired 19 under the SMCR Assignment to Series 16-11-509, a designated series of MSPRC ("Series 16-11-20 509 Assignment"): 21 Assignor ... irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, 22 ownership and interest in and to the [Assigned Claims] (and all proceeds and products thereof) as such terms are defined in the [SMCR Assignment.] 23 24 4. SummaCare, Inc. consented to, acknowledged, approved, and ratified the Series 16-25 11-509 Assignment, which is memorialized in a letter dated September 5, 2018. 26 5. Consideration was given between each party in executing the SMCR Assignment 27 and the Series 16-11-509 Assignment. 28 - 1 -

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Plaintiff MSPA's Assignment Demonstrating Standing

2	1. MSPA was irrevocably assigned any and all rights to recover payments made on
3	behalf of its Assignors' Enrollees and health plan members. These assignments authorize MSPA to
4	pursue and enforce all legal rights of recovery and reimbursement for health care services and
5	benefits. MSPA alleges the below assignment to demonstrate standing.
6	2. On December 16, 2014, Interamerican Medical Center Group, LLC ("IMC")
7	irrevocably assigned to MSP Recovery, LLC all of its rights to recover against any liable third party
8	(including the Defendants) for payments made on behalf of its Enrollees ("IMC Assignment").
9	Specifically, the IMC Assignment, states the following:
10	By way of this Agreement, [IMC] appoints, directs, and, otherwise, irrevocably assigns all of [IMC's] rights as it pertains to the rights pursuant to any plan, State or
11	Federal statute(s) whatsoever directly and/or indirectly for any of its members and/or
12	plan participants, and/or rights pursuant to any agreement[.]
13	3. On February 20, 2015, MSP Recovery, LLC irrevocably assigned all rights acquired
14	under the IMC Assignment to MSPA ("MSPA Assignment 3"):
15	Assignor hereby irrevocably assigns, transfers, conveys, sets over, and delivers to Assignee or its assigns any and all of Assignor's right, title, ownership and interest in
16 17	and all rights and entitlements, that Assignor has, may have had, or has asserted against third parties from or relating to the Claims [assigned pursuant to the IMC Assignment].
18	4. IMC consented to, acknowledged, approved, and ratified the MSPA Assignment 3.
19	5. Consideration was given between each party in executing the IMC Assignment and
20	the MSPA Assignment.
21	Plaintiff Series 44's Assignment Demonstrating Standing
22	1. Certain series of Series 44 executed irrevocable assignments of any and all rights to
23	recover payments made on behalf of their Assignors' Enrollees and health plan members. These
24	assignments authorize the designated series, and in turn Series 44 through its LLC Operating
25	Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care
26	services and benefits. Series 44 alleges the assignments below to demonstrate standing.
27	2. Effective April 28, 2016, Health First Health Plans, Inc. ("HFAP") irrevocably
28	assigned to MSP Recovery, LLC all rights under the to recover against any liable third party
	- 2 -

1 (including the Defendants) for payments made on behalf of its Enrollees ("HFAP Assignment").

2 The HFAP Assignment expressly provides in pertinent part:

3 Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, 4 ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not 5 limited to, subrogation) to pursue and/or recover monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and 6 all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer 7 protection statutes and laws, and all information relating thereto, all of which shall 8 constitute the "Assigned Claims".

- The transfer, grant, right, or assignment of any and all of Client's right, title, ownership, interest and entitlements in and to the Assigned Claims shall remain the confidential and exclusive property of MSP Recovery or its assigns. This assignment is irrevocable and absolute.
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- 3. Effective June 12, 2017, MSP Recovery, LLC assigned all rights acquired under the
- ¹³ || HFAP Assignment to Series 16-05-456, a designated series of MSPRC ("Series 16-05-456
- ¹⁴ Assignment"). The Series 16-05-456 Assignment states:
- 15 [T]he undersigned Assignor ... irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, 16 ownership and interest in and to the Claims and Assigned Claims, (and all proceeds and products thereof, including any related assigned assets and assigned documents) as such 17 terms are defined or contained in that certain (1) Assignment and (2) Addendum to the Recovery Agreement and Assignment Addendum, both given and effective April 28, 2016 18 and executed on June 1, 2018, by and between Health First Health Plans, Inc., a Florida 19 corporation and Medicare Advantage Organization and party to contract number H1099 with The Centers for Medicare & Medicaid Services, as the "Client" and health plan assignor, 20 and [MSP Recovery], a Florida limited liability company (the "Assignment"); irrespective of when the claims were vested in Client, inclusive of any and all claim(s), causes of actions, 21 proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but 22 not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have 23 had, or has asserted against any party pursuant to the Assignment from the Client, including claims under consumer protection statutes and laws, any and all rights and claims against 24 primary payers and/or third parties that may be liable to Client arising from or relating to the Claims and all information relating thereto. 25
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1	4. On October 22, 2020, Series 16-05-456 irrevocably assigned all the rights it acquired		
2	from MSP Recovery, LLC to Series 44-20-456, a designated series of Series 44 ("Series 44-20-456		
3	Assignment"):		
4	Assignor hereby irrevocably assigns, transfers, conveys, sets over, and delivers to		
5	[Series 44-20-456] and its successors and assigns, (i) any and all of Assignor's right, title, ownership, and interest in and to the [claims], as well as (ii) the "Claims" and		
6	"Assigned Claims", and all proceeds and products thereof (collectively the "Assigned Claims") as such terms are defined in the Agreements.		
7 8	5. Consideration was given between each in executing the HFAP Assignment, the		
9	Series 16-05-456 Assignment, and the Series 44-20-456 Assignment.		
10	Plaintiff Claims PROV's Assignment Demonstrating Standing		
11	1. Certain series of Claims PROV executed irrevocable assignments of any and all		
12	rights to recover payments made on behalf of their Assignors' Enrollees and health plan members.		
13	These assignments authorize the designated series, and in turn Claims PROV through its LLC		
14	Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for		
15	health care services and benefits. Claims PROV alleges the assignments below to demonstrate		
16	standing.		
17	2. On May 24, 2021, Centro de Pediatria y Medicina de Familia de Villalba, C.S.P.		
18	("CPMF") irrevocably assigned all its rights and claims to recovery against any liable entity		
19	(including the RICO Defendants) for payments made on behalf of its Enrollees pursuant to its		
20	Government Healthcare Program to Series 21-04-1561, a designated series of Plaintiff Series Prov		
21	("CPMF Assignment"). Specifically, the CPMF Assignment, states the following:		
22	Assignor irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership		
23	and any of its successors and assigns, any and an of Assignor's right, the, ownership and interest in and to all of Assignor's Claims arising from and related to the Claims Data transferred, provided or sent to MSP Recovery, these Claims encompassing the		
24	"Assigned Claims."		
25	Such assignment of the Assigned Claims is irrevocable and absolute, and is broad with respect to recovery efforts and is not limited to any particular recovery strategy		
26	regarding reimbursement or recovery efforts.		
27	CPMF Assignment, at 1.1.1, 1.1.2.		
28	3. Consideration was given between the parties in executing this assignment.		
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Plaintiff Claims CAID's Assignment Demonstrating Standing

- 1. Certain series of Claims CAID executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Claims CAID through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Claims CAID alleges the assignments below to demonstrate standing.
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2. On February 3, 2021, Sal Health Group. LLC d/b/a Salubris ("Salubris") irrevocably assigned all its rights and claims to recovery against any liable entity (including 10 Defendants) for payments made on behalf of its Enrollees to Series 19-10-1128, a designated series 11 of MSP Recovery Claims CAID, Series LLC ("Salubris Assignment"). Specifically, the Salubris 12 Assignment, states the following:

[Assignor] irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its designated series, successors and assigns, any and all of Assignor's right, title, ownership, and interest in and to all of Assignor's Claims and rights arising from and related to the claims data transferred to Assignee (or its affiliates or services providers, including MSP Recovery, LLC) for the period encompassing dates of services from June 1, 2014 and continuing up to, including and through June 30, 2020, these Claims encompassing the "Assigned Claims." The assignment of the Assigned Claims set forth herein is irrevocable and absolute and is broad with respect to recovery efforts and is not limited to any particular recovery strategy regarding reimbursement or recovery efforts.

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3. Consideration was given between the parties in executing this assignment.

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>RICO Class Action Alleges Actelion</u> <u>Schemed to Raise Prices of Blood Pressure Meds</u>