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22 **UNITED STATES DISTRICT COURT**
23 **FOR THE DISTRICT OF ARIZONA**

24 Blue Cross of California, Inc. d/b/a/ Anthem
25 Blue Cross of California; Anthem Blue Cross
26 Life and Health Insurance Company; Rocky
27 Mountain Hospital and Medical Service, Inc.
28 d/b/a Anthem Blue Cross and Blue Shield of
Colorado and Anthem Blue Cross and Blue
Shield of Nevada; Anthem Health Plans, Inc.
d/b/a Anthem Blue Cross and Blue Shield of
Connecticut; Blue Cross and Blue Shield of
Georgia, Inc.; Blue Cross and Blue Shield
Healthcare Plan of Georgia, Inc.; Anthem
Insurance Companies, Inc. d/b/a Anthem Blue
Cross and Blue Shield of Indiana; Anthem
Health Plans of Kentucky, Inc. d/b/a Anthem
Blue Cross and Blue Shield of Kentucky;
Anthem Health Plans of Maine, Inc. d/b/a
Anthem Blue Cross and Blue Shield of Maine;

No.
COMPLAINT
JURY TRIAL DEMANDED

1 Anthem Health Plans of New Hampshire, Inc.
2 d/b/a Anthem Blue Cross and Blue Shield of
3 New Hampshire; Empire HealthChoice
4 Assurance, Inc. d/b/a Empire Blue Cross and
5 Blue Shield; Community Insurance Company
6 d/b/a Anthem Blue Cross and Blue Shield of
7 Ohio; Anthem Health Plans of Virginia, Inc.
8 d/b/a Anthem Blue Cross and Blue Shield of
9 Virginia; HMO Healthkeepers, Inc. d/b/a
10 Anthem Blue Cross and Blue Shield of
11 Virginia; Blue Cross Blue Shield of Wisconsin
12 d/b/a Anthem Blue Cross and Blue Shield of
13 Wisconsin; Compcare Health Services
14 Insurance Corporation d/b/a Anthem Blue
15 Cross and Blue Shield of Wisconsin,

Plaintiffs,

v.

Insys Therapeutics, Inc.,

Defendant.

16 Plaintiffs Blue Cross of California, Inc. d/b/a/ Anthem Blue Cross of California;
17 Anthem Blue Cross Life and Health Insurance Company; Rocky Mountain Hospital and
18 Medical Service, Inc. d/b/a Anthem Blue Cross and Blue Shield of Colorado and Anthem
19 Blue Cross and Blue Shield of Nevada; Anthem Health Plans, Inc. d/b/a Anthem Blue
20 Cross and Blue Shield of Connecticut; Blue Cross and Blue Shield of Georgia, Inc.; Blue
21 Cross and Blue Shield Healthcare Plan of Georgia, Inc.; Anthem Insurance Companies,
22 Inc. d/b/a Anthem Blue Cross and Blue Shield of Indiana; Anthem Health Plans of
23 Kentucky, Inc. d/b/a Anthem Blue Cross and Blue Shield of Kentucky; Anthem Health
24 Plans of Maine, Inc. d/b/a Anthem Blue Cross and Blue Shield of Maine; Anthem Health
25 Plans of New Hampshire, Inc. d/b/a Anthem Blue Cross and Blue Shield of New
26 Hampshire; Empire HealthChoice Assurance, Inc. d/b/a Empire Blue Cross and Blue
27 Shield; Community Insurance Company d/b/a Anthem Blue Cross and Blue Shield of
28 Ohio; Anthem Health Plans of Virginia, Inc. d/b/a Anthem Blue Cross and Blue Shield of

1 Virginia; HMO Healthkeepers, Inc. d/b/a Anthem Blue Cross and Blue Shield of Virginia;
2 Blue Cross Blue Shield of Wisconsin d/b/a Anthem Blue Cross and Blue Shield of
3 Wisconsin; Compare Health Services Insurance Corporation d/b/a Anthem Blue Cross and
4 Blue Shield of Wisconsin (collectively, “Anthem”), in their Complaint against Defendant
5 Insys Therapeutics, Inc. (“Insys”) hereby states and alleges as follows.

6 **NATURE OF ACTION**

7 1. Since at least 2013, Insys, the manufacturer, marketer, and seller of the
8 branded opioid, Subsys®, has engaged in a carefully-orchestrated, illegal, and dangerous
9 scheme to obtain millions of dollars in reimbursement from health insurers, including
10 Anthem, that the company knew it was not entitled to.

11 2. Subsys® is one of the most powerful narcotics available and is estimated to
12 be 50 times as potent as heroin. Its side effects include death by respiratory suppression.
13 Accordingly, the drug was approved by FDA for only a narrow patient population –
14 individuals with breakthrough cancer pain who were opioid tolerant.

15 3. As Insys recognized, while the “on-label” market for Subsys® was limited,
16 “off-label” use could present significant financial rewards. The country’s consumption of
17 opioids is well documented and Subsys® was a particularly attractive new option given its
18 potency and its sublingual delivery.

19 4. But standing in its way of capturing that off-label market, Insys faced at
20 least two significant impediments. *First*, the company had to convince prescribers to write
21 prescriptions for this remarkably dangerous drug for treatment beyond what FDA had
22 approved it for – thereby subjecting their patient population to the accompanying risks the
23 drug presented. And *second*, Insys had to find a way to get the prescriptions paid for in a
24 world in which health insurers, including Medicare, Medicaid, and private payors such as
25 Anthem, would only cover Subsys® for on-label uses.

26 5. Insys’s solution to these two potential roadblocks was creative, fraudulent,
27 and illegal.

28

1 6. Insys drove off-label demand by, in essence, paying prescribers to write
2 prescriptions and by marketing off-label uses of the drug. Undoubtedly recognizing the
3 illegality of such a scheme, Insys attempted to disguise its payments to prescribers by
4 structuring them as sham “speaker fees.” While the exact amount of those kickbacks has
5 yet to be determined, criminal indictments of the recipients indicate that Insys paid
6 “speaker fees” of hundreds of thousands, if not millions, of dollars.

7 7. To address the reimbursement challenge that it faced, Insys simply lied about
8 the reasons the prescriptions were being written. Because of the risk profile of the drug and
9 its high cost, Anthem, like other health insurers, required that a prior authorization be
10 obtained before a claim could be submitted for a Subsys® prescription. Anthem’s prior
11 authorization required confirmation that the patient had an active cancer diagnosis, was
12 being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed
13 Subsys® to treat breakthrough pain that the other opioid could not eliminate. If any one of
14 those factors was not present, the prior authorization would be denied and the drug would
15 not be covered under Anthem’s plans – meaning no reimbursement would be due.

16 8. Information that has become publically available reveals Insys’s company-
17 wide scheme to lie to insurers during the prior authorization process. In particular, Insys
18 created its own “reimbursement team” that was tasked with taking the prior authorization
19 process out of the hands of prescribers’ offices such that Insys would control the
20 information conveyed to the insurer. And that information was decidedly false and
21 misleading. Under instruction of management, reimbursement team members routinely,
22 intentionally, and falsely represented that enrollees in Anthem plans met each of the
23 criteria necessary to render Subsys® prescriptions covered and payable when Insys knew
24 that was not the case.

25 9. Insys’s schemes paid off in spades, driving significant off-label use and
26 securing payments in excess of \$19 million from Anthem for Subsys® prescriptions that
27 were not covered, in addition to the millions of dollars in cost-sharing obligations imposed
28 on Anthem members.

1 10. But the harm inflicted by Insys’s conduct is not merely financial in nature.
2 Insys put Anthem’s members’ health at risk. As the Office of Inspector General for the
3 Department of Health and Human Services has recognized, paying kickbacks to
4 prescribers in exchange for prescriptions calls into question the clinician’s medical
5 judgment. And the risks associated with that illegal scheme are all the greater when the
6 prescriptions at issue are for a drug as dangerous as Subsys®.

7 11. Accordingly, Anthem brings this action in order to put a stop to Insys’s
8 dangerous, illegal, and fraudulent conduct and to hold Insys accountable for the financial
9 harm it has caused Anthem.

10 **PARTIES**

11 12. Plaintiff Blue Cross of California, Inc. d/b/a/ Anthem Blue Cross of
12 California is incorporated and headquartered in California.

13 13. Plaintiff Anthem Blue Cross Life and Health Insurance Company is
14 incorporated and headquartered in California.

15 14. Plaintiff Rocky Mountain Hospital and Medical Service, Inc. d/b/a Anthem
16 Blue Cross and Blue Shield of Colorado and d/b/a/ Anthem Blue Cross and Blue Shield of
17 Nevada in Nevada, is incorporated and headquartered in Colorado.

18 15. Plaintiff Anthem Health Plans, Inc. d/b/a Anthem Blue Cross and Blue
19 Shield of Connecticut is incorporated and headquartered in Connecticut.

20 16. Plaintiff Blue Cross and Blue Shield of Georgia, Inc. is incorporated and
21 headquartered in Georgia.

22 17. Plaintiff Blue Cross and Blue Shield Healthcare Plan of Georgia, Inc. is
23 incorporated and headquartered in Georgia.

24 18. Plaintiff Anthem Insurance Companies, Inc. d/b/a Anthem Blue Cross and
25 Blue Shield of Indiana is incorporated and headquartered in Indiana.

26 19. Plaintiff Anthem Health Plans of Kentucky, Inc. d/b/a Anthem Blue Cross
27 and Blue Shield of Kentucky is incorporated and headquartered in Kentucky.

28

1 20. Plaintiff Anthem Health Plans of Maine, Inc. d/b/a Anthem Blue Cross and
2 Blue Shield of Maine is incorporated and headquartered in Maine.

3 21. Plaintiff Anthem Health Plans of New Hampshire, Inc. d/b/a Anthem Blue
4 Cross and Blue Shield of New Hampshire is incorporated and headquartered in New
5 Hampshire.

6 22. Plaintiff Empire HealthChoice Assurance, Inc. d/b/a Empire Blue Cross and
7 Blue Shield is incorporated and headquartered in New York.

8 23. Plaintiff Community Insurance Company d/b/a/ Anthem Blue Cross and
9 Blue Shield of Ohio is incorporated and headquartered in Ohio.

10 24. Plaintiff Anthem Health Plans of Virginia, Inc. d/b/a/ Anthem Blue Cross
11 and Blue Shield of Virginia is incorporated and headquartered in Virginia.

12 25. Plaintiff HMO HealthKeepers, Inc. d/b/a Anthem Blue Cross and Blue
13 Shield of Virginia is incorporated and headquartered in Virginia.

14 26. Plaintiff Blue Cross Blue Shield of Wisconsin d/b/a Anthem Blue Cross and
15 Blue Shield of Wisconsin is incorporated and headquartered in Wisconsin.

16 27. Plaintiff CompCare Health Services Insurance Corporation d/b/a Anthem
17 Blue Cross and Blue Shield of Wisconsin is incorporated and headquartered in Wisconsin.

18 28. The Plaintiffs are all owned by Anthem, Inc. and are collectively referred to
19 herein as “Anthem.”

20 29. Defendant Insys Therapeutics, Inc. is a drug manufacturer, marketer, and
21 seller. Insys is a Delaware corporation and is headquartered in Arizona. Insys
22 manufactures and sells fentanyl sublingual spray, an opioid approved by FDA for
23 treatment of breakthrough pain in cancer patients who are already receiving and tolerant
24 to opioids for the management of chronic pain. The brand name for this drug is Subsys®.

25 **JURISDICTION AND VENUE**

26 30. This Court has jurisdiction over the subject matter of this action pursuant to
27 28 U.S.C. §§ 1332 and 1367.
28

1 31. This Court has personal jurisdiction over Insys, and venue is proper in this
2 Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b), because Insys has its
3 principal place of business in this Judicial District.

4 **FACTUAL BACKGROUND**

5 32. Since at least 2013, Insys has engaged in a fraudulent, illegal, and unfair
6 scheme designed to unlawfully and unjustly obtain reimbursements from Anthem for
7 prescriptions of Subsys® that are not reimbursable because the patients receiving the
8 prescriptions either do not have breakthrough cancer pain or are not tolerant to opioids.

9 **FDA Approval Process and Subsys® Indication**

10 33. Under the Food, Drug, and Cosmetics Act (“FDCA”) 21 U.S.C. §§ 301-97,
11 new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of
12 the drug demonstrates to the satisfaction of FDA that the drug is safe and effective for
13 each of its intended uses. 21 U.S.C. § 355(a) & (d). Approval of a drug by FDA is the
14 final stage of a multi-year process of study and testing.

15 34. FDA does not approve a drug for treatment of sickness in general. Instead, a
16 drug is approved for treatment of a specific condition, for which the drug has been tested
17 in patients. The specific approved use is called the “indication” for which the drug may be
18 prescribed. FDA will specify particular dosages determined to be safe and effective for
19 each indication.

20 35. The indications and dosages approved by FDA are set forth in the drug’s
21 labeling, the content of which must also be reviewed and approved by FDA. 21 U.S.C.
22 §§ 352, 355(d).

23 36. Under the Food and Drug Administration Modernization Act of 1997
24 (“FDAMA”), if a manufacturer wishes to market or promote an approved drug for
25 alternative uses – i.e. uses not approved by FDA – the manufacturer must resubmit the
26 drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C.
27 § 360aaa(b) & (c). Until subsequent approval of the new use has been granted, the
28 unapproved use is considered to be “off-label.” “Off-label” refers to the use of an

1 approved drug for any purpose, or in any manner, other than what is described in the
2 drug's labeling. Off-label use includes treating a condition not indicated on the label,
3 treating the indicated condition at a different dose or frequency than specified on the label,
4 or treating a different patient population (e.g., treating a child when the drug is approved
5 to treat adults.)

6 37. Although prescribers may prescribe drugs for off-label usage, the law
7 prohibits drug manufacturers from marketing or promoting a drug for a use that FDA has
8 not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not
9 introduce a drug into interstate commerce with an intent that it be used for an off-label
10 purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which
11 includes all marketing and promotional materials relating to the drug) describes intended
12 uses for the drug that have not been approved by FDA. 21 U.S.C. §§ 331, 352.

13 38. In sum, the FDCA prohibits drug companies from promoting approved
14 drugs for unapproved uses or from making misleading claims as to the drug's safety or
15 effectiveness. See 21 U.S.C. §§ 331, 352, 355(d). This off-label regulatory scheme
16 protects patients and consumers by ensuring that drug companies do not promote drugs
17 for uses other than those found to be safe and effective by an independent, scientific
18 government body, the FDA.

19 39. Subsys® is only FDA approved for a limited indication – for the
20 management of breakthrough pain in cancer patients 18 years of age and older who are
21 already receiving and who are tolerant to opioid therapy for their underlying persistent
22 cancer pain. Further, Subsys® may be dispensed only to patients enrolled in the
23 Transmucosal Immediate Release Fentanyl ("TIRF") Risk Evaluation and Mitigation
24 Strategy ("REMS") ACCESS program.

25 40. However, despite the limited indicated use of Subsys® for breakthrough
26 cancer pain, a very small percentage of prescribers are oncologists. The majority of
27 prescribers are pain specialists, although primary care physicians, neurologists, dentists
28 and podiatrists also write Subsys® prescriptions.

1 **Anthem’s Coverage of Subsys® Prescriptions**

2 41. Anthem offers prescription drug benefits. Anthem members who have
3 Anthem prescription drug coverage may receive reimbursement for medications that are
4 available on Anthem’s drug list, or formulary, and for which the prescriptions meet all
5 coverage criteria.

6 42. Due to the high volume of prescription drug claims for reimbursement
7 submitted to Anthem, Anthem is unable to process all of the claims directly. Anthem has
8 contracted with a pharmacy benefit manager (“PBM”), Express Scripts, Inc. (“ESI”), who
9 is responsible for enforcing Anthem’s drug coverage criteria.

10 43. Subsys® is not currently on Anthem’s formulary. However, a member can
11 make a non-formulary request which requires a medical necessity review.

12 44. Because Subsys® is a dangerous opioid and has high abuse potential,
13 Anthem – like many other insurers – will only reimburse for Subsys® prescriptions that
14 meet the FDA approved indication.

15 45. Further, to ensure that Subsys® is properly prescribed, and reimbursable,
16 the prescriber or patient must obtain a prior authorization before prescriptions for the drug
17 can be reimbursed.

18 46. To obtain a prior authorization, the prescriber must confirm that (1) the
19 patient has a diagnosis of cancer with breakthrough pain, and (2) the patient is already
20 receiving opioids and is tolerant to opioid therapy. Anthem’s Subsys® prior authorization
21 form is attached as Exhibit 1.

22 **Insys’s Scheme**

23 47. On information and belief, in order to increase the number of Subsys®
24 prescriptions for which it received reimbursement and to obtain reimbursement for off-
25 label prescriptions of Subsys®, Insys directed and engaged in a conspiracy with
26 prescribers to increase the number of Subsys® prescriptions written and to provide
27 material misrepresentations during the prior authorization process regarding whether
28

1 patients had breakthrough cancer pain and/or were opioid tolerant in order to obtain
2 reimbursements for those prescriptions.

3 **i. The Payment of Illegal Kickbacks**

4 48. Insys’s fraudulent efforts to enrich itself at the expense of Anthem (and
5 other insurers) took several forms. *First*, the company paid illegal kickbacks to clinicians
6 to write off-label prescriptions of Subsys®.

7 49. Some of these payments were made pursuant to a sham “speaker program”
8 that Insys created to shield the illegality of its financial arrangements with the conspiring
9 prescribers.

10 50. Through this “speaker program,” Insys paid prescribers to give presentations
11 on Subsys®, purportedly to increase brand awareness via peer-to-peer educational lunches
12 and dinners.

13 51. Most of the presentations, however, would make only a cursory mention of
14 Subsys®, and in some there was no mention of Subsys® at all. And many were attended
15 only by the prescriber and sales representatives or others individuals who had no authority
16 to prescribe the drug – thereby eliminating any question of the programs’ utility beyond
17 masking Insys’s real intent to pay prescribers for prescriptions.

18 52. The prescribers chosen for these lucrative speaking opportunities is further
19 evidence of the true motivation behind the program. On information and belief, Insys
20 targeted prescribers running pain clinics – particularly those who were high-volume
21 opioid prescribers – for these “speaker programs,” as opposed to oncologists treating
22 patients that met the conditions set forth in the label.

23 53. The top 10 prescribers of Subsys® were paid handsomely for their
24 participation in the speaker program – collectively receiving more than \$870,000 in
25 speaker fees in 2013 and 2014 alone.

26 54. As discussed in greater detail below, some of the practitioners on the top 10
27 Subsys® prescriber list have been criminally convicted of accepting kickbacks. Those
28

1 prescribers include Dr. Xiulu Ruan and Heather Alfonso, both of whom prescribed
2 Subsys® to Anthem members that did not have underlying cancer diagnoses.

3 55. But Insys’s efforts to funnel illegal kickbacks to Subsys® prescribers were
4 not limited to speaker fees. The company also offered valuable administrative services to
5 prescribers’ offices at no charge in exchange for Subsys® prescriptions. To that end, Insys
6 created a “reimbursement unit” that was deployed to prescriber practices to handle the
7 prior-authorization process. As discussed in greater detail below, these free services not
8 only benefited the prescribers, but also allowed Insys to control the (false) messaging to
9 insurers, including Anthem.

10 56. In addition, Insys was engaged in a scheme to promote Subsys® off-label in
11 order to increase the number of Subsys® prescriptions written.

12 57. On information and belief, Insys sales representatives aggressively targeted
13 high-volume opioid drug prescribers without regard to the suitability of the patient
14 population for the approved use of Subsys®.

15 58. On information and belief, Insys misrepresented to prescribers and patients
16 the approved use and dosage parameters for Subsys®

17 59. On information and belief, Insys sales representatives encouraged
18 prescribers to disregard FDA approved indications and FDA mandated dosing, instead
19 marketing Subsys® for breakthrough pain generically.

20 60. Then, once the prescriptions were written, using its “reimbursement unit,”
21 Insys conspired with prescribers to fraudulently obtain prior authorizations for non-
22 covered prescriptions.

23 **ii. Insys’s “Reimbursement Unit”**

24 61. *Second*, Insys’s fraudulent scheme included the creation of a vehicle to
25 ensure that the required lies would be conveyed to Anthem (and other payors) to obtain
26 prior authorizations necessary for coverage for Subsys®. Insys called this its
27 “reimbursement unit” and employed it from January 2013 through October 2016.
28

1 62. Like many other insurers, Anthem prohibits anyone other than one of its
2 members (or the member's representative) or the prescriber from making a prior
3 authorization request.

4 63. On information and belief, Insys reimbursement unit employees responded
5 to this bar by concealing or misrepresenting their identities when seeking prior
6 authorizations for Subsys® claims for Anthem members.

7 64. On information and belief, these Insys employees – at the direction of Insys
8 executives – would inform ESI that they were calling from the prescriber's office, in order
9 to lead ESI to believe that they were employees of the prescriber.

10 65. Additionally, on information and belief, Insys blocked access to the
11 reimbursement unit's phone number in order to hide the geographical location from which
12 reimbursement unit employees were calling. This was done for the sole purpose of
13 preventing those representing Anthem and other insurers from figuring out that the calls
14 were being made from a different location than the prescriber's offices.

15 **iii. Insys's Misrepresentations During the Prior Authorization Process**

16 66. *Third*, because Insys understood that PBMs and insurers would not
17 authorize payment for non-indicated uses of Subsys®, on information and belief, to obtain
18 prior authorizations, Insys employees calling in prior authorization requests would
19 represent to the PBM or insurer that the patient had a cancer diagnosis and was tolerant to
20 opioids even when that was not the case.

21 67. Specifically, according to criminal complaints filed against Insys executives
22 and a manager of an Insys team responsible for obtaining prior authorizations from
23 insurance companies, during the prior authorization process, Insys employees were
24 directed to represent that the patients for whom prior authorizations were being sought
25 had cancer even when they did not. Insys employees were trained to answer prior
26 authorization questions using a script, sometimes called "the spiel" to mislead PBMs and
27 insurers.
28

1 68. “The spiel” read: “The physician is aware that the medication is intended for
2 the management of breakthrough pain in cancer patients. The physician is treating the
3 patient for their pain (or breakthrough pain, whichever is applicable).”

4 69. The script deliberately omitted the word “cancer.”

5 70. According to the criminal complaints, Insys employees were also directed to
6 fraudulently assert that a patient had a cancer diagnosis regardless of the patient’s history
7 and regardless of whether the prescriber had prescribed Subsys® for a different diagnosis.

8 71. Similarly, Insys employees were directed to falsely confirm lists of tried and
9 failed medications that would qualify the patient to try Subsys®.

10 **Criminal Indictments, Pleas and Convictions**

11 72. Insys’s fraudulent scheme has received much scrutiny by the federal and
12 state governments.

13 73. In December of 2016, several of Insys’s pharmaceutical executives and
14 managers were indicted for, *inter alia*, conspiracy to mislead and defraud health insurance
15 providers who were reluctant to approve payment for the drug when prescribed for non-
16 cancer patients.

17 74. According to the indictment, Insys achieved its goal of increasing
18 prescriptions by setting up its “reimbursement” unit, which was dedicated to obtaining
19 prior authorization directly from insurers and pharmacy benefit managers.

20 75. Among other things, the executives were charged with conspiracy to
21 commit racketeering, conspiracy to commit wire and mail fraud, and RICO conspiracy.

22 76. Additionally, in February 2016, a former Insys sales manager, Natalie Reed
23 Perhacs, pled guilty to conspiracy to commit healthcare fraud including engaging in
24 kickback schemes.

25 77. In the plea, Perhacs admitted that she was hired to be the personal sales
26 representative for one of Insys’s most important prescribers, Dr. Xiulu Ruan.

27 78. Perhacs admitted that her primary responsibility at Insys was to increase the
28 volume of Subsys® prescribed by Dr. Ruan, and his partner Dr. John Patrick Couch. This

1 was accomplished by (1) handling prior authorizations for their patients who had been
2 prescribed Subsys®; (2) identifying patients who had been at the same strength of
3 Subsys® for several months and recommending that Dr. Ruan or Dr. Couch increase the
4 patients' prescription strength; and (3) setting up and attending paid speaker programs.

5 79. Perhacs admitted that because of her involvement in the prior authorization
6 process, she knew that the vast majority of Dr. Ruan and Dr. Couch's patients did not
7 have breakthrough cancer pain.

8 80. Perhacs admitted that she was also responsible for setting up and attending
9 speaker programs for Dr. Ruan and Dr. Couch. Perhacs scheduled approximately one
10 speaker program per doctor per week. For a majority of the speaker programs, Dr. Ruan
11 and Dr. Couch either (1) repeatedly spoke to the same prescribers about Subys®, (2)
12 spoke to just their staff about Subsys®, or (3) did not speak about Subsys®.

13 81. Perhacs admitted that the purpose of the speaker program was not to
14 promote Subsys®, but to funnel kickbacks to high-volume Subsys® prescribers.

15 82. Perhacs admitted that she was provided strong financial incentives to get
16 Dr. Ruan and Dr. Couch to prescribe Subsys®. Commissions from off-label prescriptions
17 written by Dr. Ruan and Dr. Couch resulted in Perhacs making over \$700,000 between
18 April 2013 and May 2015, when Dr. Ruan and Dr. Couch were arrested.

19 83. Relatedly, on May 20, 2015, two physicians, Xiulu Ruan and John Patrick
20 Couch were indicated for (1) conspiracy to distribute controlled substances outside the
21 usual course of professional practice and not for a legitimate medical purpose, and (2)
22 conspiracy to commit healthcare fraud.

23 84. Dr. Couch and Dr. Ruan were accused of running a pill mill and were
24 accused of prescribing controlled substances, including Subsys®, that they were paid to
25 promote.

26 85. According to the indictment, one of the objectives of their conspiracy to
27 commit healthcare fraud was the unlawful payment to and receipt of illegal kickbacks by
28

1 Dr. Ruan and Dr. Couch as an inducement and in exchange for their prescribing of
2 Subsys®.

3 86. Between August 2012 and May 2015, Insys allegedly paid Dr. Ruan and
4 Dr. Couch a combined total in excess of \$115,000 for sham “speaker fees.”

5 87. Between April 2012 and May 2015, Dr. Ruan and Dr. Couch were alleged
6 to have written thousands of prescriptions for Subsys®, nearly all of which went to
7 patients who did not have cancer.

8 88. By early 2013, Dr. Ruan and Dr. Couch had become two of the top ten
9 largest volume prescribers of Subsys® nationwide.

10 89. Those doctors were subsequently accused of killing four patients.

11 90. The federal trial of Dr. Ruan and Dr. Couch began on January 5, 2017, with
12 the doctors facing more than 20 counts ranging from violations of the RICO statute to
13 illegal drug distribution to kickbacks to wire and mail fraud to money laundering.

14 91. On February 23, 2017, Dr. Ruan and Dr. Couch were found guilty of,
15 among other things, RICO conspiracy, conspiracy to commit health care fraud, conspiracy
16 to violate the Anti-Kickback statute, and wire and mail fraud conspiracy.

17 92. Similarly, in June 2015, Heather Alfonso, an advanced practice registered
18 nurse, or nurse practitioner, pleaded guilty to accepting \$83,000 in kickbacks from Insys.

19 93. As part of her plea, Alfonso admitted that she prescribed Subsys® to
20 patients who did not have a cancer diagnosis. However, prior authorizations submitted on
21 their behalf had represented that they had cancer.

22 94. Alfonso also admitted that she was paid \$1,000 per speaking engagement
23 under Insys’s sham “speaker program.” In the majority of instances, the only attendees at
24 those programs were individuals who had no license to prescribe controlled substances,
25 such as medical assistants, receptionists, friends or co-workers. Further, at the majority of
26 those programs, Alfonso did not give any presentation about Subsys® at all.

27
28

1 95. Alfonso admitted that the “speaker program” influenced Alfonso to increase
2 the number of Subsys® prescriptions that she wrote, which she accomplished in part by
3 finding more patients for whom she could prescribe the drugs.

4 **Anthem Members Did Not Have an Underlying Cancer Diagnosis**

5 96. As a result of Insys’s scheme, many of Anthem’s members for whom
6 Subsys® prescriptions were authorized and, thus, were reimbursed, did not actually have
7 an underlying cancer diagnosis.

8 97. Anthem conducted a review of all claims for reimbursement for Subsys®
9 prescriptions and reviewed the claims and diagnostic histories of the Anthem members
10 receiving Subsys® prescriptions. Anthem’s review of those claims and diagnostic
11 histories revealed that 54% of members with Subsys® prescriptions that had been
12 reimbursed by Anthem did not actually have an underlying cancer diagnoses.

13 98. For an additional 6% of members with reimbursed Subsys® prescriptions, it
14 was unclear whether Subsys® was properly prescribed for those members according to
15 FDA’s indicated use. In most of those cases, the individual calling in the prior-
16 authorization request represented that the patient had a diagnosis of breakthrough cancer
17 pain.

18 99. As a result of Insys’s scheme, Anthem paid over \$19 million in
19 reimbursements for Subsys® prescriptions that were not covered by Anthem’s plans.

20 100. A spreadsheet with representative claims, prior authorization information,
21 and claims history analysis is attached as Exhibit 2.

22 **COUNT I – VIOLATIONS OF STATE LAWS PROHIBITING DECEPTIVE,**
23 **UNFAIR, AND UNLAWFUL BUSINESS PRACTICES**

24 101. Anthem incorporates by reference the preceding paragraphs as if fully set
25 forth herein and further alleges as follows.

26 102. Insys engaged in unfair competition or unfair, unconscionable, deceptive or
27 fraudulent acts or practices in violation of state statutes prohibiting deceptive and
28 unlawful business practices when it knowingly and intentionally misrepresented, or

1 caused others to misrepresent, that patients had cancer, when they did not, during the prior
2 authorization process. Insys also engaged in unfair competition or unfair, unconscionable,
3 deceptive or fraudulent acts or practices in violation of state statutes prohibiting deceptive
4 and unlawful business practices when it engaged in a kickback and off-label marketing
5 scheme for the purposes of inducing prescribers to write Subsys prescriptions for off-label
6 and uncovered uses.

7 103. Insys's unfair or deceptive acts and practices were specifically designed to
8 and did induce Anthem to pay for millions of dollars for Subsys prescriptions that it would
9 not have paid but for Anthem's conduct. Insys received improper reimbursements from
10 each of the individually named plaintiffs in 13 different states: California, Colorado,
11 Connecticut, Georgia, Indiana, Kentucky, Maine, Nevada, New Hampshire, New York,
12 Ohio, Virginia and Wisconsin.

13 a. Insys has engaged in unfair competition or unfair or deceptive acts or
14 practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

15 b. Insys has engaged in unfair competition or unfair or deceptive acts or
16 practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

17 c. Insys has engaged in unfair competition or unfair or deceptive acts or
18 practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

19 d. Insys has engaged in unfair competition or unfair or deceptive acts or
20 practices in violation of Ga. Stat. 10-1-392, *et seq.*;

21 e. Insys has engaged in unfair competition or unfair or deceptive acts or
22 practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

23 f. Insys has engaged in unfair competition or unfair or deceptive acts or
24 practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

25 g. Insys has engaged in unfair competition or unfair or deceptive acts or
26 practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

27 h. Insys has engaged in unfair competition or unfair or deceptive acts or
28 practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

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1 i. Insys has engaged in unfair competition or unfair or deceptive acts or
2 practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

3 j. Insys has engaged in unfair competition or unfair or deceptive acts or
4 practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

5 k. Insys has engaged in unfair competition or unfair or deceptive acts or
6 practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

7 l. Insys has engaged in unfair competition or unfair or deceptive acts or
8 practices in violation of Va. Code § 59.1-196, *et seq.*; and

9 m. Insys has engaged in unfair competition or unfair or deceptive acts or
10 practices in violation of Wis. Stat. § 100.20, *et seq.*

11 104. Anthem is a “consumer” within the definition of those statutes.

12 105. As a direct and proximate consequence of Insys and its co-conspirators acts,
13 as alleged herein, Anthem has sustained damages, the full amount to be proven at trial.

14 **COUNT II – FRAUD**

15 106. Anthem incorporates by reference the preceding paragraphs as if fully set
16 forth herein and further alleges as follows.

17 107. Insys and its co-conspirators, as alleged herein, intentionally made
18 misrepresentations of material facts to Anthem and ESI in the process of obtaining
19 reimbursement authorizations for Subsys® prescriptions.

20 108. Specifically, Insys and its co-conspirators made misrepresentations or
21 omissions of material fact regarding (1) whether the individuals calling-in prior
22 authorizations were Insys employees or employees of the prescriber and (2) whether the
23 patients for whom prior authorization was being sought had breakthrough cancer pain
24 and/or were opioid tolerant.

25 109. Insys and its co-conspirators intended to induce Anthem and ESI to rely on
26 those misrepresentations to make benefits payments for the associated claims for Subsys®.

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28

1 110. Anthem and ESI reasonably relied upon Insys and its co-conspirators’
2 misrepresentations by reimbursing claims for Subsys® prescriptions that it would not
3 have paid for but for the misrepresentations or material omissions.

4 111. As a direct and proximate consequence of Insys and its co-conspirators’
5 intentional misrepresentations, and Anthem and ESI’s reliance thereon, Anthem has
6 sustained damages, the full amount to be determined at trial.

7 112. Insys engaged in aggravated and outrageous conduct with an intent to injure
8 or defraud, or deliberately interfere with the rights of Anthem and its members,
9 consciously disregarding the unjustifiably substantial risk of significant harm to them.

10 113. The concerted action has caused Anthem to be damaged by paying
11 substantial reimbursements for Subsys® prescriptions that were fraudulent and not
12 reimbursable. By virtue of the foregoing, Anthem is entitled to an award of compensatory
13 and punitive damages together with interest and costs, an injunction prohibiting Insys
14 from continuing to engage in the tortious and unlawful conduct described above, and any
15 other relief the Court deems just and proper.

16 **COUNT III – NEGLIGENT MISREPRESENTATION**

17 114. Anthem incorporates by reference the preceding paragraphs as if fully set
18 forth herein and further alleges as follows.

19 115. As alleged herein, Insys and its co-conspirators provided misrepresentations
20 of material facts to Anthem and ESI in the process of obtaining reimbursement
21 authorizations for Subsys® prescriptions.

22 116. Insys and its co-conspirators owed Anthem and ESI a duty of reasonable
23 care in obtaining and communicating information to Anthem and ESI regarding whether
24 claims for Subsys® prescriptions were actually reimbursable. Instead, Insys and its co-
25 conspirators made the above-described misrepresentations without due care or
26 competence in obtaining or communicating the information.

27 117. Insys and its co-conspirators intended that Anthem and ESI rely on these
28 misrepresentations.

1 118. Anthem and ESI reasonably relied on these misrepresentations.

2 119. As a direct and proximate consequence of Insys and its co-conspirators'
3 negligent misrepresentations, and Anthem and ESI's reliance thereon, Anthem has
4 sustained damages, the full amount to be proven at trial.

5 120. Insys engaged in aggravated and outrageous conduct with an intent to injure
6 or defraud, or deliberately interfere with the rights of Anthem and its members,
7 consciously disregarding the unjustifiably substantial risk of significant harm to them.

8 121. The concerted action has caused Anthem to be damaged by paying
9 substantial reimbursements for Subsys® prescriptions that were fraudulent and not
10 reimbursable. By virtue of the foregoing, Anthem is entitled to an award of compensatory
11 and punitive damages together with interest and costs, an injunction prohibiting Insys
12 from continuing to engage in the tortious and unlawful conduct described above, and any
13 other relief the Court deems just and proper.

14 **COUNT IV – UNJUST ENRICHMENT**

15 122. Anthem incorporates by reference the preceding paragraphs as if fully set
16 forth herein and further alleges as follows.

17 123. Anthem has conferred a benefit upon Insys in the form of significant
18 payments of benefits based on claims and charges for non-reimbursable Subsys®
19 prescriptions.

20 124. Insys has received a direct benefit from those payments.

21 125. Insys has voluntarily accepted and retained the payments made by Anthem
22 for non-reimbursable Subsys® prescriptions.

23 126. Under the circumstances of this case, as set forth in the paragraphs above, it
24 would be inequitable for Insys to retain the payments they have received for non-
25 reimbursable Subsys® prescriptions, which payments belong in equity and good
26 conscience to Anthem.

27 127. Anthem is entitled to recover from Insys its payments for invalid Subsys®
28 prescriptions.

COUNT V – CIVIL CONSPIRACY

1
2 128. Anthem incorporates by reference the preceding paragraphs as if fully set
3 forth herein and further alleges as follows.

4 129. Insys has conspired with prescribers to unlawfully, fraudulently, and
5 deceitfully procure funds from Anthem for non-reimbursable Subsys® through violations
6 of the various Unfair and Deceptive Trade Practices statutes identified above and fraud.

7 130. On information and belief, Insys executives directed Insys employees to
8 increase reimbursements received for Subsys® prescriptions by (1) providing illegal
9 kickbacks to prescribers to induce them to write more Subys® prescriptions, (2) illegally
10 marketing Subys® to prescribers for off-label use, and (3) creating a reimbursement unit
11 that worked with prescribers to fraudulently obtain authorizations for non-reimbursable
12 Subys® prescriptions.

13 131. In order to achieve and accomplish the aforementioned unlawful acts and
14 objectives, Insys and the prescribers, including but not limited to the individuals listed in
15 Exhibit 2, conspired and agreed to have Insys fraudulently call in prior authorization
16 requests on behalf of prescribers and patients to obtain reimbursement authorization for
17 non-reimbursable Subsys® prescriptions. Such authorizations were fraudulently obtained
18 through misrepresentations that patients had breakthrough cancer pain and/or were opioid
19 tolerant. Insys and the prescribers understood that this deceptive and unlawful
20 arrangement would be mutually beneficial: Insys would be able to increase revenues and
21 profits, and prescribers were paid illegal kickbacks.

22 132. The overt acts that the conspirators have taken to further and perpetuate this
23 unlawful scheme are described in particularity in this complaint and the attachments
24 thereto. The acts include: (a) Insys’s payment of illegal kickbacks to prescribers in the
25 form of “speaker fees” and other remuneration including meals in exchange for increased
26 Subsys® prescriptions, (b) Insys’s kickbacks to prescribers in the form of free
27 administrative services for obtaining prior authorizations for Subsys® prescriptions in
28 exchange for increased Subsys® prescriptions, (c) Insys employees fraudulently calling in

1 prior authorization requests, misrepresenting that they worked for the prescribers, and (d)
2 Insys employees fraudulently misrepresenting whether patients for whom they were
3 seeking prior authorizations had breakthrough cancer pain and/or were opioid dependent
4 during the prior authorization process.

5 133. The concerted actions of Insys and the prescribers have caused Anthem to
6 be damaged in an amount to be determined at trial.

7 134. Insys and the prescribers engaged in aggravated and outrageous conduct
8 with an intent to injure or defraud, or deliberately interfere with the rights of Anthem and
9 its members, consciously disregarding the unjustifiably substantial risk of significant harm
10 to them.

11 135. The concerted action has caused Anthem to be damaged by paying
12 substantial reimbursements for Subsys® prescriptions that were fraudulent and not
13 reimbursable. By virtue of the foregoing, Anthem is entitled to an award of compensatory
14 and punitive damages together with interest and costs, an injunction prohibiting Insys
15 from continuing to engage in the tortious and unlawful conduct described above, and any
16 other relief the Court deems just and proper.

17 **DEMAND FOR JURY TRIAL**

18 Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury
19 of any and all issues in this action so triable of right.

20 **PRAYER FOR RELIEF**

21 WHEREFORE, Anthem respectfully requests an award in its favor and granting
22 the following relief:

- 23 a. An award enjoining and prohibiting Insys and/or its agents, servants,
24 employees, officers, attorneys, successors, and assigns from making false
25 statements described herein in connection with obtaining reimbursements
26 for Subsys® prescriptions from Anthem.
- 27 b. An award of actual damages in an amount to be proven at trial.
- 28 c. An award of punitive damages as requested herein;

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- d. An award of the equitable relief requested herein;
- e. An award of attorney’s fees as requested herein;
- f. An award of costs;
- g. An award of prejudgment and post-judgment interest; and
- h. An award of any other relief in law or equity that the Court deems just and proper.

Respectfully submitted this 12th day of July, 2017.

COPPERSMITH BROCKELMAN PLC

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