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UNITED STATES DISTRICT COURT
 NORTHERN DISTRICT OF CALIFORNIA

In re: ACTIMMUNE MARKETING
LITIGATION

Master File No. C 08-02376-MHP

This Document Relates to:

MEMORANDUM & ORDER

All Actions

Re: Defendants' Motion to Dismiss

_____ /

In this proposed nationwide class action, plaintiffs contend that defendants InterMune, Inc. (“InterMune”), W. Scott Harkonen (“Harkonen”), and Genentech, Inc. (“Genentech”) engaged in a fraudulent and deceptive scheme to market and sell the drug Actimmune® (interferon gamma-1b). Plaintiffs allege numerous causes of action pursuant to the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C., sections 1962(c)-(d); the California Business and Professions Code, sections 17200 *et seq.*; the California Civil Code, sections 1770 *et seq.*; various state consumer protection acts; and unjust enrichment. Now before the court are three separate motions, by Genentech, InterMune, and Harkonen, to dismiss the actions pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Having considered the parties’ arguments and submissions and for the reasons stated below, the court enters this memorandum and order.

BACKGROUND

I. Procedural Issues

According to Plaintiffs’ complaints, the allegations of which must be accepted as true for the purposes of a motion to dismiss, *see Conley v. Gibson*, 355 U.S. 41, 45-46 (1957), this case is about

1 fraudulent marketing and sales practices surrounding the pharmaceutical drug known as
2 Actimmune®, a bio-engineered form of interferon gamma. There are two complaints governing the
3 four related civil actions listed above. There are also three related criminal cases: United States v.
4 InterMune, 06-cr-00707 and United States v. Harkonen, 08-cr-00164, and Harkonen v. Arch
5 Specialty Ins. Co., 08-cr-5458, none of which is the subject of the instant motions.

6 The parties to the civil actions have agreed that the two pending complaints (the First
7 Amended Class Action Complaint, brought jointly with leave of court by plaintiffs in the first three
8 related actions, 08-2376, 08-2916 and 08-3797, and the Class Action Complaint, brought by
9 plaintiffs in the recently related action 08-4531) are substantially similar. The primary substantive
10 difference is that Genentech is named as a defendant only in the latter case for the unjust enrichment
11 claim. The parties agreed that to avoid duplicative briefing and to streamline the cases, it would be
12 preferable to adopt the arguments presented in defendants' motions to dismiss the first three cases
13 and apply those arguments to all four cases.

14 Accordingly, the court GRANTS this request and applies defendants' moving papers, along
15 with the oppositions and reply briefs, to all four cases, i.e., to the joint complaint governing the first
16 three cases as well as the second complaint governing the fourth case. The court will rely primarily
17 on the joint complaint for the factual allegations, but will distinguish between the two complaints
18 where needed.

19 II. The Parties and the Factual Background

20 Plaintiffs bring this suit on behalf of themselves and others similarly situated as consumers
21 and third-party payors ("TPPs") of Actimmune®, alleging fraud and deception in the marketing and
22 sale of the drug for scientifically unproven purposes, primarily in the treatment of idiopathic
23 pulmonary fibrosis ("IPF"). See First Amended Class Action Complaint ("Compl.") ¶ 2.
24 Plaintiffs Deborah Jane Jarrett, Nancy Eisenhower, Jeffrey H. Frankel, and Linda K. Rybkoski,
25 residing in Georgia, Indiana, Pennsylvania, and Ohio, respectively, represent current or former users
26 of Actimmune® who administered the drug by self-injection and incurred payment obligations from
27 their own funds. Id. ¶¶ 8-11.

28

1 Plaintiff Zurich American Insurance Company (“Zurich”), a New York corporation with its
2 headquarters located in Illinois, is a TPP that provides health and pharmacy benefits to its insureds
3 across the United States. During the Class Period, Zurich paid for prescriptions of Actimmune® to
4 treat IPF. Id. ¶ 12. Plaintiff Government Employees Health Association, Inc. (“GEHA”), a not-for-
5 profit organization incorporated in Missouri, is another TPP that serves as a large national health
6 insurance plan for federal employees and retirees, as well as their families, across the United States
7 and around the world. See Class Action Complaint (“GEHA Compl.”), ¶ 7. During the Class
8 Period, GEHA paid for more than \$4 million of Actimmune® prescriptions for its insureds suffering
9 from IPF. Id.

10 Genentech is a Delaware corporation with its primary place of business in San Francisco,
11 California. Compl. ¶ 15. Genentech is a publicly traded biotechnology company that uses human
12 genetic information to discover, develop, manufacture, and commercialize bio-therapeutics. Id. ¶
13 20. During the 1980s, Genentech developed a bio-engineered form of interferon gamma-1b, a
14 naturally occurring protein in the human body that stimulates the immune system. Id. ¶ 21. In 1990,
15 Genentech obtained approval from the Food and Drug Administration (“FDA”) to market and sell
16 interferon gamma-1b under the brand-name Actimmune® for the treatment of Chronic
17 Granulomatous Disease (“CGD”).¹ CGD is a rare, inherited autoimmune disease that affects about
18 400 people annually in the U.S. Id. ¶¶ 22-23. In 2000, Genentech obtained FDA approval to
19 broaden Actimmune®’s indication to include delaying disease progression in patients with severe,
20 malignant osteopetrosis, which is another rare congenital disorder that affects about 400 people
21 annually in the U.S. Id. ¶ 25.

22 In May 1998, Genentech exclusively licensed the U.S. marketing and development rights to
23 interferon gamma, including Actimmune®, to Connetics Corporation (“Connetics”). Id. ¶ 29; see
24 also Def. Br., Exh. A (“License Agreement for Interferon Gamma”).² Connetics is a Delaware
25 corporation with its principal place of business in Palo Alto, California, that was founded by
26 Genentech executives. Compl. ¶¶ 16, 29. Genentech granted Connetics an exclusive license “to use,
27 sell, offer for sale and import (but not to make or have made) Licensed Products in the Field of Use”
28 within the United States. Compl. ¶ 30; Def. Br., Exh. A § 2.1(a) at 8-9. “Licensed Products”

1 referred to any pharmaceutical formulations containing interferon gamma. Def. Br., Exh. A § 1.22
2 at 6. “Field of Use” was defined as “the administration to humans of Licensed Product for the
3 treatment or prevention” of various diseases and conditions, including, in pertinent part, CGD,
4 severe, malignant osteopetrosis, and pulmonary fibrosis. Id. §§ 1.12(c)-(e) at 3.

5 The license agreement also required Connetics to pursue research and development in an
6 effort to gain additional FDA approval of new indications for interferon gamma. Compl. ¶ 30; Def.
7 Br., Exh. A § 3.1(a) at 19. Specifically, Genentech required Connetics to “use its Best Efforts to
8 develop, *seek FDA clearance for marketing of*, commercialize and sell Licensed Products in the
9 Territory in all Areas of the Field of Use” and provided deadlines called “commercialization
10 milestones” for so doing. Id. (emphasis added). The license included annual reporting requirements
11 by Connetics to Genentech regarding these activities. Id. § 3.3 (“Review of Clinical Development
12 Plan and Marketing Programs”) at 24. These requirements stated in part that:

13 On or about each August 1 during the term of this Agreement, Connetics shall supply
14 Genentech with a report on Connetics’ development and marketing programs for
15 Licensed Products in the Field of Use in the Territory. The report shall include the
16 following: (i) a description of Connetics’ progress in such programs during the twelve
17 (12) months prior to the date of each such report, (ii) *a description of Connetics’*
18 *planned development and marketing programs for the twelve (12) months after the*
19 *date of each such report*, (iii) a copy of the most recent version of the Clinical
20 Development Milestones . . . Genentech shall have the right to comment on the
21 Clinical Development Milestones and the development and marketing programs, and
22 at Genentech’s discretion, the Parties shall meet to discuss and agree upon changes to
23 the Clinical Development Milestones.

19 Id. at 24-25; Compl. ¶ 31 (emphasis added in Complaint).

20 The license further stated that “Connetics shall conduct clinical trials . . . and shall make, use,
21 sell and distribute Licensed Products in accordance with all applicable laws and regulations.” Id. §
22 3.7(a) at 25-26.³ The license explicitly contemplated a sub-license by Connetics to its newly created
23 and wholly-owned subsidiary InterMune to carry out the development and commercialization
24 requirements. Id. § 3.1(a) at 19; Compl. ¶ 33.

25 InterMune is a pharmaceutical product marketing company, incorporated in Delaware with
26 its principal place of business in Brisbane, California. Compl. ¶ 13. InterMune generally distributes
27 its products through specialty pharmacies, which then resell to hospitals, general pharmacies and
28 physicians. Id. ¶ 34. In August 1998, Connetics sub-licensed some of its Actimmune® rights to

1 InterMune, and InterMune assumed many of Connetics' obligations to Genentech. In April 1999,
2 Connetics sub-licensed more Actimmune® rights to InterMune; and in June 2000, Connetics
3 assigned all of its Actimmune® rights to InterMune, whereupon InterMune assumed all of
4 Connetics' obligations, including the development and commercialization obligations as well as the
5 annual reporting obligation to Genentech. Id. ¶¶ 36. 38. InterMune was also required to pay
6 Genentech royalties on Actimmune® sales and to make various milestone payments. Id. ¶¶ 37-38.
7 While Genentech initially supplied Actimmune® to InterMune, InterMune employed a different
8 supplier by May 2001. Id. ¶¶ 39, 41. Genentech continues to receive royalties from InterMune on
9 Actimmune® sales. Id.

10 Harkonen is a resident of California who served as InterMune's Chief Executive Officer
11 ("CEO") and on its Board of Directors, from February 1998 through at least June 2003, and was the
12 senior vice president of Connetics during the time when Connetics held the Actimmune® license.
13 Id. ¶¶ 14, 29, 35. Plaintiffs' bring this action against InterMune, as marketer and seller of
14 Actimmune®, Harkonen, as former CEO of InterMune, and Genentech, as the original manufacturer
15 and licensor of Actimmune®, alleging they were co-conspirators in a fraudulent marketing and sales
16 scheme. Id. ¶ 2.

17 III. The Fraudulent Scheme

18 Plaintiffs allege that from the time InterMune acquired the full and exclusive license to
19 Actimmune®, defendants knew that the drug would not be profitable from sales for CGD and
20 severe, malignant osteopetrosis alone. Compl. ¶ 42. They contend that while InterMune and
21 Genentech knew that the market for Actimmune® only consisted of about 800 CGD and severe,
22 malignant osteopetrosis patients, the sales of Actimmune® soared. Id. ¶ 40. Genentech's sales of
23 Actimmune® to InterMune increased 37% from 1999 to 2000, and then more than doubled between
24 2000 (\$3.7 million) and 2001 (\$7.4 million). Id. ¶ 40. Actimmune® sales rose from less than one
25 million dollars in 1999 to \$105.8 million in 2002 and \$141.4 million in 2003 and stayed at above
26 \$90 million through 2006. Id. ¶¶ 48-49, 92. Plaintiffs attribute this increase in sales to the deceitful
27 marketing of Actimmune® for an unproven indication. Id.

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1 Plaintiffs admit that throughout 1999 Actimmune® was being promoted by InterMune only
2 for approved indications. Id. ¶ 48. InterMune admitted that substantially all Actimmune® sales
3 from 2000 to the present are attributable to prescriptions for the treatment of IPF. Id. ¶ 50. Plaintiffs
4 contend that after 1999, InterMune and Harkonen embarked on a campaign to market and promote
5 Actimmune® to treat IPF and that they “falsely claimed benefits associated with Actimmune® for
6 IPF,” “suppressed evidence that Actimmune® was ineffective in treating IPF,” and “caused
7 physicians to prescribe Actimmune® to treat IPF.” Id. ¶ 47. Under the terms of the license
8 agreement, Genentech was able to monitor and review the marketing programs of Actimmune® for
9 unproven and unapproved uses and Genentech therefore allegedly knew or should have known that
10 the increase in sales from 2000 onward was the result of marketing for an unproven, off-label
11 indication. Id. ¶¶ 40, 71, 76.

12 Plaintiffs contend that InterMune and Harkonen intentionally misrepresented, and instructed
13 InterMune’s sales force to misrepresent to pulmonologists, the medical benefits of Actimmune® for
14 IPF to increase profits. Id. ¶¶ 51-54, 72-80. Plaintiffs cite InterMune’s 2000 filings with the
15 Security and Exchange Commission (“SEC”), stating that “[t]he results of a clinical trial published
16 in October 1999 in the *New England Journal of Medicine* showed statistically significant evidence
17 that interferon gamma-1b can halt and reverse the progression of idiopathic pulmonary fibrosis.” Id.
18 ¶ 54. Plaintiffs allege this statement was false because the study included just eighteen participants,
19 eight of whom received interferon gamma-1b and the patients suffered from a less advanced stage of
20 pulmonary disease that was not clearly identified as IPF. Id. ¶ 53.

21 In October 2000, InterMune sponsored a Phase III clinical trial of Actimmune® to determine
22 whether treating IPF patients with Actimmune® was effective in decreasing disease progression and
23 death. Id. ¶ 55. In August 2002, data from the clinical trial failed to show statistical significance in
24 the rates of progression-free survival. Id. ¶ 56. InterMune and Harkonen discussed the results of the
25 trial with the FDA and the FDA allegedly advised defendants that Actimmune® was unlikely to be
26 approved for the treatment of IPF without further clinical testing. Id. In 2003, InterMune began
27 enrolling patients in a Phase II clinical trial (“the INSPIRE study”) to test Actimmune® in IPF
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1 patients with mild to moderate lung function, and in 2005 InterMune enrolled a second wave of
2 patients. Id. ¶ 99.

3 From 2002 to at least January 2003, InterMune and Harkonen engaged in a sales and
4 marketing campaign that included disseminating a number of press releases, sending sales
5 representatives to visit physicians, sending letters to patients taking Actimmune®, setting up booths
6 at medical conferences, setting up a registry known as the Actimmune® Safe and Appropriate Use
7 Program (“the ASAP registry”) for doctors to join and obtain information, creating a nonprofit
8 patient advocacy group called the Coalition for Pulmonary Fibrosis, and sponsoring meetings and
9 medical programs for pulmonologists, all of which allegedly served to tout the positive results in
10 treating IPF with Actimmune®. Id. ¶¶ 73-75, 81-87.

11 Plaintiffs allege that distributed materials promoting Actimmune® for IPF before the Phase
12 III trial had been completed served to advance false information in the absence of scientific proof.
13 Plaintiffs allege that once the clinical trial results were obtained, InterMune and Harkonen allegedly
14 misrepresented the data as “demonstrating survival benefits” and “reducing mortality by 70% in
15 patients with mild to moderate disease.” Id. ¶¶ 64-67. InterMune and Harkonen allegedly
16 encouraged patients to begin taking the drug early in the treatment of their disease even though the
17 data did not support a claim of improved survival rates. Id. ¶ 70. Plaintiffs cite a statement from an
18 independent “Data Monitoring Committee” that analyzed the clinical trial data and allegedly stated
19 the trial had “failed to establish benefit on the primary endpoint” and that InterMune’s statements
20 constituted a “serious misrepresentation of results obtained from exploratory data subgroup
21 analysis.” Id. ¶ 67. Plaintiffs allege the actions taken by InterMune and Harkonen served to
22 increase sales and profits by causing patients and TPPs to pay for useless prescriptions for the
23 longest possible period of time. Id. ¶ 71.

24 More generally, plaintiffs contend that InterMune’s sales force that visited physicians was
25 instructed and encouraged to misrepresent the state of scientific evidence relating to Actimmune® in
26 treating IPF. Id. ¶ 72-76. Plaintiffs contend that the sales representatives used other InterMune
27 drugs, such as the anti-fungal drug Amphotec which can be used to treat pulmonary aspergillosis, to
28 gain access to pulmonologists to discuss and promote Actimmune® for the treatment of IPF. Id. ¶¶

1 77-80. Plaintiffs further allege that the sales representatives used the ASAP registry to initiate
2 contact with pulmonologists and share positive data on the treatment of IPF with Actimmune®, but
3 not share any negative trends in survival or progression data with the physicians. *Id.* ¶ 81-84.
4 Plaintiffs allege the meetings, programs and patient advocacy groups sponsored by InterMune all
5 served “as a front for InterMune that was set up to sell Actimmune®, not to support IPF research.”
6 *Id.* ¶ 85-89. Plaintiffs maintain these sales and marketing efforts persisted in the face of
7 overwhelming negative information about the benefit of treating IPF with Actimmune® and that
8 InterMune and Harkonen concealed negative facts and “continued to allow the medical and patient
9 communities to rely on their misrepresentations to sell more Actimmune®.” *Id.* ¶¶ 90-94.

10 In 2004, an article in the *New England Journal of Medicine* presented the results from
11 InterMune’s Phase III clinical trial on Actimmune®. The article stated that “no significant
12 differences were noted in the primary outcome measure of progression-free survival (defined as
13 either disease progression or death)” but “[n]evertheless, we observed a trend toward enhanced
14 survival in all randomized patients who were treated with interferon gamma-1b, as compared with
15 those receiving placebo” *Id.* ¶¶ 95-96. The authors, all of whom allegedly received consulting
16 fees from InterMune, concluded that further research was needed to determine whether
17 Actimmune® increased survival of IPF patients. *Id.* Plaintiffs assert that InterMune used this
18 sentence to justify continuing their marketing campaign.

19 In 2005, an article in *CHEST*, by many of the same authors, analyzed the appropriateness of
20 the endpoints used in the Phase III clinical trial on Actimmune®. The article stated that “the
21 suggestion of benefit of [Actimmune®] on both disease progression and mortality . . . while not
22 reaching statistical significance in all, is promising and requires further exploration in larger and
23 longer clinical trials” *Id.* ¶ 98. Plaintiffs cite another article published the following year, in
24 the *Proceedings of the American Thoracic Society*, which concluded that “current evidence does not
25 justify the routine use of Actimmune® in the management of IPF.” *Id.* ¶ 100.

26 In 2007, the FDA announced the early termination of the INSPIRE study conducted by
27 InterMune. *Id.* ¶ 101. The FDA’s alert stated “the study was stopped because an interim analysis
28 showed that patients with IPF who received Actimmune® did not show benefit.” *Id.*

1 According to the complaint, defendants’ misleading and false representations to doctors,
2 patients and the general public demonstrate that InterMune and Harkonen willfully embarked on an
3 extensive “campaign of deception” and fraud to promote Actimmune® for the treatment of IPF. Id.
4 ¶¶ 43, 63, 104. Plaintiffs generally conclude that InterMune’s campaign caused physicians to
5 prescribe Actimmune®, and caused consumers and TPPs to pay for Actimmune®, despite an
6 absence of scientific proof to support its effectiveness. Plaintiffs also generally conclude that
7 Genentech knew or should have known of this campaign because it received updates on InterMune’s
8 marketing programs as well as large royalties from Actimmune® sales.

9 IV. Related Criminal Prosecution

10 A. Criminal Prosecution of InterMune

11 In October 2006, after a two-year investigation, the Department of Justice (“DOJ”) charged
12 InterMune with misbranding under 21 U.S.C. § 452(f)(1) for promoting Actimmune® for the
13 treatment of IPF with the intent to defraud and mislead. See Compl., Exh. A (Criminal Information),
14 at 3. The DOJ stated in a press release that InterMune’s wrongful actions caused the submission of
15 false and fraudulent claims for Actimmune® not eligible for reimbursement and also caused
16 governmental payors to pay for Actimmune® prescriptions they would not have paid for but for
17 InterMune’s deception. See Compl., Exh. B (DOJ Press Release).

18 InterMune agreed to pay a combined \$42.5 million, including interest, over five years to
19 settle the criminal charges that it illegally marketed Actimmune® for an off-label use. Of this sum,
20 \$30.2 million will be paid to the United States as restitution for losses suffered by governmental
21 payors such as Medicare, Medicaid, the Veteran’s Administration, the Department of Defense, and
22 the Federal Employees Health Benefits Program. See Compl., Exh. E (Civil Settlement Agreement).
23 InterMune will also pay \$6.7 million in restitution to the state Medicaid programs that paid a portion
24 of the cost of prescriptions for Actimmune® for IPF. InterMune also entered into a deferred
25 prosecution agreement, in which it agreed it would not disagree to a material extent with the facts
26 outlined in Attachment A to the Agreement. See Compl., Exh. F (Deferred Prosecution Agreement).
27 InterMune also entered into a corporate integrity agreement, in which it agreed to reform its
28

1 corporate practices and submit to monitoring and strict reporting requirements to the government for
2 five years. See Compl., Exh. G (Corporate Integrity Agreement).

3 B. Criminal Prosecution of Harkonen

4 In March 2008, Harkonen was indicted for disseminating and causing to be disseminated
5 information regarding Actimmune® for the treatment of IPF with the intent to defraud and mislead,
6 thereby causing Actimmune® to be misbranded. See Compl., Exh. C (Indictment) at 10. The DOJ
7 stated in a press release that Harkonen promoted Actimmune® as a safe and effective treatment for
8 IPF in order to sell more Actimmune® and to generate revenues and profits for InterMune. See
9 Compl., Exh. D (2008 Press Release).

10 IV. The Purported Class

11 Plaintiffs bring these actions on behalf of themselves and the Class comprised of:

12 All individuals and entities in the United States and its territories who, for purposes
13 other than resale, purchased, reimbursed, and/or paid for ACTIMMUNE for the
14 treatment of IPF during the period from May 5, 1998 through the present. For
15 purposes of the Class definition, individuals and entities purchased ACTIMMUNE if
16 they paid for some or all of the purchase price.

17 Compl. ¶ 113.

18 Plaintiffs allege that “[i]n reliance on Defendants’ representations, tens of thousands of
19 prescriptions were written by pulmonologists for the treatment of IPF and tens of thousands of
20 consumers and/or [TPPs] paid for Actimmune® prescriptions needlessly.” Id. ¶ 105. Plaintiffs
21 allege six causes of action, for RICO violations under 18 U.S.C., sections 1962(c) and (d), violations
22 of the California Unfair Competition Law under the California Business and Professions Code,
23 sections 17200 et seq.; violations of other state consumer protection statutes, and unjust enrichment.

24 Defendants filed separate motions to dismiss both complaints; all of which are related and
25 have now been adopted as being presently before the court. Genentech moves to dismiss all counts
26 against it, namely, Counts II-IV (count I is not advanced against Genentech) in the Complaint and
27 Count VI (the only count advanced against Genentech) in the GEHA Complaint, for failure to state a
28 claim. Intermune moves to dismiss all counts, arguing that plaintiffs have not alleged a claim for
RICO violations or violations of unfair competition law or the equitable doctrine of unjust
enrichment, nor have plaintiffs satisfied the injury in fact requirement for Article III standing.

1 Harkonen moves as to Counts I-V (Count VI is not advanced against Harkonen) by joining and
2 incorporating the Genentech and InterMune motions.

3
4 LEGAL STANDARD

5 I. Rule 12(b)(1), Standing

6 A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) tests the subject matter
7 jurisdiction of the court. See, e.g., Savage v. Glendale Union High Sch., 343 F.3d 1036, 1039-40
8 (9th Cir.2003). Under Article III of the Constitution, federal judicial power extends only to “Cases”
9 and “Controversies.” U.S. Const., art. III, § 2, cl. 1. Article III standing is thus a threshold
10 requirement for federal court jurisdiction. Lujan v. Defenders of Wildlife, 504 U.S. 555, 559-60
11 (1992). At a constitutional minimum, standing requires the party invoking federal jurisdiction to
12 show that it has “suffered some actual or threatened injury as a result of the putatively illegal
13 conduct of the defendant, and that the injury can be traced to the challenged action and is likely to be
14 redressed by a favorable decision.” Valley Forge Christian Coll. v. Ams. United for Separation of
15 Church and State, Inc., 454 U.S. 464, 472 (1982) (citations and internal quotations omitted). To
16 satisfy the injury in fact requirement, the alleged harm must be “an invasion of a legally protected
17 interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or
18 hypothetical.” Lujan, 504 U.S. at 560 (citations and internal quotations omitted). The party invoking
19 federal jurisdiction bears the burden of establishing these elements. Id. at 561.

20 II. Rule 12(b)(6), Failure to State a Claim

21 Pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint may be dismissed against a
22 defendant for failure to state a claim upon which relief can be granted against that defendant. A
23 motion to dismiss under Rule 12(b)(6) “tests the legal sufficiency of a claim.” Navarro v. Block,
24 250 F.3d 729, 732 (9th Cir. 2001). Because Rule 12(b)(6) focuses on the “sufficiency” of a
25 claim—and not the claim’s substantive merits—“a court may [typically] look only at the face of the
26 complaint to decide a motion to dismiss.” Van Buskirk v. Cable News Network, Inc., 284 F.3d 977,
27 980 (9th Cir. 2002). Although the court is generally confined to consideration of the allegations in
28 the pleadings, when the complaint is accompanied by attached documents, such documents are

1 deemed part of the complaint and may be considered in evaluating the merits of a Rule 12(b)(6)
2 motion. Durning v. First Boston Corp., 815 F.2d 1265, 1267 (9th Cir. 1987). In addition, pursuant
3 to Federal Rule of Evidence 201, “a court may take judicial notice of ‘matters of public record’ “
4 without converting a motion to dismiss under Rule 12(b)(6) into a motion for summary judgment.
5 Lee v. City of Los Angeles, 250 F.3d 668, 688-89 (9th Cir. 2001) (quoting Mack v. South Bay Beer
6 Distrib., 798 F.2d 1279, 1282 (9th Cir. 1986)).

7 A motion to dismiss should be granted if plaintiff fails to plead “enough facts to state a claim
8 to relief that is plausible on its face.” Bell Atl. Corp. v. Twombly, 127 S. Ct. 1955, 1974 (2007).
9 Dismissal may be based on the lack of a cognizable legal theory or the absence of sufficient facts
10 alleged under a cognizable legal theory. Balistreri v. Pacifica Police Dep’t, 901 F.2d 696, 699 (9th
11 Cir. 1990). Allegations of material fact are taken as true and construed in the light most favorable to
12 the nonmoving party. Cahill v. Liberty Mut. Ins. Co., 80 F.3d 336, 337–38 (9th Cir. 1996).
13 However, mere conclusions couched in factual allegations are not sufficient to state a cause of
14 action. Papasan v. Allain, 478 U.S. 265, 286 (1986). The court need not accept as true allegations
15 that are conclusory, legal conclusions, unwarranted deductions of fact or unreasonable inferences.
16 See Sprewell v. Golden State Warriors, 266 F.3d 979, 988 (9th Cir. 2001); Clegg v. Cult Awareness
17 Network, 18 F.3d 752, 754–55 (9th Cir. 1994). Courts may dismiss a case without leave to amend if
18 the plaintiff is unable to cure the defect by amendment. Lopez v. Smith, 203 F.3d 1122, 1129 (9th
19 Cir. 2000).

20 III Fraud-Based Claims

21 A plaintiff alleging fraud must satisfy a heightened pleading standard that requires
22 circumstances constituting fraud be pled with particularity. Fed. R. Civ. P. 9(b). In a RICO case, a
23 plaintiffs must “state the time, place and specific conduct of the false representations as well as the
24 identifies of the parties to the misrepresentation.” Schreiber Distrib. Co. v. Serv-Well Furniture Co.,
25 806 F.2d 1393, 1401 (9th Cir. 1986). In addition, plaintiffs seeking to satisfy Rule 9(b) must “set
26 forth an explanation as to why the statement or omission complained of was false and misleading.”
27 In re GlenFed, Inc. Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994) (*en banc*); see Fecht v. Price Co.,
28 70 F.3d 1078, 1082 (9th Cir. 1995). The pleading must be “specific enough to give defendants

1 notice of the particular misconduct . . . so that they can defend against the charge and not just deny
2 that they have done anything wrong.” Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1106 (9th
3 Cir. 2003) (internal quotation omitted).

4 Finally, a plaintiff seeking to state a claim for fraud must also plead knowledge of falsity, or
5 scienter. See GlenFed, 42 F.3d at 1546. The requirement for pleading scienter is less rigorous than
6 that which applies to allegations regarding the “circumstances that constitute fraud” because
7 “malice, intent, knowledge, and other condition of mind of a person may be averred generally.” Fed.
8 R. Civ. P. 9(b). Nonetheless, nothing in the Federal Rules of Civil Procedure relieves a plaintiff of
9 the obligation to “set forth facts from which an inference of scienter could be drawn.” Cooper v.
10 Pickett, 137 F.3d 616, 628 (9th Cir. 1997) (quoting GlenFed, 42 F.3d at 1546).

11 This heightened pleading standards applies to allegations of fraud and allegations that sound
12 in fraud, including false misrepresentations. Vess, 317 F.3d at 1106–07; see also Meridian Project
13 Sys., Inc. v. Hardin Constr. Co., LLC, 404 F. Supp. 2d 1214, 1219 (E.D. Cal. 2005) (“It is well
14 settled in the Ninth Circuit that misrepresentation claims are a species of fraud, which must meet
15 Rule 9(b)’s particularity requirement.”); Neilson v. Union Bank of Cal., N.A., 290 F. Supp. 2d 1101,
16 1141 (C.D. Cal. 2003) (same).

17
18 DISCUSSION

19 Defendants argue that plaintiffs improperly seek to piggyback this private class action on
20 InterMune’s settlement agreement with the federal government for the off-label promotion of
21 Actimmune® for IPF. Defendants state that the government’s case cannot create civil liability
22 because the government prosecuted criminal violations of the federal Food, Drug, and Cosmetic Act
23 (“FDCA”), 21 U.S.C. § 301 et seq., which provides no private right of action for consumers or TPPs.
24 Plaintiffs proceed primarily on a theory of liability under RICO, premised on predicate acts of mail
25 and wire fraud, claiming that plaintiffs paid for prescriptions of Actimmune® as a result of
26 defendants’ knowingly false representations that Actimmune® effectively treated IPF. Plaintiffs
27 also bring claims based on various consumer protection statutes and unjust enrichment. The court
28 first addresses the RICO claims.

1 I. RICO Claims

2 Defendants argue that plaintiffs’ complaints are fatally flawed because they cannot properly
3 allege a direct and causal link between defendants’ alleged fraudulent marketing scheme concerning
4 Actimmune®’s effectiveness for treating IPF and any damages claimed by plaintiffs. Specifically,
5 defendants argue that plaintiffs have not pled that the individual plaintiffs suffer from IPF, nor that
6 any of the plaintiff’s doctors prescribed Actimmune® to treat IPF, nor that any of plaintiff’s doctors
7 was even exposed to the allegedly fraudulent representations, nor that any such fraudulent
8 representations caused any of plaintiff’s doctors to prescribe Actimmune®. Defendants conclude
9 that plaintiffs’ alleged injuries are merely conjectural because the allegedly fraudulent marketing
10 scheme has not directly caused plaintiff actual harm. Without this causal link, plaintiffs do not have
11 standing under either Article III of the U.S. Constitution or RICO’s civil enforcement provision, 18
12 U.S.C. § 1964(c). Defendants contend these civil actions should be dismissed in their entirety for
13 failure to state a claim based on this ground—that the plaintiffs lack standing because they had not
14 suffered an injury cognizable under RICO.⁴

15 Article III standing requirements include “a causal connection between the injury and the
16 conduct complained of” that is “fairly . . . trace[eable] to the challenged action of the defendant, and
17 not . . . th[e] result [of] the independent action of some third party not before the court.” Lujan v.
18 Defenders of Wildlife, 504 U.S. 555, 559-60 (1992). If a plaintiff lacks Constitutional standing,
19 Congress may not confer standing on that plaintiff by statute Id. at 576-77. In addition to Article III
20 standing, a private civil action for fraud under RICO only grants standing to “[a]ny person injured in
21 his business or property by reason of a violation of” its substantive provisions. 18 U.S.C. § 1964(c).
22 A violation of RICO occurs under subsection (c) when a person “associated with any enterprise . . .
23 participate[s] . . . in the conduct of such enterprise’s affairs through a pattern of racketeering activity
24” Id. “Racketeering activity” is defined as including any act indictable under certain
25 enumerated federal criminal statutes, including those which make mail fraud and wire fraud criminal
26 offenses. Miller v. Yokohama Tire Corp., 358 F.3d 616, 620 (9th Cir. 2004) (citations omitted).
27 Insofar as concerns this case, subsection (d) makes it unlawful to conspire to violate subsection (c).
28

1 In order to bring a RICO claim based on fraud, therefore, the Supreme Court has ruled a
2 plaintiff must demonstrate that the injury to his “business or property” was caused “by reason of a
3 violation” of RICO. See Sedima, S.P.R.L. v. Imrex Co., Inc., 473 U.S. 479, 496 (1985) (“the
4 plaintiff only has standing if, and can only recover to the extent that, he has been injured in his
5 business or property by the conduct constituting the violation”); Haroco, Inc. v. Am. Nat’l Bank &
6 Trust Co. of Chicago, 747 F.2d 384, 398 (7th Cir. 1984), aff’d, 473 U.S. 606 (1985) (noting that a
7 defendant who violates RICO is not liable to those who have not been injured, nor to those
8 defendant might have injured by other conduct).

9 The Supreme Court affirmed the importance of the causation requirement for standing under
10 RICO, in the context of securities fraud, in holding that a class action claim under RICO requires
11 that a defendant’s violation was not only a “but for” cause of injury, but was the proximate cause as
12 well. Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 267 (1992). According to the Court,
13 proximate cause demands “some direct relation between the injury asserted and the injurious
14 conduct alleged.” Id. at 268; Bridge v. Phoenix Bond & Indem. Co., 128 S.Ct. 2131, 2139 (2008)
15 (requiring the plaintiff to establish proximate cause in order to show injury “by reason of” a RICO
16 violation); Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 461 (2006) (“When a court evaluates a
17 RICO claim for proximate causation, the central question it must ask is whether the alleged violation
18 led directly to the plaintiff’s injuries.”)

19 Defendants argue that plaintiffs lack standing to bring their RICO claims as no individual
20 plaintiff has shown the requisite “direct relation” between defendants’ purportedly fraudulent
21 misrepresentations about the effectiveness of Actimmune® to treat IPF and plaintiffs’ alleged
22 injuries. Plaintiffs counter by arguing that proximate cause elements raise factual questions that are
23 not to be resolved in a motion to dismiss. Apart from that, plaintiffs contend that the defendants’
24 unlawful action was their misrepresentation of Actimmune®’s efficacy in treating IPF, and that this
25 fraud directly caused economic loss to the individual plaintiffs as purchasers and to the TPPs as co-
26 payors or reimbursers. Plaintiffs allege they would not have made payments for a drug that was not
27 effective for the treatment of IPF and damages would not have been incurred had defendants’
28 advertisements not been deceptive and fraudulent. Nowhere do plaintiffs allege in detail who was

1 misled by the advertisements or promotions—words the plaintiffs use interchangeably—or who the
2 intended target audience was for these diverse “marketing activities.”

3 The court recognizes that the causal chain of injury plaintiffs allege in this case is similar to
4 that of many other civil RICO claims in which a plaintiff contends it incurred harm as a result of
5 defendants’ false or misleading representations.⁵ The causal chain for the instant plaintiffs’ harm is,
6 of course, more attenuated than that alleged in cases where a single defendant made false
7 representations about its own product. It is for this reason, presumably, that plaintiff has brought in
8 the RICO statute to allege a conspiracy and a pattern of racketeering activity among the parties. As
9 such, plaintiffs contend that defendants Genentech (the original manufacturer and licensor of
10 Actimmune®), InterMune (the marketer and seller of Actimmune®) and Harkonen (the former CEO
11 of InterMune) conspired to violate RICO by participating in a pattern of racketeering activity
12 (predicated on mail and wire fraud) in furtherance of the unlawful marketing and sale of
13 Actimmune®. The court examines these allegations with careful scrutiny.

14 There are a substantial number of allegations in plaintiffs’ complaints that do not depend on
15 mere off-label uses of Actimmune®. A number of them specifically allege statements made and
16 their falsity. However, many of plaintiffs’ allegations conflate a false and misleading statement
17 under the FDCA, i.e., one that occurs when the drug label does not match the promoted assertion
18 about the drug, and a false and misleading statement *about the drug itself* that can give rise to a
19 claim under RICO. The two types of statements are not the same.⁶ A RICO violation is not focused
20 on the drug’s label, but rather whether the promoted assertion was knowingly false as to a material
21 matter about the drug, i.e., if it constituted actionable fraud. See *Neder v. United States*, 527 U.S. 1,
22 *21-25 (1999)* (giving the term “defraud” in predicate act statutes to RICO, e.g., mail fraud statutes,
23 its established common law meaning). Plaintiffs need to pare down the allegations accordingly and
24 focus on those sorts of representations in this action. Plaintiffs’ blunderbuss approach to pleading is
25 ineffective here. The major problem with plaintiffs’ complaints is that they do not allege that any of
26 the individual plaintiffs suffered from IPF and that they took Actimmune® for that reason. In fact,
27 the complaint fails to specify for what reason the individual plaintiffs took the drug and for what
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1 indication it was prescribed, or indeed if it was even prescribed at all or if plaintiffs obtained the
2 drug by other means.

3 Plaintiffs spend pages recapitulating defendants' efforts to engage in sales and marketing
4 programs to increase the sales of Actimmune®. The allegations relating to the causal chain of injury
5 as a result of these marketing efforts, however, is scanty. Purchasers of Actimmune® do not suffer
6 an injury cognizable under RICO simply because they paid for the drug. To show causation,
7 plaintiffs allege that InterMune and Harkonen misrepresented the benefits of Actimmune® in the
8 treatment of IPF and "caused physicians to prescribe Actimmune® to treat IPF," and "caused
9 patients and TPPs to pay for Actimmune®." Plaintiffs allege that "[i]n reliance on Defendants'
10 representations, tens of thousands of prescriptions were written by pulmonologists for the treatment
11 of IPF and tens of thousands of consumers and/or [TPPs] paid for Actimmune® prescriptions
12 needlessly." This is not enough. Plaintiffs' mere recitations of the causation element of the RICO
13 claim do not provide sufficient grounds for entitlement to relief. See Twombly, 127 S.Ct. at 1965
14 ("[T]he pleading must contain something more . . . than . . . a statement of facts that merely creates a
15 suspicion [of] a legally cognizable right of action"). The court is not convinced that these
16 speculative allegations about doctor "reliance" and legal conclusions about a "direct and proximate"
17 causation of injuries state a claim for relief, even under the lenient pleading standard of the Federal
18 Rules of Civil Procedure. Fed. R. Civ. P. 8(a); see Papasan v. Allain, 478 U.S. 265, 286 (1986)
19 (holding that on a motion to dismiss, courts "are not bound to accept as true *a legal conclusion*
20 *couched as a factual allegation*") (emphasis added).

21 Plaintiffs need to allege what specific information the individual plaintiffs or their physicians
22 had about the drug, the extent to which they relied upon that information, and that the information
23 relied upon was false, misleading or otherwise fraudulent. Plaintiffs also need to allege when the
24 drug was prescribed, purchased and administered, and whether these actions would not have been
25 taken if not for the concealment/misrepresentations of facts made regarding the efficacy or lack
26 thereof about Actimmune® for treating IPF.⁷ The court understands that in some respects it may be
27 difficult for plaintiffs to determine what specific predicate acts occurred and when, and thus pinning
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1 down reliance with specificity may also be difficult at this stage. But plaintiffs nonetheless need to
2 provide further specificity with respect to the misrepresentations made by defendants.

3 Even setting aside the issue of whether the doctors relied on the allegedly fraudulent
4 marketing materials, plaintiffs' claims are still lacking in basis. The court is well aware that
5 plaintiffs can recover under RICO law in a variety of circumstances where their injuries result
6 directly from the defendant's fraudulent misrepresentations to a third party. See Bridge, 128 S.Ct.
7 at 2141. But here, no individual plaintiff has even alleged that their injuries resulted from
8 defendants' purported fraud. Plaintiffs have not put forth any specific allegations that *anyone*—the
9 doctors, the plaintiffs themselves, or any other third party—relied on defendants' purportedly
10 fraudulent misrepresentations to cause the injury. Id. at 2144 (a lack of first-party reliance does not
11 mean that a RICO plaintiff alleging injury by reason of a pattern of mail fraud can prevail “without
12 showing that *someone* relied on the defendant's misrepresentation . . . In most cases, the plaintiff
13 will not be able to establish even but-for causation if no one relied on the misrepresentation.”). The
14 Supreme Court explained that while a person can be injured “by reason of” a pattern of fraud, even if
15 he has not relied on any misrepresentations, the injury must still have occurred as a result of the
16 fraud to state a cause of action under RICO. Id. at 2139. Applying this reasoning to the instant case,
17 therefore, no plaintiff has alleged an injury that is sufficiently related to the alleged fraudulent
18 conduct to satisfy RICO. Again, this deficiency is a result of plaintiffs lack of specificity with
19 respect to defendants' alleged misrepresentations.

20 Having considered the parties' arguments, the court finds that plaintiffs have failed to plead
21 the requirements of its RICO claims. The private remedy provisions of RICO require a plaintiff to
22 have suffered an ascertainable loss that is in direct relation to the alleged fraudulent conduct.
23 Plaintiffs have failed to plead such a loss. In the absence of pleadings that sufficiently establish the
24 relation between the injury asserted and the injurious conduct alleged for at least one of the
25 plaintiffs, there can be no cognizable claim under RICO. The court will not make the unsupported
26 inference that the individual plaintiffs purchased the drug as a result of defendants' fraudulent
27 conduct. The chasm between plaintiffs' allegations and the legal causes of action under which they
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1 seek relief is simply too wide. Plaintiffs cannot sustain their civil RICO claims based on these
2 allegations.

3 However, the court is well aware that “in the normal course district courts should freely grant
4 leave to amend when a viable case may be presented.” Lipton v. Pathogenesis Corp., 284 F.3d 1027,
5 1038 (9th Cir.2002), citing Fed R. Civ. P. 15(a); Lopez v. Smith, 203 F.3d 1122, 1127 (9th Cir.
6 2000) (leave to amend should be granted unless the district court “determines that the pleading could
7 not possibly be cured by the allegation of other facts”). As such, the court will dismiss the RICO
8 claims without prejudice and permit plaintiffs to file an amended complaint. It would be improper to
9 determine at this stage that plaintiffs cannot cure the aforementioned flaws in their pleading.

10 II. Consumer Protection Claims and Unjust Enrichment

11 Defendants move to dismiss the instant actions for two main reasons: the first goes to the
12 underlying basis of the RICO claims, and the other to the sufficiency of its supporting allegations in
13 pleading fraudulent conduct. With the RICO claims dismissed, the court now considers the second
14 reason in the context of the state law claims and the equitable claim of unjust enrichment.

15 For the reasons described above, plaintiffs have failed to allege that it was defendants’
16 allegedly fraudulent misrepresentations about Actimmune®, rather than the scientific literature or
17 any other factor, that led directly to the plaintiffs injuries. “While a complaint attacked by a Rule
18 12(b)(6) motion to dismiss does not need detailed factual allegations. . . a plaintiff’s obligation to
19 provide the “grounds” of his “entitle[ment] to relief” requires more than labels and conclusions, and
20 a formulaic recitation of the elements of a cause of action will not do.” Twombly, 127 S.Ct. at 1964
21 -1965 (citations omitted). Plaintiffs’ RICO claims have been dismissed because of a failure to do
22 more than formulaically recite an injury that is proximately related to the injurious conduct alleged.

23 However, the proximate cause requirements of RICO are more stringent than those of the
24 laws of most states. See Desiano v. Warner-Lambert Co., 326 F.3d 339, 348 (2d Cir. 2003) (noting
25 that RICO plaintiffs are held to a more stringent showing of proximate cause than would be required
26 at common law), see also Holmes, 503 U.S. at 268-269 (defining the narrow directness requirements
27 under RICO). The legal standard of proximate cause that is relevant to the consumer protection
28 fraud claims before the court, therefore, is not the law of RICO; it is, rather, the laws of the

1 individual states in which plaintiffs reside. Notably, defendants allege that plaintiffs lack standing to
2 assert claims on behalf of the purported Class under the laws of states in which no named plaintiff
3 resides. On that issue, the court agrees with plaintiffs that the class-certification issue is logically
4 antecedent to Article III standing, where the standing concerns “would not exist but for the class-
5 action certification.” Achem Products, Inc. v. Windsor, 521 U.S. 591, 612 (1997). The court
6 focuses its instant inquiry on the standing concerns that presently exist for the individual plaintiffs.

7 Defendants contend that plaintiffs have not alleged causation or reliance to state a claim
8 under the remaining states’ statutes. Defendants argue that plaintiffs rely on vague inferences from
9 behavior that could be interpreted as fraudulent but could equally be interpreted as engaging in
10 competitive business strategy. Defendants contend that the issue of individual prescribing decisions
11 of doctors with access to scientific literature is entirely unaddressed by plaintiffs. Instead,
12 defendants argue that plaintiffs plead a fraud-on-the-market theory, which must fail because the
13 presumption of reliance does not work in non-efficient markets like prescription drug “markets” (if
14 individual patients purchasing drugs prescribed by individual doctors for personalized conditions
15 can even constitute a “market”) and it further fails to distinguish between competitive business
16 practices and fraudulent marketing efforts.

17 First, the court looks askance at any attempt on the part of plaintiffs’ to use a fraud-on-the-
18 market theory to circumvent the reliance element of the state law claims. The court will not let
19 plaintiffs escape their burden to plead and prove the element of reliance by using a market-based
20 fraud theory to handwave the requirement that there be a connection between the misdeed
21 complained of and the loss suffered under state law. As is the case with the RICO claims, even
22 under the more relaxed standard for proximate cause under state law, a fraud-on-the-market theory
23 cannot plead the necessary element of causation because the relationship between defendants’
24 alleged misrepresentations and the purported loss suffered by the patients is so attenuated, at least on
25 the facts alleged, that it would effectively be nonexistent.

26 Second, as discussed *supra*, the mere objective of a company or companies to maximize
27 profits is not in and of itself evidence of fraud. It does not necessarily follow that off-label
28 promotion plus resulting profits equals fraudulent conduct. See supra note 6; see also, In re

1 Orthopedic Bone Screw Prod. Liab. Litig., 159 F.3d 817, 830-31 (3d Cir. 1998) (Cowen, J.,
2 dissenting) (noting that off-label promotion is desirable in cases where patients could benefit from
3 having their doctors know about when and how to use a product for an off-label use), rev'd,
4 Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). Moreover, courts have routinely
5 refused to find promotional marketing of off-label uses fraudulent when they are directed at
6 sophisticated audiences, like physicians. See, e.g., Caronia, 576 F. Supp. 2d at 397-398 (refusing to
7 find defendant's speech inherently misleading when it was directed at physicians, "who are familiar
8 with the FDA-approval process and able to independently evaluate the validity of their claims").
9 Plaintiffs fail to allege that specific representations were made to the individual plaintiffs'
10 physicians, let alone that such representations were misleading.

11 Plaintiffs make tendentious leaps in concluding that defendants marketing efforts are false
12 and misleading simply because defendants presented their drug product in the best light possible.
13 For example, plaintiffs allege that many of the distributed materials promoted Actimmune® for IPF
14 before the Phase III trial had been completed and that they therefore inherently served to advance
15 "false information in the absence of scientific proof." The court disagrees with this contention.
16 There is a clear distinction in the law between puffery and fraud. See, e.g., Newcal Industries, Inc.
17 v. Ikon Office Solution, 513 F.3d 1038, 1053 (9th Cir. 2008) (describing a statement that is
18 quantifiable and makes a claim as to the "specific or absolute characteristics of a product," may be
19 an actionable statement of fact while a general, subjective claim about a product is non-actionable
20 puffery); Pizza Hut, Inc. v. Papa John's Intern., Inc., 227 F.3d 489, 497 (5th Cir. 2000) (holding that
21 statements of fact must be literally false in order for the court to assume they misled consumers).
22 Here, plaintiffs summary assertions that defendants fraudulently misrepresented the scientific
23 literature on Actimmune® are unhelpful in stating any legal claim. They lack the specificity
24 necessary to sustain plaintiffs' private civil fraud claims under consumer protection state statutes.

25 By way of example, plaintiffs contend that, beginning after 1999, InterMune and Harkonen
26 embarked on a campaign to promote Actimmune® to treat IPF and that they "falsely claimed
27 benefits associated with Actimmune® for IPF," "suppressed evidence that Actimmune® was
28 ineffective in treating IPF." The scientific articles relied on in plaintiffs' complaints belie such

1 assertions of misrepresentation and fraud. Those articles suggest at least facially that there are
2 reasons to continue using Actimmune® to treat IPF.

3 Plaintiffs’ allegations underlying the state law fraud claims focus on the generalized nature
4 of defendants’ purportedly deceptive actions, e.g., that defendants promoted the false belief that
5 Actimmune® was effective in treating IPF and that they concealed adverse study results and
6 selectively disclosed positive studies. Genentech argues the scientific literature is mischaracterized
7 in the complaints and that, instead, the literature embodies the rising and falling optimism within the
8 research community regarding the use of Actimmune® in treating IPF. Genentech further argues
9 that the trend line parallels Actimmune® sales from 1999-2007 and there is no reason or plausible
10 basis to infer that defendants engaged in attempts to defraud patients. Plaintiffs argue it is improper
11 to evaluate the substance of the scientific articles on a motion to dismiss. The merits of the scientific
12 studies are not the issue, however. The issue is whether the studies themselves could have provided
13 another basis for physician reliance, apart from the allegedly misleading representations by
14 defendants to physicians. Plaintiffs fail to address this possibility and therefore fail to sufficiently
15 allege that the purportedly fraudulent practices of defendants fostered a belief that Actimmune® was
16 effective in treating IPF and therefore caused physicians to prescribe Actimmune®, resulting in
17 plaintiffs’ harm.

18 The court has already found plaintiffs generalized assertions of fraudulent motive, without
19 more, inadequate to meet the heightened pleading requirements of RICO. See Mazur v. eBay Inc.,
20 2008 WL 2951351, *7 (N.D. Cal. 2008) (Patel, J), citing Twombly, 127 S.Ct. at 1974. Because the
21 pleading does not state with particularized facts that, taken as a whole, raise a strong inference of
22 fraud, they also fail to meet the specificity required by Rule 9(b). As with the RICO claims, here too
23 the court acknowledges that “[d]ismissal without leave to amend is proper only if it is clear . . . that
24 the [claims] could not be saved by any amendment.” Swarz v. KPMG LLP, 476 F.3 756, 760 (9th
25 Cir. 2007), citing Fed R. Civ. P. 15(a). Thus, plaintiffs are permitted leave to amend the complaint
26 to allege specific misrepresentations, subject to the requirements of Rule 9(b). The same applies for
27 plaintiffs’ efforts to seek restitution from defendants under an unjust enrichment theory.

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1 The court grants leave to amend the state law claims and unjust enrichment claims against all
2 defendants, despite the fact that the court rejects plaintiffs’ allegations that the License Agreement
3 between Genentech and Connetics/InterMune on its face reflects an agreement to defraud anyone.
4 The clause upon which plaintiffs rely to allege that Genentech knew or should have known of the
5 allegedly fraudulent marketing practices is no more than a standard due diligence clause. It does not
6 impose requirements on the licensor to provide feedback or otherwise participate to any extent in the
7 purportedly fraudulent conduct. Knowledge alone of someone else’s fraud cannot sustain state-
8 based consumer protection or fraud claims against the nonparticipant. However, the Ninth Circuit
9 has held that when a complaint specifically alleges that a party knew about the fraud, participated in
10 gathering profits from the fraud, and actually profited from the fraud, its specific intent can be
11 inferred. See, e.g., Newcal Industries, Inc. v. Ikon Office Solution, 513 F.3d 1038, 1056 (9th Cir.
12 2008) (reversing a dismissal that Newcal failed to allege its fraud allegations with sufficient
13 particularity and holding that specific intent can be inferred when a party knew about the fraud and
14 actively profited from the fraud).

15 Therefore, the court will not dismiss all claims against Genentech with prejudice. Plaintiffs
16 are allowed to amend the complaint to allege further facts as to the forms of misrepresentation and
17 deception in which Genentech purportedly engaged, such as to meet the Newcal standard. The court
18 advises plaintiffs to focus on state law claims in this state and the other states where the named
19 plaintiffs reside.

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1 CONCLUSION

2 The court **GRANTS** the parties' joint motion to adopt defendants' motions to dismiss,
3 opposition and reply briefs from related cases. The moving papers for civil cases 08-2376, 08-2916
4 and 08-3797 are deemed filed in civil action 08-4531. This order applies in all four cases.

5 The court **GRANTS** defendants' motions to dismiss the complaints in their entirety. All
6 claims—the RICO claims, the state law claims and the unjust enrichment claims—are dismissed
7 without prejudice and with leave to amend as described above. Amended complaints, if any, shall
8 be filed within thirty (30) days of the date of this order. Answers or other responses should be filed
9 within thirty (30) days of the filing of the amended complaints.

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11 IT IS SO ORDERED.

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13 Dated: April 28, 2009

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MARILYN HALL PATEL
United States District Court Judge
Northern District of California

ENDNOTES

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2 1. When the FDA approves a drug for a particular use or “indication,” that indication will be included
3 on the drug’s label or package insert and the drug may be marketed for that indication. See 21 U.S.C.
4 § 355(b)-(d). Physicians, however, may lawfully prescribe a drug for “off-label” indications to achieve
5 therapeutic goals other than those for which the drug was approved. See In re Amgen Inc. Sec. Litig.,
544 F.Supp.2d 1009, 1021 n.2 (C.D. Cal. 2008). It is unlawful to market, advertise or otherwise
6 promote the off-label use of the drug. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99.

7 2. In ruling on a motion to dismiss, a district court generally “may not consider any material beyond
8 the pleadings.” Branch v. Tunnell, 14 F.3d 449, 453 (9th Cir.1994). However, a court ruling on a
9 motion to dismiss may consider the full texts of documents which the complaint quotes only in part.
10 Cooper v. Pickett, 137 F.3d 616, 623 (9th Cir. 1997).

11 3. Whether this recitation that Connetics shall “*make, use, sell*” Licensed Products is consistent with
12 the earlier provision granting Connetics the license to “*use, sell. . . (but not make or have made)*” has
13 not been placed at issue by the instant motions before the court.

14 4. The court gives no credence to plaintiffs’ argument that defendants have improperly raised their
15 standing arguments in the context of a Rule 12(b)(1) motion to dismiss for lack of subject matter
16 jurisdiction and not under Rule 12(b)(6) for failure to plead RICO causation. The court finds that
17 defendants properly moved to dismiss the complaint for failure to state a claim for violation of RICO
18 due to defects in standing, namely, for failure to allege causation. The Table of Contents and first page
19 of InterMune’s Motion to Dismiss make this clear. See, Motion to Dismiss filed by InterMune, Docket
20 No. 71.

21 5. The purported harm here is that plaintiffs sustained a monetary loss only, as no harmful side effects
22 of the drug were alleged.

23 6. Moreover, off-label marketing of an approved drug is itself not inherently fraudulent. See, e.g., In
24 re Epogen & Aranesp Off-Label Marketing & Sales Practices Litigation, 2008 WL 5335062 (C.D. Cal.
25 2008); citing U.S. v. Caronia, 576 F.Supp.2d 385, 397 (E.D.N.Y. 2008) (“Promotion of off-label uses
26 is not inherently misleading simply because the use is off-label”); Washington Legal Found. v.
27 Friedman, 13 F.Supp.2d 51, 67-68 (D.D.C. 1998) (observing that claims made about the effectiveness
28 of prescription drugs are not inherently misleading merely because they were neither made by scientists
or academics nor evaluated by the FDA), vacated in part, 202 F.3d 331 (D.C. Cir. 2000); United States
v. Caputo, 288 F. Supp. 2d 912, 921 (N. D. Ill. 2003) (noting that the sophistication of the audience to
whom off-label uses are promoted should be taken into account when evaluating the legitimacy of such
promotion).

7. The court recognizes this may not be an easy task. See, e.g., Ironworkers Local Union No. 68 v.
AstraZeneca Pharm.L.P., 585 F.Supp.2d 1339, 1344 (M.D. Fla. 2008) (dismissing civil RICO claims
for lack of causation, noting that “establishing that Plaintiffs’ injuries were caused by Defendants’
misconduct would require an inquiry into the specifics of each doctor-patient relationship implicated
by the lawsuit . . . each physician who prescribed [the drug at issue] to an individual consumer . . .
would have to be questioned as to whether his or her independent medical judgment was influenced by
Defendants’ misrepresentations, and to what extent.”) However, as noted by the Ironworkers court, the
Supreme Court has held that detrimental reliance by a plaintiff is not required to sustain a RICO claim
predicated on mail fraud. See Bridge, 128 S.Ct. at 2141-44 (ruling that plaintiffs can recover for injuries
resulting from defendant’s fraudulent misrepresentations to “someone” and first-party reliance is neither
a required element of a civil RICO claim nor a prerequisite to establishing proximate cause.)