UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ACTIMMUNE MARKETING LITIGATION

No. C 08-02376 MHP

MEMORANDUM & ORDER

Re: Defendants' Motions to Dismiss Plaintiffs Jarrett, Isenhower, Rybkoski and Stevens' Third Amended Complaint and GEHA's Second Amended Complaint, and Plaintiffs' Motion for Leave to File a Fourth Amended Complaint

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In this proposed nationwide class action, consumer plaintiffs Deborah Jane Jarrett ("Jarrett"), Nancy Isenhower ("Isenhower"), Jeffery Frankel ("Frankel"), Linda Rybkoski ("Rybkoski") and Joan Stevens ("Stevens"), along with third-party payor ("TPP") plaintiff Government Employees Health Association, Inc. ("GEHA") (collectively "plaintiffs"), filed suit against defendants InterMune, Inc. ("InterMune"), Dr. W. Scott Harkonen ("Harkonen") and Genentech, Inc. ("Genentech") (collectively "defendants"). Plaintiffs allege that defendants illegally marketed the drug Actimmune (interferon gamma-1b) to individuals afflicted with and to doctors who treat patients suffering from idiopathic pulmonary fibrosis ("IPF"), a painful disease of the lungs without a known cure, even though Actimmune was not approved by the Food and Drug Administration ("FDA") to treat IPF and defendants knew that Actimmune was not effective to treat IPF.

Initially, plaintiffs asserted a variety of fraud-based causes of action, primarily under California law. Upon motions by the defendants, in April 2009, the court dismissed plaintiffs original complaint, without prejudice and in its entirety, for failure to allege defendants' fraudulent

scheme with the particularity required by Federal Rule of Civil Procedure 9(b). *See In re Actimmune Marketing Litig.*, 614 F. Supp. 2d 1037 (N.D. Cal. 2009) (*Actimmune I*). Plaintiffs filed an amended complaint, which defendants again moved to dismiss. In November 2009, the court dismissed all of plaintiffs' fraud-based claims with prejudice. *See In re Actimmune Marketing Litig.*, No. C 08-02376 MHP, 2009 WL 3740648 (N.D. Cal. Nov. 6, 2009) (Patel, J.) (*Actimmune II*). In *Actimmune II*, the court provided plaintiffs with a final opportunity to amend claims asserted under the unfair and unlawful prongs of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200, so that they might adequately allege non-fraudulent unfair competition. The court also provided GEHA and defendants with the opportunity to simultaneously brief whether GEHA's allegations stated a claim under Missouri's Merchandising Practices Act (MMPA), Mo. Rev. Stat. § 407.010.

Now before the court are separate motions filed by each of the three defendants to dismiss the remaining causes of action, as well as the consumer plaintiffs' motion for leave to file a fourth amended complaint. Having considered the parties' submissions and arguments and for the reasons set forth below, the court enters the following memorandum and order.

BACKGROUND

I. Factual Allegations

The allegations in this case have been discussed, at length, on two occasions by this court. *See Actimmune II*, 2009 WL 3740648, at *1-5; *Actimmune I*, 614 F. Supp. 2d at 1040-46. The court will not recount the facts for a third time, especially because the central allegations in this action—Genentech's development of Actimmune, the FDA's approval of Actimmune as a treatment for diseases other than IPF, InterMune's purchasing of the rights to develop and market Actimmune, the studies that InterMune conducted to determine whether Actimmune was an effective treatment for IPF, the results of and the articles published about those studies, the representations that InterMune made to doctors, investors and the public regarding Actimmune's efficacy in treating IPF, and the FDA's ultimate refusal to allow InterMune to continue to test Actimmune as a treatment for

IPF—are unchanged. Similarly, the averments regarding when and why plaintiffs decided to take Actimmune to treat their IPF, both in terms of their substance and specificity, have not been altered. What has been added in the amended complaints is detail regarding plaintiffs' non-fraudulent theories of recovery under the UCL's unfair and unlawful prongs. The court discusses these changes below.

II. Procedural History

This action consolidated four separate actions against defendants filed in this district: (1) a suit by Frankel, Isenhower, and Jarrett, 08-2376; (2) a suit by Rybkoski, 08-2916; (3) a suit by Zurich American Insurance Company ("Zurich"), 08-3797 (which Zurich has since voluntarily dismissed, Docket No. 110); and (4) a suit by GEHA, 08-4531. The first three actions were related on September 5, 2008, and Frankel, Isenhower, Jarrett, Rybkoski and Zurich filed a combined first amended complaint ("FAC") on September 21, 2008. Docket Nos. 60, 63. The defendants moved to dismiss the three related actions on October 20, 2008, before GEHA's suit was related on December 12, 2008. Docket Nos. 67, 69, 71, 80. In order to avoid duplicate efforts, the court then granted defendants' motion for the court to apply defendants' arguments for dismissal in the three related cases against GEHA's complaint. Docket No. 100. The primary substantive difference between the FAC and GEHA's initial complaint was that in GEHA's complaint, Genentech was only named as a defendant in the unjust enrichment cause of action.

In *Actimmune I*, the court dismissed without prejudice the claims of the plaintiffs in all four related actions. In an effort to comply with the court's order, Frankel, Isenhower, Jarrett, Rybkoski and Zurich filed a second amended complaint ("SAC"), Docket No. 101, and GEHA filed its first amended complaint ("GEHA's FAC"), Docket No. 102. The SAC added Stevens as an additional plaintiff. The SAC and GEHA's FAC asserted five identical claims: Count I, for violations of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200 *et seq.*; Count II, for violations of California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500 *et seq.*; Count III, for violations of California's Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750 *et seq.*; Count IV for violations of consumer protection statutes in 39 states other than

California; and Count V for unjust enrichment. In the SAC, Frankel, Jarrett, Isenhower, Stevens and Rybkoski brought Counts I though IV against all three defendants and Count V against only InterMune and Genentech; in GEHA's FAC, it brought Counts I through IV against only InterMune and Harkonen and Count V against InterMune and Genentech. Thus, as with the first set of pleadings, the primary substantive difference between the complaints was that GEHA's FAC only named Genentech as a defendant in Count V for unjust enrichment.

In *Actimmune II*, the court dismissed all of the claims in both complaints because plaintiffs failed to satisfy the heightened pleading requirement of Rule 9(b) for claims that "sound in fraud." Despite the myriad claims being prosecuted by plaintiffs, the SAC and GEHA's FAC essentially relied upon a single, paradigmatically fraud-based theory of causation and injury: Plaintiffs were injured when they justifiably relied, to their detriment, upon defendants' knowing misrepresentations regarding the efficacy of Actimmune as a treatment for IPF. Although the SAC identified particular false statements made by defendants about Actimmune's efficacy, plaintiffs' complaints lacked specific factual allegations "connecting the doctors' alleged beliefs that Actimmune was efficacious for the treatment of IPF to some fraudulent representation or omission made by InterMune." *Actimmune II*, 2009 WL 3740648, at *11.

Because of the shortcomings in the pleadings, the court dismissed with prejudice all claims under the UCL's fraudulent prong, the FAL, the CLRA, the consumer protection statutes of Alaska, Arkansas, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Maryland, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin, and for unjust enrichment. The court also dismissed Jarrett, Isenhower, Frankel, Rybkoski and Stevens's claims under the Missouri consumer protection statute with prejudice. Dismissal with prejudice was in order both because plaintiffs had already been provided with an opportunity to amend their fraud-based claims and because most of

the facts necessary for the submission of legally adequate complaints were within the possession of plaintiffs and their doctors.

On the face of GEHA's FAC, it appeared that GEHA, as a Missouri resident, might be able to state a claim under the MMPA. However, because neither party had briefed the issue in any detail, the court ordered additional simultaneous briefing with respect to whether GEHA's claims under the MMPA should be dismissed.

Finally, the court dismissed without prejudice plaintiffs' claims under the UCL's unfair and unlawful prongs. The court instructed plaintiffs that in order for the amended complaint to survive dismissal, it

> must (1) state a claim under the unfair prong, clearly identify[ing] the 'legislatively declared policy' that defendants' conduct contravened, and, (2) state a claim under the unlawful prong, clearly identify[ing] the specific statutory and/or regulatory provisions they allege that InterMune and Harkonen violated. Plaintiffs must also allege exactly how they were injured "as a result of" InterMune and Harkonen's unfair and/or unlawful conduct. They shall not, however, couch their UCL claims on a theory of fraud . . . .

Id. at 19. The court also explained that in order "[t]o establish aiding and abetting liability with respect to Genentech, plaintiffs should carefully aver how Genentech had 'actual knowledge' of and provided 'substantial assistance' to InterMune and Harkonen's unfair or unlawful conduct." *Id.*

On December 23, 2009, Frankel, Jarrett, Isenhower, Stevens and Rybkoski filed their third amended complaint ("TAC") and GEHA filed its second amended complaint ("GEHA's SAC"). Docket Nos. 132, 133. With very few exceptions, which the court will note where relevant, the factual allegations in the TAC and GEHA's SAC are identical; to avoid confusion, the court will refer and cite to a single complaint, the TAC, throughout this order. Plaintiffs revised the complaint with *Actimmune II* in mind, seeking to plead sufficient, non-fraudulent conduct by defendants to state a claim under the UCL's unfair and unlawful prongs. In some respects, particularly with regard to the manner in which plaintiffs explained the bases for their unfair and unlawful claims, plaintiffs made substantial revisions. *See* TAC ¶¶ 198-221. In other respects, plaintiffs' changes were merely cosmetic, replacing words that were evocative of fraud—fraud, fraudulent, false, deceptive and misleading—with the words "unlawful" and "unfair." In addition, the complaint realleged the

causes of action that had previously been dismissed with prejudice in order to preserve review of their dismissal on appeal.

Defendants then moved, for the third time, for the dismissal of plaintiffs' action. Defendants argue that dismissal of the UCL claims was required for at least three reasons. Firstly, as they had done in their previous motions to dismiss, defendants suggest that under any pleading standard, plaintiffs had failed to allege sufficient facts to establish either constitutional or statutory standing. Specifically, defendants assert that plaintiffs' complaint still lacks essential allegations linking defendants' unfair and unlawful conduct to the decisions, made by plaintiffs and their doctors, to take Actimmune. Secondly, defendants argue that even if plaintiffs have standing, Jarrett, Isenhower, Stevens and Rybkoski failed to file their actions within the relevant four-year statute of limitations for suits under the UCL. Finally, defendants assert that even if plaintiffs have standing and filed timely complaints, various substantive legal barriers preclude plaintiffs from asserting their UCL claims.

All three defendants additionally argue that GEHA, as a corporation, is not permitted to bring suit under the MMPA.

Finally, Genentech asserts that, even if plaintiffs state a claim for relief against InterMune and Harkonen, the factual allegations in the TAC are insufficient to support either direct or aiding and abetting liability against Genentech.

After the filing of defendants' motion to dismiss, plaintiffs filed a statement noting Frankel's death after a long battle with IPF. Docket No. 151. Frankel's heirs decided not to open a probate estate, making it impossible for them to pursue a claim in his name, and necessitating the withdrawal of his claims.

LEGAL STANDARD

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

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) tests the subject matter jurisdiction of the court. *See, e.g., Savage v. Glendale Union High Sch.*, 343 F.3d 1036, 1039-40

(9th Cir. 2003). Under Article III of the Constitution, federal judicial power extends only to "Cases" and "Controversies." U.S. Const., art. III, § 2, cl. 1. Article III standing is thus a threshold requirement for federal court jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559-60 (1992). At a constitutional minimum, standing requires the party invoking federal jurisdiction to show that it has "suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant, and that the injury can be traced to the challenged action and is likely to be redressed by a favorable decision." *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982) (citations and internal quotation marks omitted). To satisfy the injury in fact requirement, the alleged harm must be "an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (citations and internal quotation marks omitted). The party invoking federal jurisdiction bears the burden of establishing these elements. *Id.* at 561.

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

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint may be dismissed against a defendant for failure to state a claim upon which relief can be granted against that defendant. A motion to dismiss under Rule 12(b)(6) "tests the legal sufficiency of a claim." *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). Dismissal may be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory. *Balistreri v. Pacifica Police Dep't.*, 901 F.2d 696, 699 (9th Cir. 1988). A motion to dismiss should be granted if a plaintiff fails to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 569 (2007). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, ___ U.S. ___, ___, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 556).

Allegations of material fact are taken as true and construed in the light most favorable to the non-moving party. *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337-38 (9th Cir. 1996). The court need not, however, accept as true pleadings that are no more than legal conclusions or the "formulaic

recitation of the elements" of a cause of action. *Iqbal*, 129 S. Ct. at 1950; *see also Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001); *Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994). "Determining whether a complaint states a plausible claim for relief . . . [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 129 S. Ct. at 1950.

DISCUSSION

I. Motion to Dismiss

A. The UCL Claims

The UCL prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising . . . ." Cal. Bus. & Prof. Code § 17200. Because section 17200 is written in the disjunctive, "a business act or practice need only meet one of the three criteria—unlawful, unfair, or fraudulent—to be considered unfair competition under the UCL." *Daro v. Superior Court*, 151 Cal. App. 4th 1079, 1093 (2007). The court previously dismissed, with prejudice, all of plaintiffs' claims under the fraudulent prong of the UCL. Thus, all that remains for the court to consider are the amended claims brought by plaintiffs pursuant to the unlawful and unfair prongs of the UCL.

1. The Unlawful Prong

As the court recounted in *Actimmune II*, "[u]nder its 'unlawful' prong, the UCL borrows violations of other laws . . . and makes those unlawful practices actionable under the UCL." *See Berryman v. Merit Prop. Mgmt.*, 152 Cal. App. 4th 1544, 1554 (2007) (internal quotation marks and citation omitted; alteration in original). "Thus, a violation of another law is a predicate for stating a cause of action under the UCL's unlawful prong." *Id.*; *see Smith v. State Farm Mut. Auto. Ins. Co.*, 93 Cal. App. 4th 700, 717-18 (2001) (holding the unlawful prong forbids "anything that can be properly called a business practice and that at the same time is forbidden by law").

In *Actimmune II*, the court dismissed plaintiffs' unlawful-prong claims because plaintiffs' SAC—while alluding vaguely to violations of the CLRA, the Food, Drug and Cosmetics Act

("FDCA") and Federal Trade Commission ("FTC") and FDA regulations—failed to identify any specific statutory or regulatory provisions that defendants' conduct violated. *Actimmune II*, 2009 WL 3740648, at *15. Without knowing which provisions were at issue, it was impossible to determine whether the SAC stated a "plausible" claim for relief. Because the complaint did not satisfy even Federal Rule of Civil Procedure 8(a), dismissal of the claims without prejudice was appropriate.

In the TAC, plaintiffs now allege that defendants violated various federal and state statutory provisions, including the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733; the FDCA, 21 U.S.C. § 331(k)-(n) & 360aaa-6; and California's Sherman Food, Drug, and Cosmetic Laws ("the Sherman Laws"), Cal. Health & Safety Code §§ 110390, 110403, 110405, 11450, 11398 & 111330. With the exception of the False Claims Act allegations, the statutory provisions relate, as best as can be discerned, to the off-label marketing of Actimmune, that is defendants' promotion of Actimmune as a treatment for indications for which it had not been approved by the FDA. The court addresses these off-label marketing allegations first.

i. Off-label Marketing

Defendants contend that plaintiffs lack standing to assert any UCL unlawful-prong claims predicated upon violations of the FDCA or the Sherman Laws. As will be explained below, despite the additional allegations included in plaintiffs' amended pleadings, plaintiffs still fail to properly allege that defendants' conduct caused plaintiffs' injuries. Therefore, plaintiffs lack standing to pursue their off-label marketing claims under the UCL's unlawful prong.

a. The Elements of a Prima Facie Claim Under the UCL's Unlawful Prong

After the California voters approved of Proposition 64 in 2004, a private individual only has standing to pursue a UCL claim, on behalf of himself or others, if he "has suffered injury in fact and has lost money or property *as a result of* the unfair competition." Cal. Bus. & Prof. Code § 17204 (emphasis added). In the context of an unlawful-prong claim, a plaintiff must establish that a defendant engaged in unlawful conduct, i.e., violated a federal, state or municipal statute, ordinance

or regulation, and that, as a result of the defendant's unlawful conduct, the plaintiff "suffered an injury in fact and has lost money or property . . . ."

The FDCA, through a convoluted series of statutory provisions and regulations, makes it unlawful for any person to advertise, promote or market a drug off-label.

> The FDCA prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). Further, it prohibits the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded." 21 U.S.C. § 331(k) (emphasis added). Pursuant to 21 U.S.C. § 352(f), a drug is "misbranded" if its labeling does not bear "adequate directions for use." FDA regulations provide that "adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended[,]" 21 C.F.R. § 201.5, and further provide that a drug's "intended use" is determined by considering the "objective intent of the persons legally responsible for the labeling of the drugs[,]" as evidenced by the "labeling claims, advertising matter, or oral or written statements by such persons or their representatives." 21 C.F.R. § 201.128; *see also Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir.1980) ("[I]t is well established that the 'intended use' of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source.") (internal citations and quotation marks omitted). Consequently, if a manufacturer or its representatives promote the "off-label" use of a drug, then the drug's labeling will not bear adequate directions for the "purposes for which it is intended", and the drug will be considered to be "misbranded".

United States v. Caronia, 576 F. Supp. 2d 385, 389 n.2 (E.D.N.Y. 2008). A person found to have violated section 331 is guilty of a misdemeanor, 21 U.S.C. § 333(a)(1); an individual who violates section 331 for the second time or who violates the statute "with intent to defraud or mislead," is guilty of a felony, 21 U.S.C. § 333(a)(2).

Critically, in order to establish a misdemeanor misbranding violation, the government need not adduce any evidence that the individual or entity that promoted the product off-label did so with an intent to defraud. "An article may be misbranded pursuant to the misdemeanor provision 'without any conscious fraud at all,' thus creating a form of strict criminal liability." *United States v. Watkins*, 278 F.3d 961, 964 (9th Cir. 2002) (quoting *United States v. Dotterweich*, 320 U.S. 277, 281 (1943)). Thus, it is sufficient that the government can establish that the product was promoted for a purpose for which it did not display an approved label.

California's Sherman Food, Drug, and Cosmetic Laws also prohibits off-label marketing of pharmaceuticals, as well as additional conduct in which plaintiffs allege that defendants engaged. As with the 21 U.S.C. section 331 of the FDCA, the Sherman Laws make it unlawful "for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded." Cal. Health & Safety Code § 111440; *see also* Cal. Health & Safety Code § 111450 ("It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device."). The same statutory scheme also makes "[i]t . . . unlawful for any person to advertise any . . . drug . . . that is . . . misbranded." Cal. Health & Safety Code § 110398.[1] As with the FDCA, a drug is misbranded if "its labeling is false or misleading in any particular," Cal. Health & Safety Code § 111330, and/or if the drug's labeling does not bear "adequate directions for use." Cal. Health & Safety Code § 111375. Further, under the Sherman Laws, it is also "unlawful for any person to disseminate any false advertisement of any . . . drug . . . ." Cal. Health & Safety Code § 110390. An advertisement is false "if it is false or misleading in any particular." *Id.*

As with the federal criminal enforcement of the FDCA, the Sherman Laws regulating the misbranding and false advertisement of drugs impose strict liability on violators. *See People v. Stuart*, 47 Cal. 2d 167, 172 (1956) ("Because of the great danger to the public health and safety that the preparation, compounding, or sale of adulterated or misbranded drugs entails, the public interest in demanding that those who prepare, compound, or sell drugs make certain that they are not adulterated or misbranded, . . . [makes it necessary to impose] strict liability to prevent the escape of great numbers of culpable offenders . . . .").

Establishing that a defendant violated a law only accomplishes half of a plaintiff's burden in a UCL unlawful prong action. If plaintiffs, here, can make out a violation of the FDCA or the Sherman Laws, plaintiffs would then be required to prove that they were injured "as a result of" defendants' law-violating conduct. In the context of the instant case, the "as a result of" language places the burden on plaintiffs to establish that they actually relied upon the representations delivered through defendants' off-label marketing.

The California Supreme Court, in its seminal decision, *In re Tobacco II Cases*, made clear that for claims under the UCL's fraudulent prong, a plaintiff must allege "actual reliance" in order to establish standing. 46 Cal. 4th 298, 326 (2009) (*Tobacco II*) (holding that the "as a result of language" in the UCL "imposes an actual reliance requirement on plaintiffs prosecuting a private enforcement action under the UCL's fraud prong."). *Tobacco II* left some doubt as to whether the "actual reliance" requirement would apply to all UCL claims, including those brought under the unlawful and unfair prongs. *See id.* at 235 n.17 ("We emphasize that our discussion of causation in this case is limited to such cases where, as here, a UCL action is based on a fraud theory involving false advertising and misrepresentations to consumers. . . . There are doubtless many types of unfair business practices in which the concept of reliance, as discussed here, has no application."). Since *Tobacco II*, at least one California Court of Appeal and one federal district court have held that a plaintiff must plead "actual reliance," even if their claim arises under the unlawful or unfair prongs, so long as the pleadings assert a cause of action grounded in misrepresentation or deception. *See Durell v. Sharp Healthcare*, 183 Cal. App. 4th 1350, 1363 (2010) ("Construing the phrase 'as a result of' in Business and Professions Code section 17204 in light of Proposition 64's intention to limit private enforcement actions under the UCL, we conclude the reasoning of *Tobacco II* applies equally to the 'unlawful' prong of the UCL when, as here, the predicate unlawfulness is misrepresentation and deception."); *see also Carney v. Verizon Wireless Telecomm'cns, Inc.*, 2010 WL 1947635, at *3 (S.D. Cal. May 13, 2010) (holding that "for UCL claims based on misrepresentations, the plaintiff must show actual reliance regardless of whether the claim arises under the 'unfair,' 'unlawful' or 'fraudulent' prong of the UCL"). Importantly, however, "[a] consumer's burden of pleading causation in a UCL action should hinge on the nature of the alleged wrongdoing rather than the specific prong of the UCL the consumer invokes." *Durell*, 2010 WL 1529322, at *6.

In the TAC, plaintiffs plainly allege that defendants marketed Actimmune for the treatment of IPF, even though Actimmune was not approved by the FDA for that purpose, in violation of the FDCA and Sherman Laws. In the context of pharmaceuticals, marketing is no different from

advertising in that it involves the dissemination of a message with the intent of raising awareness about and potentially convincing consumers to purchase a product. Because this case, as in *Tobacco II*, *Durell* and *Laster*, involved representations intended to persuade a consumer to purchase a product, the court holds that plaintiffs must plead actual reliance in order to establish their standing under the UCL.

Accordingly, the elements that comprise plaintiffs' unlawful-prong claims are: (1) a violation of the FDCA and/or the Sherman Laws, namely off-label marketing of Actimmune; (2) actual reliance upon the off-label marketing; and (3) injury.

b. Pleading Standard

Having determined the elements of plaintiffs' off-label marketing unlawful-prong claims, the court must determine what pleading standard—the notice pleading standard under Rule 8(a) or the heightened pleading standard under Rule 9(b)—should be applied to plaintiffs' complaint. Ordinarily a plaintiff must only satisfy Rule 8(a)'s notice pleading standard, which requires that a plaintiff's complaint provide a short and plain statement of a plausible entitlement to relief. Fed. R. Civ. Proc. 8(a). However, where a plaintiff's allegations "sound in fraud," a complaint must meet Rule 9(b)'s heightened pleading standard, *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103 (9th Cir. 2003), which requires that the circumstances constituting fraud be pled with particularity, Fed. R. Civ. P. 9(b). "Rule 9(b) demands that the circumstances constituting the alleged fraud 'be specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just deny that they have done anything wrong.' " *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (quoting *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001)) (some quotation marks omitted). To satisfy Rule 9(b), plaintiffs must explicitly aver "the who, what, when, where, and how" of the alleged fraudulent conduct. *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997). In addition, plaintiffs must "set forth an explanation as to why [a] statement or omission complained of was false and misleading." *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc); *see Fecht v. Price Co.*, 70 F.3d 1078, 1082 (9th Cir. 1995).

In California, the elements of fraud are: " '(a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or 'scienter'); (c) intent to defraud, i.e., to induce reliance; (d) justifiable reliance; and (e) resulting damage.' " *Kearns*, 567 F.3d at 1126 (quoting *Engalla v. Permanente Med. Group, Inc.*, 15 Cal. 4th 951, 974 (1997)). In order to establish violations of the above-discussed provisions of the FDCA and the Sherman Laws, plaintiffs would be required to prove only three of those elements—misrepresentation, reliance and damages.[2] However, because the FDCA and Sherman Laws impose strict liability on those who promote drugs off-label, and in the case of the Sherman Laws, those who falsely advertise a drug, plaintiffs would be absolved from having to establish scienter and an intent to defraud, the two pivotal elements of fraud. Accordingly, plaintiffs' off-label marketing claims do not "sound in fraud," and plaintiffs' averments that rely on the FDCA and Sherman Laws need only satisfy Rule 8(a), not Rule 9(b).[3]

c. The Allegations in the TAC

Even with the benefit of the lower pleading standard under Rule 8(a), plaintiffs have failed to adequately allege causation, and therefore lack constitutional and statutory standing for their UCL claims predicated on defendants' off-label marketing of Actimmune. Although plaintiffs may be relieved of alleging the specific "who, what, when, where, and how" of the elements of UCL claims, they still must allege a plausible entitlement to relief, including a plausible causal chain of injury. *See Iqbal*, 129 S. Ct. at 1949; *Twombly*, 550 U.S. at 569. A review of the amended pleadings specific to each plaintiff demonstrates that none of them have done so.

The shortcoming in the consumer plaintiffs' pleadings is simple: all of the consumer plaintiffs fail to allege that their doctors believed that Actimmune was an effective treatment for IPF "as a result of" defendants' off-label promotion of Actimmune. With respect to each plaintiff, the TAC alleges, in the most general of terms, that their doctors were "exposed to at least some of InterMune's unfair and unlawful off-label marketing." SAC ¶¶ 177 (Frankel's doctor), 179 (Eisenhower's doctor), 180 (Rybkoski's doctor), 185 (Jarrett's doctor), 186 (Stevens' doctor). Eisenhower and Stevens go so far as to allege that their doctors "believed Actimmune was efficacious," TAC ¶ 179, 186; Jarrett and Rybkoski's claims contain no similar allegation, *see* TAC

¶¶ 180-85. Crucially, however, none of the plaintiffs allege that their doctors believed that Actimmune was an effective treatment for IPF "as a result of" the marketing information conveyed by defendants. For this causal leap, plaintiffs appear to rely upon an identical allegation included in all of their claims: that their doctors, "like virtually all pulmonologists in the country who prescribed Actimmune for IPF patients, did so in substantial part because of Defendants' unfair and unlawful marketing." TAC ¶¶ 177-86. Such pleadings are merely formulaic recitations of the elements of the cause of action, and thus must be disregarded by the court. Therefore, even under Rule 8(a), plaintiffs allegations insufficiently aver causation.

GEHA's complaint fails to state a claim for a slightly different, but related reason. GEHA's SAC adequately alleges that the doctors relied upon information about Actimmune disseminated by defendants when deciding to write prescriptions for GEHA members suffering from IPF. GEHA's SAC ¶ 174 ("At least ten of the 50 pulmonologists who prescribed Actimmune for GEHA's members . . . relied on information they received from InterMune in making the decision to prescribe Actimmune for the treatment of IPF."). However, the complaint fails entirely to allege that the information was disseminated through defendants' unlawful behavior, i.e. off-label marketing. In fact, the complaint avers exactly the opposite: that the pulmonologists received information about Actimmune's efficacy in treating IPF through perfectly legitimate channels of communication. *See id.* (describing how the pulmonologists "worked directly with InterMune on Actimmune matters"); *id.* ¶ (explaining how the pulmonologists at issue "either consulted for InterMune, participated in the [clinical] trial [for IPF], or are affiliated with the Coalition for Pulmonary Fibrosis, the entity started by InterMune in order to . . . advocate the prescription of Actimmune for the treatment of IPF"). The absence of any allegations linking defendants' off-label marketing of Actimmune to doctors' decisions to prescribe Actimmune for patients with IPF dooms GEHA's claims.

Because all of the plaintiffs have failed to adequately plead causation, they lack standing to pursue any UCL unlawful claims predicated on defendants' alleged violations of the FDCA and the Sherman Laws. Accordingly, defendants' motion to dismiss all such claims is GRANTED.

ii. False Claims Act

Plaintiffs' unlawful-prong claims based upon defendants' alleged violations of the False Claims Act (FCA), 31 U.S.C. § 3729-33, require far less discussion. Whether an FCA claim is brought by the government or as a *quit tam* action, the prosecuting entity must establish that the defendant defrauded the United States government by submitting a false claim. 31 U.S.C. § 3729. Although plaintiffs have submitted sufficient allegations to support an inference that defendants violated the FCA, plaintiffs have included no allegations regarding how they were injured "as a result of" that conduct. As is discussed above at length, a claim under the UCL requires that a plaintiff establish that he "has suffered injury in fact and has lost money or property *as a result of* the unfair competition." Cal. Bus. & Prof. Code § 17204 (emphasis added). As defendants explain, "plaintiffs do not allege a single fact connecting their alleged injury in paying for Actimmune to treat IPF to the submission of allegedly false claims to government payors." Docket No. 160 (InterMune's Reply) at 19. Nor have plaintiffs provided any explanation in their moving papers regarding how defendants' allegedly FCA-breaching conduct caused them injury. Accordingly, defendants' motion to dismiss plaintiffs' claims under the unlawful prong of the UCL predicated on the FCA is GRANTED.

2. The Unfair Prong

As the court recounted in *Actimmune II*, "there is some uncertainty about the appropriate definition of the word 'unfair' " in the UCL. *Camacho v. Auto. Club of S. Cal.*, 142 Cal. App. 4th 1394, 1400 (2006). There was no uncertainty in *Actimmune II*, however, regarding whether plaintiffs would be permitted to replead unfair conduct that sounded in fraud. As the court explained, in the SAC, "plaintiffs' unfair prong claims overlap[ped] entirely with their claims of fraud." *Actimmune II*, 2009 WL 3740648, at *14. The court dismissed the unfair-prong claims because of plaintiffs' failure to plead allegations of fraudulent conduct with the specificity necessary to satisfy Rule 9(b). The court then explained to plaintiffs that in amended pleadings, plaintiffs "shall not . . . couch their UCL claims on a theory of fraud; all such claims are dismissed from this action with prejudice." *Id.* at *19.

All of plaintiffs' amended allegations fail to heed the court's instructions, and must therefore be dismissed with prejudice. Over and over again, plaintiffs complain that defendants' conduct was unfair because they knew that Actimmune was ineffective in treating IPF, but nonetheless represented to doctors and patients suffering from IPF that Actimmune could effectively treat IPF. *See, e.g.*, TAC ¶¶ 203 ("Defendants [sic] business practices were immoral, unethical, oppressive, and unscrupulous because: (I) Defendants marketed Actimmune for the treatment of IPF knowing that Actimmune was not proven effective in the treatment of IPF . . . ; and (vi) Defendants continued the marketing knowing all of the above, solely motivated to gain significant profits at the expense of persons suffering usually terminal illness."); 204 (exact same allegation); 205 (same); 206 (same). Such allegations are quintessential examples of fraud. Moreover, as is discussed above, plaintiffs have failed to allege that any of defendants' conduct—unfair or unlawful—actually caused doctors to prescribe Actimmune for patients suffering from IPF. Accordingly, defendants' motion to dismiss plaintiffs' claims under the UCL unfair prong is GRANTED.[4]

B. The MMPA

In *Actimmune II*, the court stated that GEHA's FAC "appear[ed] to state a claim under Missouri's Merchandising Practices Act ([M]MPA)." In making that statement, the court relied primarily upon the extraordinarily low showing of causation required under the MMPA. *See Collora v. R.J. Reynolds Tobacco Co.*, No. 002-00732, 2003 WL 23139377, at *2 (Mo. Cir. Ct. Dec. 31, 2003) ("[A] plaintiff must show that he purchased a product that was falsely represented in violation of the Act, and that as a result of such purchase transaction he received a product that would have been worth more if it in fact had truly been as represented."); *Plubell v. Merck & Co., Inc.*, 289 S.W.3d 707, 714 (Mo. Ct. App. 2009) ("The MMPA does not require that an unlawful practice cause a 'purchase.' . . . [A] plaintiff's loss should be a result of the defendant's unlawful practice, but the statute does not require that the purchase be caused by the unlawful practice. Therefore, [plaintiffs] are not . . . required to show what they would or would not have done had the product not been misrepresented and the risks known."). As the issue had not been briefed in any

detail, the court ordered limited, simultaneous briefing regarding whether GEHA can, in fact, state a claim under the MMPA.

With the benefit of the briefing, the court now holds that GEHA cannot pursue a claim under the MMPA because it lacks standing to do so. The MMPA limits the class of individuals with standing to pursue a claim to "[a]ny person who purchases or leases merchandise primarily for personal, family or household purposes and thereby suffers an ascertainable loss of money or property, real or personal, as a result of" a forbidden business practice. Mo. Rev. Stat. § 407.025. Although the term "person" explicitly includes corporations like GEHA, the statute has been interpreted as requiring that a person purchase the property for his, her or its *own* "personal, family or household purposes." Accordingly, the claims of health care plans and third-party payors have been dismissed for lack of standing. *See In re Express Scripts, Inc., Pharmacy Ben. Mgmt. Litig.*, MDL No. 1672, 2006 WL 2632328, at *10 (E.D. Mo. Sept. 13, 2006) (dismissing claim of health benefit plan against prescription drug administrator because the pharmaceuticals purchased by the plan were not "for the Plan's personal, family, or household purposes. Instead, they were purchased for a business purpose: to serve the Plan's clients."); *In re Pharm. Indus. Average Wholesale Price Litig.*, 252 F.R.D. 83 (D. Mass. 2008) (dismissing claims of third-party payors). In line with these decisions, the court holds that GEHA lacks standing to pursue a claim under the MMPA because the money it expended to pay for Actimmune was for a business purpose, not for a personal, family or household purpose. Defendants' motion to dismiss GEHA's claims under the MMPA is therefore GRANTED.[5]

II. Motion to Amend

On the same date that plaintiffs filed their opposition to defendants' motion to dismiss, plaintiffs filed a motion for leave to file a fourth amended complaint, their fifth complaint in this action. The sole reason for the motion was so that plaintiff could insert the following language that relates to Rybkoski's claims: "An unidentified female InterMune sales representative frequently 'detailed' the clinic where [Rybkoski's doctor] worked. This representative promoted the use of Actimmune for IPF, meeting with the doctors and staff and leaving marketing materials that also

promoted the use of Actimmune for IPF." Because that factual allegation does not address causation, its inclusion in an amended complaint would not affect the court's analysis of the instant motions in any way. Accordingly, denies plaintiffs' motion to amend is DENIED as moot. The court notes, however, that it likely would have denied the motion even if the new allegation were relevant, as the court clearly indicated that the TAC would be plaintiffs' final opportunity to amend their pleadings

CONCLUSION

For the aforementioned reasons, defendants' motions to dismiss Frankel, Jarrett, Isenhower, Stevens and Rybkoski's TAC and GEHA's SAC are GRANTED in their entirety. All of the claims discussed above are dismissed with prejudice; plaintiffs, to whom the court provided three opportunities to substantively amend their complaint, have had ample opportunity to cure the deficiencies in their pleadings.

Plaintiff Rybkoski's motion to amend the consumer plaintiffs' complaint is DENIED.

IT IS SO ORDERED.

Dated: August 31, 2010

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

ENDNOTES

1. The term advertising is defined broadly to include "any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase or use of any food, drug, device, or cosmetic." Cal. Health & Safety Code § 109885.

2. Plaintiffs suggest that because the FDCA and Sherman Laws criminalize off-label promotion of drugs, regardless of whether a defendant misrepresented the efficacy of the product, misrepresentation will not be an element for at least their claims founded on the misbranding provisions of federal and state law. What plaintiffs overlook is that without a false representation, plaintiffs could not possibly suffer any injury. If defendants promoted Actimmune as an effective treatment for IPF and it was, in fact, an effective treatment for the disease, plaintiffs would have received exactly what they sought. A consumer protection suit will not lie where a plaintiff actually receives the "benefit of the bargain." *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. 2002).

3. Defendants suggest that the TAC still contains numerous allegations that sound in fraud, and thus the court should either dismiss it outright, in light of *Actimmune II*'s categorical dismissal of all fraud-based claims, or require that plaintiffs satisfy Rule 9(b). In so arguing, defendants miss the above-discussed distinction regarding the unlawful-prong UCL claims now asserted by plaintiffs. To be certain, given the court's directions in *Actimmune II*, plaintiffs could have more studiously avoided phrases that "sound in fraud," and would have been well-served, in certain places, to do more than replace the words "fraud" and "fraudulent" with "unlawful," "unlawfully," "unfair" and "unfairly." That said, at this stage the court must make all reasonable inferences in favor of plaintiffs. And given that requirement, plaintiffs may assert a claim that they were injured as a result of defendants' unlawful, off-label marketing of Actimmune.

4. Because the court holds that none of plaintiffs' UCL claims adequately allege causation, the court need not address defendants' other arguments for those claims' dismissal.

5. Because this order dismisses all of plaintiffs' claims with prejudice, the court need not address the individualized arguments raised by Harkonen and Genentech as to why, even if the TAC states a claim against InterMune, it does not do so against them.