

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>In re: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION</b>	:	<b>AVANDIA MDL 1871 2007-MD-1871</b>
<b>THIS DOCUMENT RELATES TO <i>County of Santa Clara v. GSK</i></b>	:	<b>Case No. 10-1637</b>

**MEMORANDUM OPINION AND ORDER**

**RUFE, J.**

**October 26, 2011**

The County of Santa Clara, California (“Santa Clara” or “the County”) has filed a false advertising and deceptive marketing claim against GlaxoSmithKline (“GSK”), on its own behalf as a government payor for Avandia and Avandia-related injuries and on behalf of the citizens of California, pursuant to California’s False Advertising Law (“FAL”).<sup>1</sup> GSK has filed a motion to dismiss, arguing that Santa Clara does not have standing to sue under the FAL, and that Santa Clara has failed to adequately state a claim for false advertising on behalf of itself and on behalf of the citizens of California. GSK also argues that Santa Clara is seeking remedies not available under the FAL. For the reasons set forth herein, GSK’s Motion to Dismiss will be granted in part and denied in part.

**I. BACKGROUND**

Santa Clara’s complaint alleges that for more than a decade, GSK aggressively marketed Avandia as a safe and effective “wonder drug” which lowers the blood-sugar of patients with

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<sup>1</sup> Cal. Bus. & Prof. Code § 17500 *et seq.*

Type 2 diabetes.<sup>2</sup> Santa Clara alleges that GSK aggressively promoted Avandia use through television and print advertising, press releases, product labeling, ghostwritten articles, and marketing materials targeting doctors and third-party payors.<sup>3</sup> Santa Clara also alleges that even before Avandia went on the market in 1999, and certainly while vigorously promoting Avandia, GSK knew that the drug increased a diabetic’s risk of adverse cardiovascular events (including heart attack and other health risks),<sup>4</sup> yet deliberately concealed this risk in its fraudulent and deceptive marketing program,<sup>5</sup> and in fact affirmatively represented that Avandia could reduce cardiovascular risk.<sup>6</sup> GSK is also alleged to have misled consumers by claiming that Avandia offered superior efficacy compared to older (and cheaper) diabetes drugs, while deliberately failing to conduct studies which could demonstrate relative efficacy.<sup>7</sup> Santa Clara alleges that on several occasions the United States Food and Drug Administration (“FDA”) cited GSK for engaging in false and deceptive advertising of Avandia,<sup>8</sup> such as making statements in advertising which minimized the FDA approved warnings on the Avandia label.<sup>9</sup> GSK also continued to market Avandia as safe for use with insulin, even after the FDA’s European counterpart required a label change warning that Avandia should not be used with insulin

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<sup>2</sup> Am. Compl. ¶ 3.

<sup>3</sup> Am. Compl. ¶¶ 39, 43, 80, 83, 94.

<sup>4</sup> Am. Compl. ¶¶ 35, 41, 44, 51.

<sup>5</sup> Am. Compl. ¶ 1, 4.

<sup>6</sup> Am. Compl. ¶¶ 3, 40.

<sup>7</sup> Am. Compl. ¶ 68, 82, 91.

<sup>8</sup> Am. Compl. ¶¶ 45, 52, 54, 55.

<sup>9</sup> Am. Compl. ¶ 54.

because of the increased risk of heart attack.<sup>10</sup>

According to the Complaint, in 2007, four independent peer-review research studies, including Dr. Steven Nissen’s meta-analysis published in the New England Journal of Medicine, finally revealed the truth about Avandia’s risks. By November 2007 the FDA required GSK to include a black box warning on Avandia’s label, informing consumers of the cardiovascular risks associated with Avandia.<sup>11</sup>

The Complaint contains one count, alleging a violation of California’s False Advertising Act. The County sues on behalf of the people of California, for the benefit of “all California diabetics who purchased Avandia and all other entities that purchased Avandia in California,”<sup>12</sup> as county counsel are explicitly authorized to do under the FAL.<sup>13</sup> Santa Clara also sues on its own behalf as a government payor for health care.<sup>14</sup> Plaintiff alleges that GSK made false, deceptive and misleading claims regarding Avandia’s safety and efficacy which were likely to deceive the people (namely California diabetics and other Avandia purchasers and prescribers)

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<sup>10</sup> Am. Comp. ¶ 60.

<sup>11</sup> Am. Compl. ¶¶ 6, 66.

<sup>12</sup> Am. Compl. ¶ 14.

<sup>13</sup> Cal. Bus. & Prof. Code § 17535 reads: “Actions for injunctions under this section may be prosecuted by the Attorney General or any district attorney, county counsel, city attorney or city prosecutor in this state in the name of the people of the State of California . . .” In Section 17535, the term “injunctions” incorporates both injunctions against further wrongful conduct *and* awards of restitution “to restore to any person in interest any money or property, real or personal, which may have been acquired by means of any practice in this chapter declared to be unlawful.” *Id.* In addition, Section 17536 allows county counsel to seek civil penalties for violations of the FAL in an action on behalf of the people. If civil penalties are awarded in such an action, the entire amount of any penalty collected is paid to the treasurer of the county to be used for the enforcement of consumer protection laws. Cal. Bus. & Prof. Code § 17536 (c).

<sup>14</sup> Santa Clara county operates the Santa Clara Valley Health and Hospital System (“SCVHHS”), which “provides integrated hospital, clinic-based, pharmaceutical, and preventative medical services to a largely indigent population.” Am. Compl. ¶ 15. Santa Clara allegedly spent approximately \$2 million on Avandia prescriptions during the ten years that Avandia was on its formulary (1999-2009). Am. Compl. ¶ 85.

and government payors like Santa Clara County. As a result, it is alleged, Santa Clara County and the people of California paid a significant premium to use Avandia, when older and cheaper diabetes medications may have been safer and equally effective.<sup>15</sup> By this action, Plaintiff seeks injunctive relief, civil penalties, restitution, and damages on behalf of Santa Clara County and the people of California.

## **II. STANDARD OF REVIEW**

Dismissal of a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted is appropriate where a plaintiff's "plain statement" does not possess enough substance to show that plaintiff is entitled to relief.<sup>16</sup> In determining whether a motion to dismiss should be granted the court must consider those facts alleged in the complaint, accepting the allegations as true and drawing all logical inferences in favor of the non-moving party.<sup>17</sup> Courts are not, however, bound to accept as true legal conclusions couched as factual allegations.<sup>18</sup> Something more than a mere *possibility* of a claim must be alleged; plaintiff must allege "enough facts to state a claim to relief that is plausible on its face."<sup>19</sup> The complaint must set forth "direct or inferential allegations respecting all the material elements necessary to sustain recovery under *some* viable legal theory."<sup>20</sup> The court has

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<sup>15</sup> Am. Compl. ¶¶ 10, 89-92, 94.

<sup>16</sup> Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557 (2007).

<sup>17</sup> ALA, Inc. v. CCAIR, Inc., 29 F.3d 855, 859 (3d Cir. 1994); Fay v. Muhlenberg Coll., No. 07-4516, 2008 WL 205227, at \*2 (E.D. Pa. Jan. 24, 2008).

<sup>18</sup> Twombly, 550 U.S. at 555, 564.

<sup>19</sup> Id. at 570.

<sup>20</sup> Id. at 562 (quoting Car Carriers, Inc. v. Ford Motor Co., 745 F.2d 1101, 1106 (7th Cir. 1984)).

no duty to “conjure up unpleaded facts that might turn a frivolous . . . action into a substantial one.”<sup>21</sup>

### **III. DISCUSSION**

#### **A. Adequacy of the Pleadings**

Santa Clara alleges violations of California’s False Advertising Law,<sup>22</sup> which makes it unlawful to make or disseminate any statement concerning property or services that is untrue or misleading.<sup>23</sup> “To state a claim for false advertising, a plaintiff must allege that (1) the statements in the advertising are untrue and misleading; and (2) the defendants knew, or by the exercise of reasonable care should have known, that the statements were untrue or misleading.”<sup>24</sup>

Fraud is not an essential element of an FAL claim, but where the facts alleged sound in fraud, the claims are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b).<sup>25</sup> Whether the allegations here sound in fraud, and therefore must be pled with such specificity, turns on whether the complaint “brims with allegations of intentional conduct” or characterizes GSK’s conduct as negligent.<sup>26</sup>

The Court finds that Santa Clara’s Complaint does sound in fraud. The Complaint is

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<sup>21</sup> Id. at 562 (citing McGregor v. Industrial Excess Landfill, Inc., 856 F.2d 39, 42-43 (6th Cir. 1988)).

<sup>22</sup> Cal. Bus. & Prof. Code § 17500.

<sup>23</sup> Id.

<sup>24</sup> Goldsmith v. Allergan, Inc., No. 09-7088, 2011 WL 147714, at \*3 (C.D. Cal. Jan. 13, 2011)(citing People v. Lynam, 253 Cal.App.2d 959, 965 (1967)).

<sup>25</sup> Kearns v. Ford Motor Co., 567 F.3d 1120, 1124, 1126 (9th Cir. 2009); Vess v. Ciba-Geigy Corp. U.S.A., 317 F.3d 1097, 1105 (9th Cir. 2003).

<sup>26</sup> Mattson v. Bristol-Myers Squibb Co., No. 09-07908, 2009 WL 5216966 (D.N.J. Dec. 30, 2009) (applying California law).

replete with allegations that GSK knew the risks associated with Avandia even before it was approved by the FDA in 1999 and certainly thereafter. Santa Clara further alleges that GSK took deliberate actions, such as intimidating researchers, suppressing study findings, manipulating study designs and data, etc., to prevent this adverse information from reaching the public. Rather than disclosing the risks to consumers, Santa Clara claims, GSK aggressively promoted Avandia with misleading marketing messages about Avandia's safety and efficacy, and did so with scienter and the intent to induce reliance. Under California law, these allegations of knowledge and intent sound in fraud.<sup>27</sup>

To plead an FAL claim under the heightened Rule 9(b) standards, Santa Clara must (a) “articulate the who, what, when, where, and how” of the false representation, concealment or non-disclosure with particularity;<sup>28</sup> and (b) plead knowledge of falsity and intent to defraud.<sup>29</sup> GSK argues that Santa Clara failed to adequately plead its FAL claim. Upon examination of the pleadings, the Court disagrees.

Santa Clara's Amended Complaint alleges that GSK conducted a long-term marketing and promotional campaign in California,<sup>30</sup> and that GSK's marketing materials created a false and misleading impression of the drug's safety and efficacy. Although Santa Clara does not identify any *particular* misleading advertisement, the County does allege that the false marketing began in 1999, and included television and print advertising, press releases, product labeling,

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<sup>27</sup> Kearns, 567 F.3d at 1126.

<sup>28</sup> Id. (affirming dismissal of a claim where plaintiff “failed to articulate the who, what, when where, and how of the misconduct alleged”).

<sup>29</sup> Id.; Moore v. Brewster, 96 F.3d 1240, 1245 (9th Cir. 1996).

<sup>30</sup> Am. Compl. ¶¶ 38, 90.

ghostwritten articles, and marketing materials and strategies targeting doctors and third-party payors. Plaintiff describes what was misleading about the promotional materials, alleging that GSK knowingly overstated the efficacy and underplayed the cardiac risks in their marketing. Santa Clara also alleges that the FDA repeatedly cited GSK for engaging in false and deceptive advertising of Avandia. Finally, the County alleges a plethora of facts from which the Court can infer that GSK knew or should have known that its marketing messages were false or misleading from the time Avandia went on the market in 1999.

The claim as alleged is sufficient to satisfy the federal pleading standard the Supreme Court articulated in Bell Atlantic Corp. v. Twombly,<sup>31</sup> as well as the heightened pleading standard required under Federal Rule of Civil Procedure 9(b).<sup>32</sup>

**B. Santa Clara's Statutory Standing to Sue on Its Own Behalf**

Santa Clara filed this suit on its own behalf and on behalf of the people of California. Section 17535 of the FAL provides that county counsel may bring an action for injunctive relief “in the name of the people of the State of California,” but does not expressly provide for suits by a county on its own behalf. GSK challenges Santa Clara’s standing to bring a claim on its own behalf under the FAL. In response, Plaintiff argues that the County of Santa Clara is incorporated, and corporations can bring FAL suits.<sup>33</sup> However, notwithstanding the County’s incorporation, at least one federal court has found that Santa Clara County does not have

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<sup>31</sup> 550 U.S. 544.

<sup>32</sup> Plaintiff’s pleadings regarding the “who, what, when, where, and how” of the false representations may present as thin, but nevertheless sufficient under Rule 9(b).

<sup>33</sup> See also Cal. Bus. & Prof. Code § 17506, which defines “person” as “any individual, partnership, firm, association, or corporation”; Cf. County of Santa Clara v. Astra U.S., Inc., 428 F. Supp. 2d 1029 (N.D. Cal. 2006).

standing to bring individual claims under the FAL's sister statute, the Unfair Competition Law ("UCL"),<sup>34</sup> which also includes corporations in its list of parties who may sue.<sup>35</sup> Santa Clara has not shown why the definition under the FAL should be interpreted differently.<sup>36</sup> Therefore, the Court finds that Santa Clara lacks standing to sue on its own behalf, although it has statutory standing to proceed on behalf of the people.<sup>37</sup>

**C. Reliance**

Although the Court finds that Santa Clara does not have standing to sue on its own behalf, for the purpose of completeness, and as it may provide an alternative ground for its dismissal, the Court will consider GSK's final argument: that Santa Clara failed to adequately allege that it relied upon GSK's misleading marketing. Therefore, GSK argues, the Court must dismiss Santa Clara's claim on its own behalf even if it finds that Santa Clara had standing to sue.

Under California's Proposition 64, adopted by California voters in 2004 and integrated into § 17535, a person or corporation filing an FAL claim must allege both that the plaintiff suffered injury-in-fact and that the injury was caused by the plaintiff's reliance on the misleading

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<sup>34</sup> A violation of the UCL, which prohibits deceptive advertising as well as other unfair competitive practices, may also be a violation of the FAL. Committee on Children's Television v. General Foods Corp., 35 Cal. 3d 197, 210 (1983); Brockey v. Moore, 107 Cal. App. 4th 86, 98 (2003).

<sup>35</sup> In Astra, 428 F. Supp. 2d 1029, both Santa Clara and GSK were parties. In that case, the court found that Santa Clara lacked standing to sue under the UCL, and Santa Clara did not appeal that ruling.

<sup>36</sup> Santa Clara argues that the FAL importantly differs from the UCL in that the UCL does not permit counties to sue on behalf of the people, whereas the FAL does permit such suits. Far from bolstering Santa Clara's argument, the Court notes that, had the legislature so intended, it would have explicitly provided that counties had standing to bring claims either in an enforcement role or on their own behalf. That the legislature did not leads the Court to conclude that the FAL does not confer on counties the standing to bring FAL claims on their own behalf.

<sup>37</sup> GSK does not challenge Santa Clara's standing to sue on behalf of the people. See GSK's Motion to Dismiss at page 9.



advertising.<sup>38</sup>

Because the FAL explicitly exempts county counsel suing *on behalf of the people* from pleading individualized injury and reliance,<sup>39</sup> Santa Clara argues that the FAL should also be read as exempting the County from pleading injury and reliance when suing *on its own behalf*. Upon review of the statute, the Court finds that even if Santa Clara had the right to sue on its own behalf, it would be required to allege injury and reliance, just as private hospitals and private third-party payors must do.

Therefore, to plead reliance, Santa Clara must identify which marketing devices it found material and allege that it relied upon them in making its choices about medication coverage and formularies.<sup>40</sup> The Court finds that Santa Clara failed to plead that it relied upon misleading promotional materials when it opted to include Avandia on its formulary or when it approved payments for individual Avandia prescriptions.<sup>41</sup> The process behind a third-party payor's decision to include a drug on a group formulary is different from the process behind an individual's decision to purchase a drug. Formulary decisions are made by sophisticated and well-funded committees that conduct regular reviews of the published literature (and sometimes

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<sup>38</sup> Id. at 326.

<sup>39</sup> The FAL does not require the County to plead individualized deception, reliance or injury to state a claim for injunctive relief on behalf of the people. Cal. Bus. & Prof. Code § 17535. Instead, in alleging claims on behalf of the people, Santa Clara must plead that GSK's campaign was likely to deceive a reasonable consumer. In re Tobacco II Cases, 46 Cal. 4<sup>th</sup> 298, 320, 326 (2009). Santa Clara has pled that GSK engaged in a long-term marketing campaign in which the safety and efficacy of Avandia were misrepresented, and also pled that GSK took steps to prevent countervailing messages from reaching consumers. This is sufficient to plead that a marketing campaign was likely to deceive a reasonable consumer.

<sup>40</sup> In re Vioxx Class Cases, 180 Cal. App. 4<sup>th</sup> 116, 131-32 (Cal. 2009) (discussing the requirements for showing reliance where a third party payor sues on its own behalf).

<sup>41</sup> In re Actimmune Mktg. Litig., 2009 WL 3740648, at \* 12.

even independent research studies) regarding drugs on or proposed for the formulary.<sup>42</sup> Santa Clara has not alleged facts from which the Court can infer that the County's decision to put Avandia on the formulary was made in reliance upon any of GSK's allegedly false advertisements.<sup>43</sup> Accordingly, for the alternative reason that Santa Clara has not demonstrated reliance, the Court finds that Santa Clara lacks standing to sue under the FAL on its own behalf.

**D. Availability of Remedies Sought**

*1. Injunctive Relief*

The FAL allows the Court to award injunctive relief in actions filed by county counsel on behalf of the people of California.<sup>44</sup> The Court may “make such orders or judgments . . . as may be necessary to prevent the use or employment by any [corporation] . . . of any practices which violate this chapter.”<sup>45</sup> Plaintiff's Amended Complaint does not set forth facts from which the Court can infer that there is a plausible risk that GSK continues to or will resume violating the FAL in marketing Avandia.

Moreover, the injunctive relief sought by the County is unreasonably broad and does not focus on marketing materials. For example, the County seeks an injunction prohibiting GSK's marketing employees from “influencing decisions regarding scientific, medical, or clinical research, analysis or disclosure . . .” and “enjoining GSK's existing scientific data publication

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<sup>42</sup> In re Vioxx Class Cases, 180 Cal. App. 4th at 131-32.

<sup>43</sup> In fact, Santa Clara's decision to allow the drug to remain on the formulary until the Fall of 2009, a full two years after the truth about Avandia's risks and efficacy came to light, gives rise to an inference that Santa Clara's decisions about Avandia's inclusion on the formulary relied upon factors other than GSK's representations about Avandia's safety and efficacy.

<sup>44</sup> Cal. Bus. & Prof. Code § 17535.

<sup>45</sup> Cal. Bus. & Prof. Code § 17535.

policy, and requiring GSK to fully and publically disclose all of the source data for completed and ongoing clinical trials . . .”<sup>46</sup> Although the FAL grants the Court authority to impose an injunction to prevent a company from making misleading statements in advertising or other marketing, nothing in the statute gives this Court the authority to impose the broad injunctions the County seeks.<sup>47</sup>

## 2. *Civil Penalties*

The FAL also permits the courts to award and civil penalties in suits filed by county counsel on behalf of the people of California (\$2,500.00 for each violation).<sup>48</sup> Here, the County asks the Court to assess civil penalties on a per-prescription basis, seeking \$2,500.00 for each Avandia prescription filled in California from May 25, 1999 through the present. The Court finds that it would be improper to award civil penalties on a per-prescription basis, as the FAL’s language and purpose requires the Court to focus on GSK’s *conduct* (i.e. violations of the FAL by GSK).<sup>49</sup> If the County prevails in this case, then, the Court may assess penalties for instances of misstatements made in marketing, but will not assess penalties on a per-prescription basis.

## 3. *Restitution*

The County also claims that it is entitled to restitution if it prevails in this suit. Claims for restitution *may* be cognizable under Section 17535, which reads, in relevant part: “The court

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<sup>46</sup> Am. Compl. ¶ 96.

<sup>47</sup> Belitskus v. Pizzigrilli, 343 F.3d 632, 649-50 (3d Cir. 2003) (a court may not issue an injunction which is broader than needed to address the legal violation); Heary Bros. Lightening Prot. Co. Inc. V. Lightening Prot. Inst., 262 Fed. Appx. 815, 817 (9th Cir. 2008).

<sup>48</sup> Cal. Bus. & Prof. Code § 17536.

<sup>49</sup> In re Tobacco II Cases, 46 Cal. 4th at 312, 320.

may make such orders or judgments . . . which may be necessary to restore to any person in interest any money or property, real or personal, which may have been acquired by means of any practice in his chapter declared to be unlawful.”<sup>50</sup> “[P]ursuant to Business and Professions Code section 17535, [a trial court] possesses the authority to order restitution of moneys . . . in order to preclude an entity which has engaged in an unlawful trade practice from improperly profiting from its wrongdoing.”<sup>51</sup> Because restitution under the FAL focuses on the defendants’ wrongful gains, rather than the purchasers’ losses, restitution can be awarded without individualized proof of deception or loss.<sup>52</sup>

It is not clear to this Court what measure of restitution Santa Clara will be seeking,<sup>53</sup> and therefore the Court cannot assess the viability of Santa Clara’s claims for restitution. The Court reminds the parties that the FAL’s emphasis is on addressing profits defendants earned through alleged wrongdoing, and not on alleged injuries to individuals, and any award of restitution must be made with this guidance in mind. The Court further notes that courts have generally awarded this type of restitution in class action lawsuits, which Santa Clara has elected not to file here, instead filing a representative action. Any restitution requested should reflect this difference in posture.

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<sup>50</sup> Cal. Bus. & Prof. Code § 17535.

<sup>51</sup> Fletcher v. Security Pacific National Bank, 23 Cal. 3d 442, 446 (Cal.1979); see also, In re Vioxx, 180 Cal. App. 4th at 131; Committee on Children’s Television., 35 Cal. 3d at 211.

<sup>52</sup> Fletcher, 23 Cal. 3d at 446, 449.

<sup>53</sup> Indeed, in Santa Clara’s Response to the Motion, the County notes “. . . the People have yet to offer *any* monetary recovery model . . .”

#### 4. *Damages*

Actual damages are not available under the FAL. “To achieve its goal of deterring unfair business practices in an expeditious manner, the Legislature limited the scope of remedies available . . . [and] damages cannot be recovered.”<sup>54</sup> Santa Clara cannot, then, recover damages for the amounts the citizens of California (including Avandia users, California insurance companies, public health care providers, and government payors) have spent on Avandia and/or on treatment for injuries allegedly caused by Avandia use.<sup>55</sup>

#### **IV. CONCLUSION**

For the reasons set forth above, GSK’s motion to dismiss will be granted as to Santa Clara’s claim on its own behalf, and denied as to its claim on behalf of the people of California.

An appropriate Order follows.

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<sup>54</sup> Id.

<sup>55</sup> Am. Compl. ¶ 14 and Prayer for Relief.