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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

RELIANCE MEDICAL SYSTEMS, LLC, a Utah limited liability company,

Plaintiff,

v.

UNITED STATES OF AMERICA, DEPARTMENT OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL; DANIEL R. LEVINSON, Inspector General of the United States Department of Health & Human Services,

Defendants.

Case No.

COMPLAINT FOR DECLARATORY RELIEF (28 U.S.C. § 2201)

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Comes now Plaintiff RELIANCE MEDICAL SYSTEMS, LLC, and complains, avers and alleges as follows:

INTRODUCTION

1. The federal government has launched an ill-advised crusade against physician-owned companies—innovative companies that design, manufacture, and distribute medical devices and reduce healthcare costs. In doing so, the government has sided with large corporations over small businesses and chilled the First Amendment rights of small business owners and physicians.

2. At the core of the federal government's crusade is its recent declaration that physician-owned companies are "inherently suspect." This declaration not only clashes with court decisions and government guidance affirming the legality of physician-owned companies, but signals that any person wishing to speak about the formation of a physician-owned company will be "inherently suspect[ed]" of violating laws that carry severe criminal and civil penalties. This unfairly and unconstitutionally burdens First Amendment rights of free speech and due process rights.

3. Reliance Medical Systems is a small business that collaborates with spine surgeons to design highly customized spinal implant devices and surgical tools. Reliance and its owners wish to speak to surgeons regarding the formation of physician-owned companies. But the government's "inherently suspect" designation has cloaked such speech in a presumption of guilt (in violation of Reliance's rights of due process under the Fifth and Fourteenth Amendments) and chilled any speech on this subject (in violation of Reliance's First Amendment rights). In this case, Plaintiff asks that this Court unburden its Constitutional rights and declare the federal government's "inherently suspect" designation invalid.

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THE PARTIES

4. Plaintiff Reliance Medical Systems, LLC ("Plaintiff" or "Reliance") is, and at all times material herein was, a Utah limited liability company. Reliance manufactures customized spinal implant devices and surgical tools.

5. Defendant the Office of Inspector General (the "OIG") is an office within the United States Department of Health and Human Services ("HHS"), which is a department of the United States federal government. The OIG was established at HHS by Congress in 1976 "to identify and eliminate fraud, abuse and waste in Health and Human Services programs."

6. Defendant Daniel R. Levinson is sued in his official capacity as the Inspector General of the HHS. As the Inspector General, Mr. Levinson is the senior official responsible for all actions taken by the OIG, and is directly responsible for the OIG's declaration that physician-owned entities are "inherently suspect." (The OIG and Mr. Levinson are collectively referred to herein as "Defendants.").

JURISDICTION AND VENUE

7. This action seeks declaratory relief under the Federal Declaratory Judgment Act, 28 U.S.C. § 2201.

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because all causes of action arise under the Constitution and laws of the United States.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e). A substantial part of the events giving rise to Reliance's claims occurred in this judicial district in that Reliance seeks to exercise its First Amendment rights to communicate with physicians located in this judicial district, but it cannot because of the OIG's threat of criminal and civil penalties.

10. There is currently an actual, justiciable controversy between the parties regarding the legality of physician-owned entities, the OIG's declaration

that physician-owned entities are "inherently suspect," and the interpretation and application of relevant court decisions that have previously ruled on this issue. The controversy between the parties is "definite and concrete, touching the legal relations of parties having adverse legal interests." *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 240-41 (1937). The OIG is currently investigating Reliance, and physicians with whom Reliance previously communicated, in connection with Reliance's prior formation of physician-owned entities, and Reliance cannot exercise its First Amendment rights to communicate with physicians about forming new physician-owned entities out of fear that any such entities are instantaneously cloaked with a presumption of guilt, in violation of Reliance's due process rights, since these entities are presumed by the OIG to be "inherently suspect." Declaratory relief will resolve this controversy and eliminate the chill that the OIG's "inherently suspect" designation currently has on Reliance's First Amendment rights and the presumption of guilt that violates Reliance's due process rights.

GENERAL ALLEGATIONS

11. Reliance is a design company that collaborates with spine surgeons to design highly customized spinal implant devices and surgical tools. Reliance is not a mere distributor of medical devices manufactured by others. The key element of Reliance's business model is harnessing the design insights of physicians, whose expertise in spinal surgeries enables Reliance to design implants and surgical tools that lead to better patient outcomes.

12. From its inception in 2006 through 2012, Reliance and its related companies included physicians as owners. Reliance has found that physician ownership is the model that maximizes and optimizes physician design input. In 2012, Reliance moved away from a physician ownership model. Now, Reliance wishes to return to physician ownership and structure a business model that, like

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its prior business model, fully complies with federal law, including the anti-kickback statute, 42 U.S.C. § 1320a-7b.

13. In a physician-owned company, physicians have an ownership interest in a company designing and manufacturing the medical devices that are sold to hospitals. This ownership model is lawful under the anti-kickback statute. The leading case considering the limitations that the anti-kickback statute imposes on physician-owned entities is *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995) ("*Hanlester*"). In *Hanlester*, the Ninth Circuit addressed "whether appellants violated the provisions of the Medicare-Medicaid anti-kickback statute by (1) offering or paying remuneration to physician limited partners to induce the referral of program-related business to limited partnership laboratories, or (2) soliciting or receiving remuneration 'in return for' referrals by virtue of their management agreement." *Id.* at 1394. The court found that "mere encouragement would not violate the statute." *Id.* at 1398. Thereafter, the *Hanlester* court interpreted the phrase "to induce" in the anti-kickback statute (42 U.S.C. § 1320a-7b(b)(2)) to connote "an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business." *Id.* at 1398.

14. In applying the facts of *Hanlester* to the court's definition of "to induce," the court found that the following conduct was permissible under the anti-kickback statute:

> (1) enlisting physician investors who were in a position to refer substantial quantities of tests to the joint venture laboratories;
>
> (2) intending to encourage limited partners to refer business to the joint venture laboratories;
>
> (3) offering physicians the opportunity to profit indirectly from referrals by referring patients to laboratories they owned when

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they could not profit directly;

(4) telling potential investors that the success of their investments depended upon referrals from investors, with the practical effect of low referral rates being failure of the business;

(5) making substantial cash distributions to investors based on each individual's ownership interest, and not on the volume of their referrals; and

(6) offering a potentially high rate of return on investment if the investors made a large number of referrals.

Id. at 1399. By approving this conduct, the court held that the foregoing are "insufficient to prove that appellants offered or paid remuneration to induce referrals." *Id.*

15. After the *Hanlester* court approved the foregoing six kinds of conduct, the *Hanlester* court underscored specific actions which the court held were violations of the anti-kickback statute and constituted an offer of payment to induce referrals of program-related business. *Id.* In particular, the *Hanlester* court emphasized that the following conduct is in violation of the anti-kickback statute:

(1) implying that eligibility to purchase an investment interest in a business depends on an agreement to make referrals;

(2) telling prospective investors that the size of the investment interest they would be permitted to purchase depends on the volume of business that the investor referred to the laboratories;

(3) stating that investors who did not refer business to the laboratories would be pressured to leave the business; and

(4) telling potential investors that the investors' return on their investment would be virtually guaranteed.

Id.

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16. The *Hanlester* court then continued to analyze the anti-kickback statute and construed the phrase "knowingly and willfully" to mean to "(1) know that [the anti-kickback statute] prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law." *Id.* at 1400.

17. Finally, the *Hanlester* court addressed the portion of the anti-kickback statute which prohibits the receipt of remuneration in return for referrals. *Id.* at 1401. The court noted that although *Hanlester* received substantial economic benefit from its relationship with the laboratories, the agreement reflected a common practice in the clinical laboratory field and did not violate the anti-kickback statute. The court further emphasized that the *Hanlester* appellants believed that their conduct was lawful and there was no evidence that they intentionally solicited or received remuneration from the laboratories in return for referrals. *Id.*

18. Following the decision in *Hanlester*, on February 27, 2006, the California Attorney General issued an opinion, which also establishes the lawfulness of physician-owned entities under the anti-kickback statute. *Opinion of Bill Lockyer*, 89 Ops. Cal. Atty. Gen. 25 (2006) ("*Lockyer*"). The Honorable Joseph L. Dunn, member of the State Senate, requested an opinion on the following two questions: "(1) May a physician prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest?" and "(2) If the physician may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest, may the company solicit physicians as investors in the company?"

19. The California Attorney General held that: (1) "a physician generally may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest, provided that any return on investment is based upon the physician's proportional ownership

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share and requisite disclosures are made;" and (2) "where a physician may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest, the company generally may solicit physicians as investors in the company." *Id.* at *2.

20. The California Attorney General held that: (1) if a company's profits would be distributed based upon the physician's proportional investment interest in the company and the profits would not be contingent upon either the number or value of the referrals made, a physician may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest; and (2) if a physician investor discloses his financial interest to the patient, or the parent or legal guardian of the patient, in writing, at the time of the referral or request for consultation is sought from an organization in which the physician investor has a financial interest, a physician may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest. *Id.* at *8-10.

21. Because the law, as set forth in *Hanlester* and *Lockyer*, allows physician-owned entities to do business and manufacture medical devices, large corporations that are also in the business of manufacturing medical devices (the "Big Corporations") were forced to compete in the marketplace against smaller physician-owned entities like Reliance. That competition diminished the Big Corporations' market share. Unable to win in the marketplace, the Big Corporations embarked on a multi-year effort to win at the legislative/agency level through substantial lobbying efforts. Specifically, the Big Corporations formed lobby entities, made substantial campaign contributions, and hired a major international law firm (the "Law Firm") to advocate on their behalf "for stronger legislative and regulatory action to halt the proliferation of" physician-owned entities. According to the Law Firm's website, the Law Firm has represented the Big Corporations "in their petitions to OIG, CMS [Centers for

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Medicare and Medicaid Services], Congress, and state legislative and regulatory agencies on POC [physician-owned companies] issues, published numerous papers and articles on the abuses inherent in these physician investment vehicles, and developed legislative and regulatory strategies to combat POC proliferation."

22. The Big Corporations' lobbying efforts led to congressional hearings, and in June 2011, the United States Senate issued a report entitled "Physician Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight – An Inquiry by the Senate Finance Committee Minority Staff, U.S. Senator Orrin Hatch, (R-Utah), Ranking Member" (hereinafter, the "Hatch Report). The Hatch Report lamented the lack of clear guidance regarding the issue of physician-owned entities, and concluded:

> It appears that hospitals and physicians, like medical device manufacturers, would benefit greatly from clear legal guidance regarding doing business with PODs. The most consistent comment from individuals interviewed by the Committee on this topic was "it was unclear to them if PODs were legal or illegal." As a result, potential physician investors typically choose the legal theory that best supports their inclination to join or refrain from joining a POD entity. This lack of clarity seems to be the vastly disparate legal interpretations posited regarding PODs cited above and OIG's limited guidance on this issue to date.

The Hatch Report further stated that "it is incumbent upon the Committee to work with OIG to address this rapidly evolving healthcare market issue."

23. In response to the Hatch Report, Inspector General Levinson sent a letter to Senator Hatch and the Committee Members, dated September 13, 2011, expressing that no additional guidance was necessary regarding the issue of physician-owned entities. In his letter to Senator Hatch, Inspector General Levinson expressed that the OIG's views regarding physician-owned entities have previously been set forth "in various guidance documents, including Special Fraud Alerts." In 1989, the OIG had issued a Special Fraud Alert on Joint

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Venture Arrangements, which addressed the issue of physician-owned entities (the "1989 SFA"). The 1989 SFA did not declare that physician-owned entities were unlawful or "inherently suspect."

24. After conveying to Congress that no additional guidance was necessary regarding physician owned entities, on March 26, 2013, the OIG issued a Special Fraud Alert regarding Physician-Owned Entities (the "2013 SFA"). (The 2013 SFA refers to physician-owned entities as "physician-owned distributors" or "PODs," despite the fact that it addresses entities that, like Reliance, design and manufacture devices and are not mere distributors.) In the 2013 SFA, the OIG states, repeatedly, "that PODs are inherently suspect under the anti-kickback statute." The OIG also states that "an arrangement may not exhibit any . . . suspect characteristics and yet still be found to be unlawful." Further, in the 2013 SFA, the OIG warns hospitals and ambulatory surgery centers that they "may be at risk" under the anti-kickback statute if they "enter into arrangements with PODs." According to the OIG, a Special Fraud Alert "provide[s] the OIG with a means of notifying the industry that we have become aware of certain abusive practices which we plan to pursue and prosecute, or bring civil and administrative action, as appropriate."

25. In the 2013 SFA, the OIG references the 1989 SFA. The OIG's prior statements on physician-owned entities, as set forth in its 1989 SFA, were more general and less critical of physician-owned entities, and did not contain the strongly-worded statements that appear in the 2013 SFA.

26. The OIG's position as set forth in the 2013 SFA—"that PODs are inherently suspect"—is wrong and inconsistent with the law. The 2013 SFA represents a significant departure from the 1989 SFA that preceded the holdings in *Hanlester* and *Lockyer*, and fails to acknowledge that certain physician-owned entities, specifically those that comply with *Hanlester* and *Lockyer*, are not

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"inherently suspect." It is the OIG's position that *Hanlester* was wrongly decided even though it remains good law today.

27. The 2013 SFA resulted in media reports confirming that the OIG's "inherently suspect" designation of physician-owned entities has caused a substantial number of hospitals to stop doing business with physician-owned entities. Indeed, the website of the Law Firm representing the Big Corporations states that "*Wall Street Journal* publishes new exposé on PODs; hospitals continue to adopt anti-POD policies." Inappropriately leaked details of HHS-OIG's efforts to enforce the policies set forth in the 2013 SFA against physician-owned entities, including Reliance, have appeared in more recent *Wall Street Journal* articles and elsewhere, further impacting Reliance. Thus, the 2013 SFA has not only infringed on Reliance's constitutional rights, but also substantially affected Reliance's business.

28. After the Hatch Report was published in 2011, but well before the 2013 SFA was issued, Plaintiff Reliance moved away from the physician-owned entity business model, after careful consideration and out of an abundance of caution. Reliance now wishes to return to the physician-owned entity business model, but it cannot speak with physicians about the formation of a physician-owned entity out of concern that any such entity that is formed will be "inherently suspect[ed]" of violating laws that carry severe criminal and civil penalties. Reliance is also concerned that any efforts to form new physician-owned entities will result in additional investigations of Reliance and the physicians with whom they speak. Separately, even if Reliance could form a physician-owned entity, the physician-owned entity's ability to enter into arrangement with hospitals and ambulatory surgery centers would be severely curtailed since the OIG's 2013 SFA warns hospitals that they "may be at risk" if they enter into such arrangements with physician-owned entities.

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FIRST CAUSE OF ACTION

(DECLARATORY RELIEF AGAINST ALL DEFENDANTS)

29. Plaintiff re-alleges and incorporates herein by this reference each and every allegation set forth in paragraphs 1 through 28 of this Complaint as though set forth fully herein.

30. There is currently an actual, justiciable controversy between Reliance and Defendants regarding the legality of physician-owned entities, the OIG's declaration that physician-owned entities are "inherently suspect under the anti-kickback statute," and the interpretation and application of relevant court decisions that have previously ruled on this issue.

31. The First Amendment protects Reliance's right to speak to physicians about the formation of physician-owned entities that comply with the law. The OIG's arbitrary and capricious designation of all physician-owned entities as "inherently suspect under the anti-kickback statute" is having a chilling effect on Reliance's First Amendment right of free speech and has cloaked Reliance in a presumption of guilt in violation of Reliance's due process rights under the Fifth and Fourteenth Amendments.

32. Reliance has no adequate remedy at law.

33. Reliance therefore seeks entry of a judgment declaring that physician-owned entities that comply with the law, as set forth in *Hanlester* and *Lockyer*, are not "inherently suspect under the anti-kickback statute," and hospitals and ambulatory surgery centers are not "at risk" if they enter into arrangements with physician-owned entities that comply with the law, as set forth in *Hanlester* and *Lockyer*.

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PRAYER FOR RELIEF

Wherefore, Reliance respectfully requests that this Court:

1. Declare that the OIG's designation of all physician-related entities as "inherently suspect under the anti-kickback statute" (42 U.S.C. § 1320a-7b) is invalid, incorrect and/or inaccurate.

2. Declare that physician-owned entities that comply with the law, as set forth in *Hanlester* and *Lockyer*, are not "inherently suspect under the anti-kickback statute" (42 U.S.C. § 1320a-7b).

3. Declare that Reliance, physicians, and/or hospitals may enter into arrangements that comply with the law, as set forth in *Hanlester* and *Lockyer*.

4. Award such other and further relief as this Court deems equitable and just.

Dated: October 8, 2013

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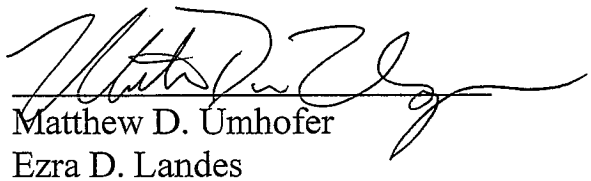
By: 

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