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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,)	Case No. CV 14-06979 DDP (JCx)
)	
Plaintiff,)	
)	
v.)	
)	ORDER DENYING DEFENDANTS' MOTION
RELIANCE MEDICAL)	TO DISMISS FIRST AMENDED
SYSTEMS, LLC; APEX MEDICAL)	COMPLAINT
TECHNOLOGIES, LLC; KRONOS)	
SPINAL TECHNOLOGIES, LLC;)	
BRET BERRY; JOHN HOFFMAN;)	[Dkt. 232]
ADAM PIKE,)	
)	
Defendants.)	

Presently before the court is Defendants' Motion to Dismiss the First Amended Complaint.¹ Having considered the submissions of the parties and heard oral argument, the court denies the motion and adopts the follow Order.

I. Background

The United States' First Amended Complaint alleges that Defendants used Physician-Owned Distributorships ("PODs") to present false or fraudulent claims to Medicare. (First Amended Complaint ("FAC") ¶¶ 76, 310, 315.) As alleged in the FAC, Defendants operated a scheme through which physician-investors in, or

¹ For purposes of this Order, "Defendants" refers to all named defendants, with the exception of John Hoffman.

1 employees of, spinal implant distribution companies were paid a
2 portion of the distribution companies' profits from spinal implant
3 device sales. (See, e.g., FAC ¶ 96.) In short, the government
4 alleges that spinal fusion surgeries related to this scheme were
5 tainted by kickbacks to the doctors choosing the spinal implant
6 products, and were, in some cases, not medically necessary. (FAC
7 ¶¶ 3-4.) This scheme, the government alleges, violated the Anti-
8 Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and, by
9 extension, the False Claims Act, 31 U.S.C. § 3729, insofar as the
10 tainted surgeries led to false or fraudulent claims to Medicare.

11 The FAC also includes allegations regarding the Department of
12 Health and Human Services' ("HHS") Office of Inspector General
13 ("OIG") regulatory authority related to the AKS. The government
14 alleges, for example, that OIG, pursuant to its regulatory
15 authority, has issued several "fraud alerts" concerning joint-
16 ventures between physicians and non-physicians that are "intended
17 not so much to raise investment capital legitimately to start a
18 business, but to lock up a stream of referrals from the physician
19 investors and to compensate them indirectly for these referrals."
20 (FAC ¶ 70 (quoting Special Fraud Alert: Joint Venture Arrangements
21 (OIG-89-4)).) The government further alleges that Defendants were
22 aware of the AKS' prohibitions, "including the OIG guidance . . .
23 ." (FAC ¶ 71.) The government's allegations include several
24 references to what "OIG guidance states." (FAC ¶¶ 183, 190, 208,
25 215, 223.)

26 Defendants now move to dismiss the FAC, contending that
27 Congress has impermissibly delegated lawmaking authority to OIG.

28 **II. Legal Standard**

1 A complaint will survive a motion to dismiss when it
2 "contain[s] sufficient factual matter, accepted as true, to state a
3 claim to relief that is plausible on its face." Ashcroft v. Iqbal,
4 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550
5 U.S. 544, 570 (2007)). When considering a Rule 12(b)(6) motion, a
6 court must "accept as true all allegations of material fact and
7 must construe those facts in the light most favorable to the
8 plaintiff." Resnick v. Hayes, 213 F.3d 443, 447 (9th Cir. 2000).
9 Although a complaint need not include "detailed factual
10 allegations," it must offer "more than an unadorned,
11 the-defendant-unlawfully-harmed-me accusation." Iqbal, 556 U.S. at
12 678. Conclusory allegations or allegations that are no more than a
13 statement of a legal conclusion "are not entitled to the assumption
14 of truth." Id. at 679. In other words, a pleading that merely
15 offers "labels and conclusions," a "formulaic recitation of the
16 elements," or "naked assertions" will not be sufficient to state a
17 claim upon which relief can be granted. Id. at 678 (citations and
18 internal quotation marks omitted).

19 "When there are well-pleaded factual allegations, a court
20 should assume their veracity and then determine whether they
21 plausibly give rise to an entitlement of relief." Iqbal, 556 U.S.
22 at 679. Plaintiffs must allege "plausible grounds to infer" that
23 their claims rise "above the speculative level." Twombly, 550 U.S.
24 at 555-56. "Determining whether a complaint states a plausible
25 claim for relief" is "a context-specific task that requires the
26 reviewing court to draw on its judicial experience and common
27 sense." Iqbal, 556 U.S. at 679.

28 **III. Discussion**

1 All legislative powers granted in the Constitution are vested
2 in Congress. U.S. Const. art. I. Congress cannot cede or transfer
3 its legislative authority to any other branch of government. See
4 Gundy v. United States, 139 S. Ct. 2116, 2123 (2019). Congress
5 may, however “confer substantial discretion on executive agencies
6 to implement and enforce the laws.” Id. (quoting Mistretta v.
7 United States, 488 U.S. 361, 372 (1989) (internal quotation marks
8 omitted). It is well established that a delegation of authority to
9 an executive agency is constitutionally permissible so long as the
10 statutory delegation supplies an “intelligible principle to guide
11 the . . . use of discretion.” Gundy, 139 S. Ct. at 2123. Thus,
12 the non-delegation principle sets a low bar. The Supreme Court has
13 upheld, for example, such broad guiding commandments as a mandate
14 “to regulate in the public interest” and “to protect the public
15 health.” Id. at 2129 (internal quotation marks and citations
16 omitted). Indeed, the Court has never found a particular guiding
17 principle insufficiently intelligible, and has found a delegation
18 of authority impermissible only twice in its history, where
19 Congress supplied no guiding policy or standard whatsoever. Id.

20 Nevertheless, Defendants contend here that Congress has
21 unconstitutionally delegated policy-making authority to OIG.
22 Defendants’ argument centers on two, related statutory provisions.
23 In 1987, Congress required HHS to identify practices that do not
24 constitute impermissible kickbacks. Sec. 14, PL 100-93, 101 Stat
25 680. HHS must update these “safe harbor” provisions at least
26 annually. 42 U.S.C. § 1320a-7d(a)(1)(A). HHS may also, where
27 appropriate, issue a “special fraud alert” that “informs the public
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1 of practices which the Inspector General considers to be suspect or
2 of particular concern” 42 U.S.C. § 1320a-7d(c).

3 Congress provided not one, but nine principles to guide HHS in
4 these two tasks. 42 U.S.C. § 1320a-7d(a) (2). Among those guiding
5 considerations are a particular practice’s effect on the “quality
6 of healthcare services,” “access to health care services”, and
7 “competition among healthcare providers.” Id. The last of the
8 guiding principles allows HHS to consider “[a]ny other factors the
9 Secretary deems appropriate in the interest of preventing fraud and
10 abuse in Federal health care programs” 42 U.S.C. §
11 1320a-7d(a) (2) (I).

12 Defendants seize upon the last criterion’s use of the phrase
13 “any other factors” to support their argument that Congress has
14 impermissibly abdicated its lawmaking authority to HHS. That
15 phrase cannot, however, be read in isolation from the remainder of
16 the criterion, which specifies that “any other factors” must be
17 related to “the interest of preventing fraud and abuse.” There can
18 be no serious dispute that if principles such as “the public
19 interest” and “the public health” are sufficiently intelligible to
20 steer statutory authorizations clear of the non-delegation
21 doctrine, so too is “the interest of preventing fraud and abuse in
22 Federal health care programs.” See Gundy, 139 S. Ct. at 2129.
23 Defendants do not engage with the reality of this low bar,
24 contending instead that “the Supreme Court, as currently
25 constituted, disfavors broad delegations of legislative authorities
26 . . . [a]nd the ‘intelligible principle’ standard is likely to have
27 a short future.” (Mot. at 15 n. 6.) This Court, of course, must
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1 apply the law as it currently stands.² Because Congress'
2 delegation of authority to HHS to determine safe harbors and issue
3 notices regarding OIG's opinion of certain payment practices is
4 guided by an intelligible principle, it does not violate the
5 Constitution.

6 The court notes that Defendants' concerns appear to be rooted
7 less in the propriety of Congress' delegation of authority than in
8 Defendants' own assumptions about how the government can or will
9 seek to prove its claims. Defendants assert that "OIG drives [AKS]
10 prosecutions," and that "[i]t takes a courageous prosecutor to defy
11 the wishes of the OIG." (Mot. at 17-18.) The government concedes,
12 however, that OIG special fraud alerts are akin to advisory
13 opinions, and do not have the force of law. (Opposition at 7:18-
14 18:2.) Furthermore, wish as it might, OIG does not have any role
15 in determining how the law will be applied in this case, regardless
16 whether the government's allegations echo OIG's opinions.

17 **IV. Conclusion**

18 For the reasons stated above, Defendants' Motion to Dismiss is
19 DENIED.

20 IT IS SO ORDERED.
21



22 Dated: 8-6-2021

23 DEAN D. PREGERSON
24 United States District Judge

25 ² For this same reason, the court declines Defendants
26 invitation to ignore the Ninth Circuit's decision in Hanlester
27 Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995) and find the
28 AKS unconstitutionally vague. The Hanlester court explicitly
addressed, and rejected, a vagueness challenge to the AKS. Id.
Indeed, the appellants in Hanlester, like Defendants here, argued
that HHS' promulgation of safe harbors rendered the AKS vague. Id.
at n.11.