

Court Dismisses POD Lawsuit Against OIG

On February 5, 2014, a federal court dismissed a challenge to the U.S. Department of Health and Human Services' Office of Inspector General's ("OIG") March 26, 2013 Special Fraud Alert ("2013 SFA") on physician-owned distributors ("PODs"). The lawsuit was filed in the U.S. District Court in the Central District of California by Reliance Medical Systems, LLC ("Reliance"), which had historically included physician owners, and was considering a return to the POD business model. Reliance filed suit against the OIG on October 8, 2013, alleging that the 2013 SFA violated (i) the First Amendment right of speech, (ii) due process rights under the Fifth and Fourteenth Amendments, and (iii) the Administrative Procedures Act.

The Court dismissed Reliance's claims, without reaching the merits, by holding that Reliance had no standing because it had not suffered an injury-in-fact. Specifically, the 2013 SFA had not been enforced in any way against Reliance. The Court made much of the fact that Reliance was not, at the time of the lawsuit, a POD, and, as such, could not conceivably have suffered any injury.

Additionally, and perhaps most significantly, the Court rejected Reliance's argument that the 2013 SFA "chilled" speech regarding formation of a POD, noting that all criminal statutes, by their very nature, may have a "chilling effect" on personal behavior, but that such effect—which is merely part of an agency's authority to regulate economic conduct—does not amount to an actionable claim.

The case leaves unanswered how a court would rule if a plaintiff could demonstrate an injury-in-fact—for example, if an existing POD could show that the OIG imposed penalties pursuant to the 2013 SFA. However, courts typically grant significant deference to administrative agencies in their interpretation of laws they are charged with administering, and thus the 2013 SFA is likely to be viewed simply an exercise of OIG's authority to interpret the AKS and implementing regulations. Thus, any injury to a POD in an enforcement action would be due to its alleged violation of the AKS, as interpreted by the applicable agency, and the 2013 SFA itself could not be the cause of the injury.

If you have any questions about the Reliance case, please do not hesitate to contact [Tom Bulleit](#) or [Peter Holman, Jr.](#)