

## Overreach on anti-kickback rule stymies medical innovation

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A federal court ruling out of Florida was allowed to stand, potentially stymieing health care innovation, meaning patients would ultimately be the ones hurt as they see fewer new treatment options, physicians told a federal appeals court.

A U.S. District Court for the Southern District of Florida jury convicted Georgia podiatrist Alap Shah of one count of conspiracy to defraud the United States and receive health care kickbacks and two counts of receiving kickbacks. The conviction stems from a consultant-director arrangement Shah had with a compounding pharmacy he used to fill prescriptions he designed for individual patients' needs. Under the arrangement, the podiatrist would work with the pharmacy to promote their products and possibly help develop and conduct trials for new products.

The jury convicted Shah using the “one purpose” rule that allows conviction under the federal anti-kickback statute if any “one purpose” of an arrangement is to induce or reward referral reimbursable by federal health care programs. In an amicus brief, the Litigation Center of the American Medical Association and State Medical Societies told the court that the rule contradicted the anti-kickback statute’s safe harbor regulations and that it is inconsistent with innocent business practices in the health care industry.

“By necessity, the industry functions with the understanding that doctors, nurses, therapists and other practitioners each will be a potential source of referrals,” the brief said. “This is the nature of the health care industry—indeed, it is the nature of almost any industry.”

The brief went on to say that broadly criminalizing “the ability of a therapy service provider to refer patients to a not-for-profit hospital or a physician to refer patients to a medical device manufacturer would jeopardize routine business practices followed by the health care industry across the country, to the detriment of the patients benefiting from these innocuous practices.”

The brief urged the 11th U.S. Circuit Court of Appeals to reverse the conviction and send the case, *United States of America v. Shah*, back to the district court for a new trial.

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## Safe harbors well established

The AMA Litigation Center brief told the court the fiscal integrity of federally-funded health care programs needs to be maintained, but said it's also important to encourage business transactions that promote effective health care.

Congress created safe harbors to protect legitimate business arrangements and the Department of Health and Human Services Office of the Inspector General issued advisory opinions and promulgated regulatory safe harbors designed to rein in the anti-kickback statute that otherwise would extend to certain non-abusive arrangements, the brief explains.

"The safe harbor provisions ... envision that health care providers may solicit or receive referrals even when they have entered a contract for products or services with the assurance they will not be subject to prosecution," the brief said. "The 'one purpose' rule does not trump the safe harbor provisions."

There is evidence Shah firmly believed compounding medications benefited his patients and it was reasonable for the compounding pharmacy to believe Shah was in a superior position to help develop and promote its products, physicians tell the court.

Applying the "one purpose" rule would prohibit the agreement "no matter how much business sense the arrangement would have made and no matter how much patients would have benefited," the brief said.

The rule also shows a lack of insight into how the health care industry exists in the real world, which includes the way physicians, hospitals, laboratories, pharmaceutical companies and medical device manufactures operate.

The brief concluded that "because this rule chills transactions beneficial to public health and stymies innovation in the health care industry, it should be jettisoned."

The 11th U.S. Circuit Court of Appeals ruled Nov. 24, determining that the error in jury instruction was harmless, and the court affirmed the conviction.