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### United States v. Holland and its importance to compliance professionals

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by Gabriel L. Imperato, Esq.

The recent decision of a U.S. Federal District Court in *United States v. Holland*<sup>[1]</sup> is an important development in the application of the federal Anti-Kickback Statute (AKS); however, it is also significant for healthcare organization compliance programs and compliance professionals in addressing and managing risks under the AKS. The court in *United States v. Holland* first discussed and analyzed the “one-purpose test” and concluded that it was not settled law but also stated that the “one-purpose test” must be considered in connection with the knowing and *willful* standard under the AKS. The court further concluded that the mere existence of an arrangement for services where referrals and payments were involved (i.e., “one purpose of a payment”) did not establish knowing and willful conduct, which would violate the AKS. The court decided that it could not automatically impute willfulness simply based on the identification that “one purpose” of an arrangement was to induce referrals without a basis to show that the parties knew they were breaking the law.

The court found that in this particular case, the individuals who established the arrangement (between a hospital and a referring clinic), which became the basis for the AKS criminal enforcement action, had a “good faith” basis for believing the arrangements were compliant. This is perhaps a more critical part of the decision than analyzing the “one-purpose test” application. A “good faith” basis for believing that an arrangement is compliant provides healthcare organizations and their management and compliance professionals an opportunity to manage compliance risk once it is discovered in a sensible way. A “good faith” and reasonable belief in the compliant nature of an arrangement can protect the organization and involved individuals from being found to have willfully violated the law. The opportunity to respond to reports of noncompliant activity and consider and rely on reasonable advice in good faith for addressing compliance risk is a critical best practice for managing compliance risk.

Nevertheless, healthcare organizations and their compliance professionals must continue to be vigilant and respond accordingly to reports of potential noncompliance with the AKS involving their organizations. The decision in *United States v. Holland* does not materially change the arch of compliance efforts necessary for healthcare organizations to respond to reports of and manage the risk of violations of the AKS. It may, however, make it easier for compliance professionals and counsel to vet and consider advice in connection with the application of the AKS in a way that they may rely on in “good faith.” This can be essential for moving an organization beyond the first report of noncompliant activity and assisting with managing the compliance risk associated with the AKS.

The following additional points were highlighted in the decision:

- The court stated that “willfully” under the AKS means the act was committed voluntarily and purposely with the specific intent to do something the law forbids, that is, with bad purpose to either disobey or disregard the law.
- The court further stated that “willfulness” requires proof of an intentional wrongful act, and a defendant who believes in “good faith” that he has not committed a wrongful act, no matter how unreasonable that belief is, is not guilty.
- The court also decided that, under the circumstances, the defendants had a reasonable “good faith” basis to believe that the arrangements were compliant because counsel for both parties (hospital and clinic counsel) reviewed and approved the contractual arrangements.

## Takeaways

- The decision in *United States v. Holland* addresses and highlights, for the first time, that the “one purpose test” is at odds with the express purpose and language of the Anti-Kickback Safe Harbor regulations.
- The court concluded that the per se application of the “one purpose test” must give way to the requirement that one must engage in “knowing and willful” conduct to violate the Anti-Kickback Statute (AKS).
- The court advises that willfulness requires someone to do what the law forbids, with bad purpose, and if one believes in “good faith” that they have not committed a wrongful act, then there is no violation of the law.
- The court essentially exposed the legal shortcomings of the “one purpose test” and pointed out how it can lead to liability for activities that do not violate the AKS.

<sup>1</sup> United States v. Holland, Criminal Action no. 1:17-CR-00234-AT-CMS (N.D. Ga. Aug. 6, 2018), <https://casetext.com/case/united-states-v-holland-115>.

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