

## CLIENT ALERT: *Astellas Decision Has Profound Insurance Coverage Implications For Companies That Do Business With The Federal Government*

**ASTELLAS US HOLDING INC. ET AL. V. FEDERAL INS. CO.,  
NO. 21-3075, 2023 WL 3221737 (7TH CIR. MAY 3, 2023)**

A recent decision by the U.S. Court of Appeals for the Seventh Circuit will likely have profound insurance coverage implications for companies that do business with the federal government, including those in the healthcare, general services, and defense industries. When engaging with the federal government, companies are potentially exposed to significant liability under the Anti Kickback Statute and the False Claims Act (“FCA”). Unfortunately for policyholders, insurers have repeatedly argued that settlements arising under the Anti-Kickback Statute and FCA constitute restitution and are therefore uninsurable. The Seventh Circuit rejected this view in *Astellas US Holding Inc. et al. v. Federal Ins. Co.*, No. 21-3075, 2023 WL 3221737 (7th Cir. May 3, 2023) and in doing so rendered a favorable policyholder decision.

In *Astellas*, the insured made a \$100 million payment to the federal government to settle alleged violations of the Anti Kickback Statute and the FCA. *Astellas* sought coverage under a D&O policy issued by Federal Insurance Company (“Federal”). The insurer denied the Claim and the central coverage issue was whether Illinois public policy prohibited a liability insurer from covering part of an insured’s payment to settle the government’s potential claims on the ground that such payment constituted uninsurable restitution. Ultimately, the Court ruled in favor of the insured, explaining that the FCA allows for compensatory damages, not for restitution. In so holding, the Court provided a roadmap for insureds seeking insurance coverage for settlements arising under the FCA. Indeed, the *Astellas* decision goes beyond a simple discussion of the insurability of restitution and instead offers a number of instructive coverage lessons for policyholders.

This coverage dispute arose from the following underlying fact pattern: In 2012, the pharmaceutical company *Astellas* launched a cancer treatment drug, *Xtandi*. While Medicare covered \$6,000 of the \$7,800 per month cost, a significant monthly co-pay of \$1,800 remained for patients. To mitigate the remaining cost to patients, *Astellas* began making contributions to “patient assistance plans.” However, the government had raised concerns that “patient assistance plans” could potentially be operated in a way that ran afoul of the Anti-Kickback Statute and the FCA, by effectively rewarding doctors and patients for choosing to use particular drugs. During the period 2013-2016, *Astellas* contributed approximately \$130 million to various “patient assistance plans.” In 2017, the Department of Justice commenced an investigation into these contributions, including issuing a Civil Investigative Demand that led to a tolling of the relevant statutes of limitations. Prior to active litigation, *Astellas*

and the government settled the potential claims for \$100 million, \$50 million of which was labeled as “restitution to the United States.”

*Astellas* then demanded that Federal pay its \$10 million policy limit to cover a portion of the \$100 million settlement. The applicable insuring clause provided that the “Insurer shall pay on behalf of the Company the Loss arising from a Claim ... against the Company for any Wrongful Act.” The court explained that the insuring clause “clearly includes” potential violations of the Anti-Kickback Statute and the FCA by *Astellas* in funding “patient assistance plans.” The court then instructed that the dispositive language in the policy was the definition of “Loss” which includes “damages, settlements or judgments” but excludes coverage for “matters which may be deemed uninsurable under applicable law.” Critically, the Court ruled that this definition operated as exclusionary language and thus placed the burden on the insurer to prove the “Loss” was uninsurable. The Court also importantly found that any exclusions requiring “final adjudication” were inapplicable because the parties resolved the matter by way of settlement.

Next, the Court instructed that Illinois public policy precludes insurance coverage for losses incurred from settlement payments that are “restitutionary in character.” That is, Illinois law draws a distinction between insurable “compensatory” damages and uninsurable “restitution” payments. Federal took the position that *Astellas*’ settlement payment was restitutionary in nature because the settlement agreement labeled half of the \$100 million payment as “restitution to the United States” and in any event because it disgorged *Astellas* of at least some of its purported fraudulent gains.

The Court rejected Federal's argument, ruling first that the "restitution" label in the settlement agreement was for tax purposes, and, in any event the "restitution" label only applied to half the settlement. More fundamentally, however, the court explicitly held that "the False Claims Act does not provide for restitutionary damages" and ruled that at least part of Astellas' settlement came within the scope coverage.

Federal also raised the argument that the settlement must have been based on uninsurable proceeds of "knowing fraud" because the underlying statutory violations required proof that the defendant acted "knowingly and willfully." The court

was equally unpersuaded by this argument and reasoned that Federal's position confused mere allegations of fraud with conclusive proof of fraud. Here, of course, conclusive proof of fraud was lacking as the parties resolved the claim by settlement. In short, the Court held that Federal failed to meet its burden that Astellas acted with fraudulent intent or that the settlement of the potential claims was entirely restitutionary. According to the Seventh Circuit, because the settlement payment was not restitutionary, insurance coverage is available.

## WHAT INSUREDS NEED TO KNOW

Policyholders are presented with challenging coverage issues when navigating insurance claims arising under the Anti Kickback Statute and the FCA. Chief among these challenges has been the common refrain from insurers that relief sought under these statutory schemes constitutes uninsurable restitution. Astellas explicitly rejected the view that the FCA provides for restitution and instead the Court agreed that damages under the FCA are compensatory. In doing so, the Astellas opinion plainly brought damages under the FCA within the scope of coverage of the applicable D&O policy and, just as importantly, provided compelling precedent for insureds to cite when seeking coverage for similarly situated claims.

The *Astellas* Court articulated additional benefits insureds potentially gain by resolving FCA claims by way of settlement. For example, the settlement in *Astellas* prevented the insurer from asserting a series of exclusionary provisions which required "final adjudication." The settlement in *Astellas*, which occurred prior to any litigation, also helped to nullify the insurer's argument that

the policyholder was seeking indemnity for "knowing fraud." That is, in *Astellas*, in seeking to defeat coverage the insurer was only able to point to allegations of fraud, not conclusive proof of fraud. The settlement agreement in *Astellas* also offers cautionary lessons. Here, \$50 million of the settlement was designated as "restitution to the United States." Ultimately, the designation of half the settlement as "restitution" did not prove to be a bar to coverage. However, insureds should be mindful that insurers will use the "label" of how damages are characterized in a settlement agreement as a basis to support coverage defenses.

Finally, a subtle but important aspect of the *Astellas* decision is the burden the Court placed on the insurer. In holding that the definition of "Loss" operated as exclusionary language, the Court required Federal to make the required showing that the settlement was uninsurable. The burden proved to be insurmountable for Federal in this case.

**In sum, the *Astellas* decision offers a number of useful lessons for insureds seeking coverage for claims in the Anti Kickback and FCA space. Policyholders looking to maximize insurance recovery for such claims should look to *Astellas* for guidance on how best to position their claims and how to argue analogous coverage issues.**

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