In the

United States Court of Appeals

For the Seventh Circuit

No. 21-3075

ASTELLAS US HOLDING, INC. and
ASTELLAS PHARMA US, INC.,

Plaintiffs-Appellees,

v.

FEDERAL INSURANCE COMPANY,

Defendant-Appellant.

Appeal from the United States District Court for the
Northern District of Illinois, Eastern Division.
No. 1:17-cv-08220 — **Franklin U. Valderrama**, *Judge*.

ARGUED SEPTEMBER 9, 2022 — DECIDED MAY 3, 2023

Before ROVNER, HAMILTON, and SCUDDER, *Circuit Judges*.

HAMILTON, *Circuit Judge*. Plaintiffs Astellas US Holding, Inc. and Astellas Pharma US, Inc. (we can treat them here as one entity, Astellas) paid the federal government $100 million to settle potential claims for violations of the federal Anti-Kickback Statute and the federal False Claims Act. The potential claims stemmed from Astellas' contributions to so-called "patient assistance plans" to cover the costs of treatment with

an expensive new cancer drug. Astellas had a $10 million directors-and-officers liability insurance policy with defendant Federal Insurance Company. The many questions raised in this appeal boil down to whether Illinois public policy forbids the liability insurer from covering part of its insured's payment to settle the federal government's potential claims. The district court granted summary judgment for the insured, concluding that Illinois public policy does not forbid coverage of the settlement. In a thorough opinion, the court held that Federal owes Astellas the policy limit of $10 million. *Astellas US Holding, Inc. v. Starr Indem. & Liab. Co.*, 566 F. Supp. 3d 879 (N.D. Ill. 2021).

We affirm. Under Illinois law, a party may not obtain liability insurance for genuine restitution it owes the victim of its intentional wrongdoing, but a party may obtain insurance for compensatory damages it may owe. Further, in cases of ambiguity and uncertainty, Illinois favors settlements and freedom of contract, and Federal wrote its insurance policy to try to extend insurance coverage to the very limit of what Illinois law would allow in such cases. Federal bears the burden of showing that the portion of the settlement payment for which Astellas seeks coverage is uninsurable restitution. Federal has not carried that burden with evidence that would allow a reasonable jury to decide in its favor.

I. *Facts for Summary Judgment & Procedural History*

A. *Patient Assistance Plans*

To frame the controlling issue of Illinois insurance law, we must first provide some background about the insured's dispute with the federal government. Drug manufacturers sponsor "patient assistance plans" to help patients obtain needed

medicines at affordable prices. In 2005, Congress amended the Medicare program to offer prescription drug coverage. In planning to implement the new legislation, the government raised concerns that patient assistance plans could be operated in ways that could violate the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and the False Claims Act, 31 U.S.C. § 3729, by effectively rewarding doctors and patients for choosing to use particular drugs. See *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70623-03 (Nov. 22, 2005). The government cautioned that patient assistance plans would need to be "properly structured" to avoid illegally channeling contributions by drug makers to patients and impermissibly influencing their drug choices. *Id.* at 70626, 70627.

B. *Astellas' Contributions to Patient Assistance Programs*

In 2012 plaintiff Astellas launched Xtandi, a so-called "androgen receptor inhibitor" used to treat metastatic prostate cancer that has not responded to surgery. Initially priced at $7,800 per month, Xtandi prescriptions were to be covered by Medicare up to about $6,000 per month, leaving patients with a steep monthly co-pay of about $1,800.

When it launched Xtandi, Astellas began making contributions to a patient assistance plan run by the Chronic Disease Fund. A few months later, Astellas also started contributing to another plan run by the Patient Network Foundation. Apparently, these two funds kept running out of money. In May 2013, an Astellas marketing executive encouraged both the Chronic Disease Fund and the Patient Network Foundation to create special funds that would provide co-pay assistance for only androgen receptor inhibitors like Xtandi and just a few other medications.

In-house lawyers at Astellas and the two patient assistance plans and several outside law firms considered the government's November 2005 regulatory guidance. The lawyers blessed the plan for such narrowly targeted funds. The Chronic Disease Fund and the Patient Network Foundation then set up funds limited to helping patients who needed androgen receptor inhibitors. In July 2013, Astellas began making donations to these funds. Astellas stopped contributing to them after a few months, at the end of 2013. During those months, Astellas contributed about $27 million to the two funds. Astellas continued contributing to broader prostate-cancer funds until 2016. Astellas contributed a total just shy of $130 million to the targeted and broader funds.

C. *The Department of Justice Investigation and the Settlement*

The United States Department of Justice began investigating Astellas' contributions to patient assistance plans for potential health care offenses. In April 2017, the Astellas marketing executive at the center of the inquiry made a "proffer" to the Department. He acknowledged that he had "hoped" and "expected" that the contributions would produce financial benefits for Astellas. But he maintained that the "primary purpose of the donations … was charitable," and he asserted that Astellas had made no efforts to calculate "a return on investment."

In September 2017 the Department of Justice issued a more specific and detailed Civil Investigative Demand to the same executive. One month later, Astellas agreed with the government to toll the relevant statutes of limitations for potential litigation relating to Astellas' possible violations of the False Claims Act, the Anti-Kickback Statute, and the criminal health

care fraud provision of the Health Insurance Portability and Accountability Act, 18 U.S.C. § 1347.

Early in 2018, Astellas authorized its outside counsel to begin settlement negotiations. The government initially estimated its damages at approximately $460 million. As negotiations continued, the government narrowed its focus to Medicare losses attributable to Astellas' contributions to only the narrowly focused androgen receptor inhibitor funds. The government disclosed a new, narrower damages estimate of $82 million. Applying a standard multiplier, the government sought approximately $164 million. In April 2019, Astellas settled with the government for $100 million, $50 million of which was labeled as "restitution to the United States" for tax reasons discussed below.

D. *The Federal Insurance Policy and the Coverage Dispute*

After agreeing to the settlement, Astellas turned to several liability insurers, including Federal, to help cover portions of the $100 million settlement payment. Astellas' directors-and-officers excess liability insurance policy with Federal had a policy limit of $10 million. Astellas demanded the policy limit from Federal. Federal and the other insurers denied coverage.

Astellas then filed this suit for breach of the insurance contracts. Settlements with other insurers left only Federal as a defendant. On cross-motions for summary judgment, the district court ruled in favor of Astellas, concluding that Illinois law and public policy did not prohibit insurance coverage of at least $10 million of the settlement payment.[1]

[1] In the district court, Astellas waived seeking defense costs in exchange for Federal waiving an unspecified defense relating to coverage.

II. *Analysis*

A. *Legal Standard*

The parties agree that Illinois law governs Astellas' claim for breach of contract. "Our task is to decide a question of state law 'as it either has been determined by the highest court of the state or as it would be by that court if the present case were before it now.'" *Sun Life Assurance Co. of Canada v. Wells Fargo Bank, N.A.*, 44 F.4th 1024, 1031 (7th Cir. 2022), quoting *H.A.L. NY Holdings, LLC v. Guinan*, 958 F.3d 627, 632 (7th Cir. 2020), and citing 28 U.S.C. § 1652 and *Erie Railroad Co. v. Tompkins*, 304 U.S. 64, 79 (1938) ("[T]he voice adopted by the State … should utter the last word."). Since the district court granted Astellas' motion for summary judgment, we give Federal the benefit of conflicting evidence and reasonable inferences from the evidence. *BASF AG v. Great American Assurance Co.*, 522 F.3d 813, 818 (7th Cir. 2008).

In Illinois, as in most states, insurance policies are construed according to the same principles that govern other types of contracts. *Windridge of Naperville Condominium Ass'n v. Philadelphia Indem. Ins. Co.*, 932 F.3d 1035, 1039 (7th Cir. 2019), quoting *Hobbs v. Hartford Ins. Co. of the Midwest*, 214 Ill. 2d 11, 291 Ill. Dec. 269, 823 N.E.2d 561, 564 (2005). Our "primary objective in construing the language of an insurance policy is to ascertain and give effect to the intentions of the parties as expressed by the language of the policy." *BASF AG*, 522 F.3d at 819, quoting *Valley Forge Ins. Co. v. Swiderski Electronics, Inc.*, 223 Ill. 2d 352, 307 Ill. Dec. 653, 860 N.E.2d 307, 314 (2006).

Illinois law places the initial burden on the insured to show that a loss is covered. *Crescent Plaza Hotel Owner, L.P. v.*

Zurich American Ins. Co., 20 F.4th 303, 308–09 (7th Cir. 2021), citing *Addison Ins. Co. v. Fay*, 232 Ill. 2d 446, 328 Ill. Dec. 858, 905 N.E.2d 747, 752 (2009). If the insured makes that showing, "the burden shifts to the insurer to establish that an exclusion applies." *Id.* at 309. "Exclusions are read narrowly and apply only if their application is 'clear and free from doubt.'" *Id.*, quoting *National Fire Ins. of Hartford v. Walsh Constr. Co.*, 392 Ill. App. 3d 312, 330 Ill. Dec. 572, 909 N.E.2d 285, 288 (2009); accord, *American Bankers Ins. Co. of Florida v. Shockley*, 3 F.4th 322, 330 (7th Cir. 2021), citing *Pekin Ins. Co. v. Miller*, 367 Ill. App. 3d 263, 305 Ill. Dec. 101, 854 N.E.2d 693, 697 (2006).

B. *Coverage Under the Federal Policy*

When we work through the terms of Astellas' policy with Federal, the $10 million question in this case does not depend on any linguistic nuances in the policy. The key provisions in essence delegate the limits of coverage to Illinois case law drawing public policy boundaries between liabilities that are insurable and those that are not.

To explain, we start with the insuring clause: "The Insurer shall pay on behalf of the Company the Loss arising from a Claim … against the Company for any Wrongful Act." A "Wrongful Act" is "any actual or alleged breach of duty, neglect, error, misstatement, misleading statement, omission or act by the Company." That definition clearly includes potential violations of the Anti-Kickback Statute and the False Claims Act by Astellas in funding unduly narrow patient assistance plans for use in paying for Astellas' own products, for which Astellas ultimately obtained payment from Medicare. Under the policy, a "Claim" includes a "written request to toll or waive the applicable statute of limitations relating to

a potential Claim against an Insured for a Wrongful Act." The government made such a request of Astellas in October 2017.

The critical language in the policy concerns the term "Loss," which includes "damages, settlements or judgments" and "punitive, exemplary or the multiplied portion of any multiple damages awards, but only to the extent that such damages are insurable under the applicable law." The separate definition of "Loss" also excludes coverage for "matters which may be deemed uninsurable under applicable law." We agree with the district court that these two mirror-image references to insurability under applicable law function as exclusions and should be construed as such even though they are not in the policy's list of exclusions. See *Astellas*, 566 F. Supp. 3d at 897.

The parties' briefs also address two "final adjudication" exclusions in the Policy:

> This policy shall not cover any Loss in connection with any Claim:
>
> (a) arising out of, based upon or attributable to the gaining of any profit or advantage or improper or illegal remuneration if a final non-appealable adjudication in an action or proceeding other than an action or proceeding initiated by the Insurer to determine coverage under the policy establishes that such remuneration was improper or illegal;
>
> (b) arising out of, based upon or attributable to any deliberate fraudulent act or any willful violation of law by an Insured if a final non-appealable adjudication in an action or

> proceeding other than an action or proceeding initiated by the Insurer to determine coverage under the policy establishes that such act or violation occurred ….

By their terms, these "final adjudication" exclusions do not apply to the facts of this case. There was never a "final adjudication" of the government's allegations against Astellas, so Federal could not—and does not—rely on these exclusions to deny coverage. But these exclusions may tell us something about the scope of the policy. Because the "final adjudication" exclusions do not preclude coverage where wrongdoing is merely alleged—so Astellas argues—Federal and Astellas had contemplated coverage of a settlement payment like the one here.

The district court agreed with Astellas that the "final adjudication" exclusions "inform the analysis about the parties' intent." *Astellas*, 566 F. Supp. 3d at 907. We agree that the "final adjudication" exclusions help us "to ascertain and give effect to the intentions of the parties as expressed by the language of the policy." See *BASF AG*, 522 F.3d at 819, quoting *Valley Forge Ins. Co.*, 860 N.E.2d at 314. Together with the policy's inclusion of "settlements" in its definition of "Loss," these "final adjudication" exclusions confirm that the parties intended to cover even settlement payments to resolve allegations of illegal remuneration, deliberate fraudulent acts, and willful violations of law. In essence, the "final adjudication" exclusions show that Federal wrote the policy to extend coverage to the limits of applicable law and public policy. Federal was willing to extend coverage, if permissible, to settlements

even for claims for deliberate fraud and willful violations of the law, so long as there was no final adjudication. [2]

C. *Policy Exclusions & Public Policy*

The policy's more general and mirror-image exclusions based on whether a loss is properly insurable direct us to case law applying Illinois law. Illinois "forbids certain types of insurance as being against public policy because of the acute moral hazard that the insurance creates." *Mortenson v. National Union Fire Ins. Co. of Pittsburgh*, 249 F.3d 667, 669, 672 (7th Cir. 2001) (barring liability insurance for tax penalties for employer's "willful" failure to pay payroll taxes). For example, one may not insure against criminal fines or punitive damages. *Id.* at 672, citing *Beaver v. Country Mut. Ins. Co.*, 95 Ill. App. 3d 1122, 51 Ill. Dec. 500, 420 N.E.2d 1058, 1060 (1981), and *Bernier v. Burris*, 113 Ill. 2d 219, 100 Ill. Dec. 585, 497 N.E.2d 763, 776 (1986).

Turning to the specific issue here, Illinois similarly prohibits insurance coverage for losses incurred from settlement payments that are "restitutionary in character." *Level 3 Communications, Inc. v. Federal Ins. Co.*, 272 F.3d 908, 910–11 (7th Cir. 2001) (payment to settle shareholders' claims that insured defrauded them into selling their shares for too little money

[2] We are not suggesting that the "final adjudication" exclusions override public policy. In applying Illinois law of insurability, we have said there is no "line [that] runs between judgments and settlements." *Level 3 Communications, Inc. v. Federal Ins. Co.*, 272 F.3d 908, 911 (7th Cir. 2001). As a matter of public policy, just because a "case is settled before entry of judgment" does not mean that "the insured is covered regardless of the nature of the claim against it." *Id.* Nevertheless, the "final adjudication" exclusions show that Federal wrote the policy to extend coverage as far as Illinois law and public policy would allow.

was restitutionary and not insurable). Accord, e.g., *Illinois Municipal League Risk Mgmt. Ass'n v. City of Genoa*, 2016 IL App (4th) 150550, 402 Ill. Dec. 381, 51 N.E.3d 1133, 1134–35, 1137–38 (2016) (insurer had duty to defend city on claim by regional transit authority for allegedly depriving transit authority of sales tax revenue by agreeing to kickback scheme to persuade business to relocate in city; transit authority sought compensation, not restitution); *Rosalind Franklin University of Medicine & Science v. Lexington Ins. Co.*, 2014 IL App (1st) 113755, 380 Ill. Dec. 89, 8 N.E.3d 20, 37 (2014) (payment to settle claims of patients in experimental cancer treatment program was not restitutionary and thus was insurable); *Local 705 Int'l Bhd. of Teamsters Health & Welfare Fund v. Five Star Managers, L.L.C.*, 316 Ill. App. 3d 391, 249 Ill. Dec. 75, 735 N.E.2d 679, 683–84 (2000) (payment by union to settle claim by affiliated pension fund deemed restitutionary and not insurable); *Ryerson Inc. v. Federal Ins. Co.*, 676 F.3d 610, 612–13 (7th Cir. 2012) (payment by company to purchaser of subsidiary to settle allegations that seller concealed bad news about subsidiary, leading to inflated purchase price, was partial refund of purchase price and thus uninsurable restitution). Before we address whether the settlement payment here was entirely uninsurable, the concept of "restitution" needs some explaining.

1. *Compensation v. Restitution*

Illinois cases draw a line between "compensatory" payments, which are insurable, and "restitutionary" payments, which are not. Where a payment compensates a victim or plaintiff for a loss, the payment takes on the character of compensatory damages. See *Raintree Homes, Inc. v. Village of Long Grove*, 209 Ill. 2d 248, 282 Ill. Dec. 815, 807 N.E.2d 439, 445 (2004). Such payments are insurable in Illinois. *Standard Mut.*

Ins. Co. v. Lay, 2014 IL App (4th) 110527-B, 377 Ill. Dec. 972, 2 N.E.3d 1253, 1258 (2014) (contrasting "actual compensation for injury caused" with uninsurable punitive damages); *Ryerson*, 676 F.3d at 613 (distinguishing a claim for "'damages' in the proper sense of the word" from uninsurable restitution).

On the other hand, where a payment restores to a victim or plaintiff what has been taken from it or forces the perpetrator or defendant to disgorge fraudulently obtained profits, the payment is deemed restitutionary. *Raintree Homes*, 807 N.E.2d at 445 ("restitution is measured by the defendant's unjust gain"), quoting 1 D. Dobbs, Remedies § 3.1, at 278 (2d ed. 1993). See also Black's Law Dictionary 1571 (11th ed. 2019) (defining *restitution* as the "set of remedies … in which the measure of recovery is usu[ally] based not on the plaintiff's loss, but on the defendant's gain" as well as the "[r]eturn or restoration of some specific thing to its rightful owner or status").

These can be tricky concepts to discern from case law, especially because "sometimes courts use the term damages when they mean restitution." *Raintree Homes*, 807 N.E.2d at 444, quoting Remedies § 3.1, at 280; see generally Colleen P. Murphy, *Misclassifying Monetary Restitution*, 55 SMU L. Rev. 1577 (2002) (reviewing disagreements and inconsistencies in legislative, judicial, and scholarly treatment of "restitution" for various purposes). And "restitution" itself is "an ambiguous term, sometimes referring to the disgorging of something which has been taken and at times referring to compensation for injury done." Black's Law Dictionary 1571 (11th ed. 2019), quoting John D. Calamari & Joseph M. Perillo, *The Law of Contracts* § 9-23, at 376 (3d ed. 1987). "Restitution" can therefore

encompass both disgorgement and "compensation." And "damages" can demand "restitution" if "the defendant has been unjustly enriched at the plaintiff's expense." *Restitution damages*, Black's Law Dictionary 491 (11th ed. 2019). In other words, we cannot always trust the labels applied in case law.

While the words themselves ("restitution," "compensation," and "damages") can be both misused and misunderstood, cases applying Illinois law teach that a payment is restitutionary in character under two broad sets of circumstances. First, a settlement payment is restitutionary if the payment disgorges "something that belongs of right not to [the defendant] but to the plaintiff." *Ryerson*, 676 F.3d at 613, citing *Tull v. United States*, 481 U.S. 412, 424 (1987) ("Restitution is limited to 'restoring the status quo and ordering the return of that which rightfully belongs'" to someone else), quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 402 (1946). If a car thief steals a car, for example, the victim has lost a car and the thief has gained a car. Under these circumstances, the plaintiff's "loss and the defendant's gain coincide." Black's Law Dictionary 1571 (11th ed. 2019), quoting Calamari & Perillo, *The Law of Contracts* § 9-23, at 376. Where that is the case, a settlement payment marks the "restoration" to the plaintiff of the defendant's "ill-gotten gain," *Level 3*, 272 F.3d at 910, citing *Local 705*, 735 N.E.2d at 683, and that "gain" just happens to equal the suffered "loss." The return of the car to the victim is therefore both "compensation" and "restitution." Because any alleged "loss" the thief suffered in having to return the car is just as much restitution as it is compensation, the thief cannot insure against liability for that "loss" as a matter of public policy.

Second, a settlement payment is restitutionary if the payment "seeks to deprive the defendant of the net benefit of the unlawful act." *Level 3*, 272 F.3d at 911. This form of restitution certainly encompasses the thief's return of the car since the stolen car was his "net benefit." But it also means that an insured may not "retain the profit it had made from a fraud." *Id.* See also *Ryerson*, 676 F.3d at 613 ("[T]here is no insurable interest in the proceeds of a fraud."). To treat this form of payment as restitution, there must be not only fraud, but also profit.[3]

The settlement payment here could be deemed uninsurable restitution if Federal could show that the payment disgorged either "something that belong[ed] of right not to" Astellas but to the federal government, *Ryerson*, 676 F.3d at 613, or profit that Astellas made from the alleged scheme. *Level 3*, 272 F.3d at 911. Federal argues that the settlement payment here both compensated the government for its losses and disgorged at least some of Astellas' fraudulent gains. Federal contends that, while the proceeds of Astellas' fraud may have been greater than the government's losses, the settlement payment constituted at least a "subset" of Astellas' gains. According to Federal, this "overlap" between Astellas' gains and the government's losses renders the $100 million settlement payment wholly restitutionary so that not even $10 million would be insurable.

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[3] One example of fraud without profit would be "a fraudulent statement by a corporate officer that inflated the price of the corporation's stock without conferring any measurable benefit on the corporation." *Level 3*, 272 F.3d at 911.

2. *"Primary Focus"*

Here, the settlement agreement did not make explicit that the payment constituted restitution either for funds obtained fraudulently from the United States by Astellas or for profits Astellas might have made along the way. To be sure, the settlement labels half of the $100 million payment as "restitution to the United States." But as discussed below, that "restitution" label was applied for tax purposes. Even if the label were accurate, it would apply to only half of the payment, leaving another half for Federal to cover in part. We have also said that the parties' "label isn't important" in deciding whether a settlement payment is restitutionary. See *Ryerson*, 676 F.3d at 613.

So what do courts do with imprecise language and these conflicting signals in the case law? Where it is not obvious whether a settlement payment was restitutionary or compensatory, we and the Illinois courts have developed an analytic framework that can often resolve the uncertainty. This framework tries to balance two competing concerns implicated by settlement agreements.

On one hand, we worry "that the settlement was entered into in order to obtain insurance coverage for an otherwise uninsurable" liability. *United States Gypsum Co. v. Admiral Ins. Co.*, 268 Ill. App. 3d 598, 205 Ill. Dec. 619, 643 N.E.2d 1226, 1244 (1994). On the other hand, we worry "that an insured will be deterred from entering into a settlement agreement" if it can obtain coverage only by proving its own liability. *Id*.

We are dealing here with a sizable settlement to resolve potential high-dollar claims in a complex area of federal health care law. The law generally favors the settlement of

claims, and Illinois courts do not apply public policy in a way that discourages them. Settlements, of course, afford certain "advantages to the insured." *Id.*, quoting *Uniroyal, Inc. v. Home Ins. Co.*, 707 F. Supp. 1368, 1378 (E.D.N.Y. 1988). For all parties, settlements eliminate the "uncertainties of outcome in litigation," and promote "the avoidance of wasteful litigation and expense." *Airline Stewards & Stewardesses Ass'n v. American Airlines, Inc.*, 573 F.2d 960, 963 (7th Cir. 1978), quoting *Florida Trailer & Equip. Co. v. Deal*, 284 F.2d 567, 571 (5th Cir. 1960). Benefits accrue to courts as well, so "the law generally favors the encouragement of settlements." *Id.* See also *Delta Air Lines, Inc. v. August*, 450 U.S. 346, 363 (1981) (Powell, J., concurring in judgment) ("[P]arties to litigation and the public as a whole have an interest—often an overriding one—in settlement rather than exhaustion of protracted court proceedings.").

"In cases where an insured enters into a settlement that disposes of both covered and non-covered claims, the insurer's duty to indemnify encompasses the entire settlement if the covered claims were 'a primary focus of the litigation.'" *Rosalind Franklin University*, 8 N.E.3d at 39, quoting *Commonwealth Edison Co. v. Nat'l Union Fire Ins. Co. of Pittsburgh*, 323 Ill. App. 3d 970, 256 Ill. Dec. 675, 752 N.E.2d 555, 565 (2001); see also *Federal Ins. Co. v. Binney & Smith, Inc.*, 393 Ill. App. 3d 277, 332 Ill. Dec. 448, 913 N.E.2d 43, 53–54 (2009). On the other hand, "if the 'primary focus' of the claims that were settled is not a covered loss, then the insurer is not required to reimburse the settlement." *Rosalind Franklin University*, 8 N.E.3d at 40, citing *Santa's Best Craft, LLC v. St. Paul Fire & Marine Ins. Co.*, 611 F.3d 339, 352 (7th Cir. 2010). Put another way, if Federal could show that the settlement payment was "not even potentially covered," then it would not need to cover Astellas' settlement. See *Santa's Best*, 611 F.3d at 352.

This case presents unusual difficulties in resolving the "primary focus" inquiry, and those difficulties fall more heavily on Federal, the party seeking to prove that a policy exclusion applies. The Department of Justice investigated Astellas but never even filed a civil or criminal action. In all relevant case law we have found, complaints had at least been filed and legal claims had been asserted before settlements were reached. See, e.g., *United States Gypsum*, 643 N.E.2d at 1232, 1245 (seven of approximately 250 property damage cases settled after discovery had commenced); *Commonwealth Edison*, 752 N.E.2d at 557–58 (settled after nearly two years of civil litigation); *Binney & Smith*, 913 N.E.2d at 47–48 (class action settled six months after action filed); *Santa's Best*, 611 F.3d at 343–44 (settled after two years of civil litigation); *Rosalind Franklin University*, 8 N.E.3d at 26–27 (settled after filing of complaint and hearing on motion for preliminary injunction); *Selective Ins. Co. of South Carolina v. Target Corp.*, 845 F.3d 263, 264 (7th Cir. 2016) (settled after discovery had commenced).

In this case, no claims ever became "a primary focus of the *litigation*," *Rosalind Franklin University*, 8 N.E.3d at 39, quoting *Commonwealth Edison*, 752 N.E.2d at 565 (emphasis added), because there was no litigation. We have only potential claims that the government investigated and then settled without ever bringing any legal action. The potential claims included violations of the False Claims Act, the Anti-Kickback Statute, and the Program Fraud Civil Remedies Act, and "the common law theories of payment by mistake, unjust enrichment, and fraud." Virtually all of these relinquished claims sounded in fraud.

The problem is that "fraud" is a broad category and is not per se uninsurable in Illinois. Public policy necessarily bars

insurance coverage for only restitution of the proceeds of proven fraud. *Ryerson*, 676 F.3d at 613. Here, we are concerned with whether the settlement payment was restitutionary. The fact that the potential claims sounded in fraud is not decisive. In other words, the settlement agreement alone cannot do the work that Federal needs.

So how does a court decide whether a settlement was restitutionary rather than compensatory? In other cases, courts have had much more than a settlement agreement to go on. They have had complaints, answers, hearings, discovery, and so on.

When a complaint is filed, it not only asserts claims but also requests relief that may shed some light on the nature of a later settlement payment. See *United States Gypsum*, 643 N.E.2d at 1230 (plaintiffs sought cost of removing asbestos from structures and repairing damage that material caused); *Edison*, 752 N.E.2d at 557–58 (estate sought compensatory and punitive damages in wrongful death action); *Binney & Smith*, 913 N.E.2d at 47, 54 (class sought compensatory damages for purchase price of crayons); *Santa's Best*, 611 F.3d at 343 (plaintiffs sought compensatory damages, punitive damages, and disgorgement of profits); *Rosalind Franklin University*, 8 N.E.3d at 26 (plaintiffs sought compensatory damages and disgorgement); *Selective Insurance*, 845 F.3d at 271–72 (plaintiff sought compensatory damages). To be sure, not all of these cases were concerned, as we are, with the nature of the settlement payment. In *United States Gypsum*, *Commonwealth Edison*, and *Selective Insurance*, for example, the insurers were trying to show that the insureds would not have been liable for physical property damage or personal injury if they had litigated. *United States Gypsum*, 643 N.E.2d at 1237–38; *Commonwealth*

Edison, 752 N.E.2d at 559, 564–65; *Selective Insurance*, 845 F.3d at 271–72. In *Binney & Smith*, the insurer was trying to show that the insured would not have been liable for an advertising injury. 913 N.E.2d at 58.

In cases where the nature of the settlement payment was disputed, both the claims and the requested relief helped courts determine whether the payments were covered. Most notably, in *Rosalind Franklin University*, the Illinois Appellate Court considered, as we do here, whether a settlement payment was uninsurable restitution. 8 N.E.3d at 36–39. Among other things, the court considered the relief the "underlying plaintiffs [had] sought," which included both compensatory damages and disgorgement of funds that the insured defendant "never had the right to possess." *Id.* at 37–39. Because the underlying plaintiffs had pursued both forms of relief and the settlement had "disposed of all the underlying plaintiffs' claims," the court concluded that it was "apparent that the settlement did not represent" restitution. *Id.* at 39. In other words, the court took the requested relief into account, but it also gave the benefit of the doubt to the insured, treating the payment as entirely insurable even though a portion of it was likely restitutionary. See also *Santa's Best*, 611 F.3d at 350–52 (addressing apportionment of an undifferentiated settlement payment and remanding after clarifying legal standard so that district court could determine whether "the primary focus of settlement was damages payments for a covered" claim based on record evidence and allegations in complaint, which requested "profits, damages, costs, and punitive damages").

Here the government never requested any specific remedies. The settlement agreement broadly released Astellas from "any civil or administrative monetary claim the United

States" might have under relevant statutes or the common law. We have even less information than the Illinois court had in *Rosalind Franklin University*. To assess the character of this settlement payment, we can rely only on inferences drawn from predictions about the claims the government *likely* would have brought and the remedies the government *likely* would have sought if it had proceeded beyond investigating Astellas to litigating a civil (or criminal) action. This is not an easy task because, well, the dispute was settled.

The district court undertook this "primary focus" inquiry and found that the government was primarily focused on possible violations of the False Claims Act with underlying Anti-Kickback Statute violations. *Astellas*, 566 F. Supp. 3d at 904. Federal now agrees. We accept that premise, but from it, Federal asks us to make an unwarranted leap. Federal argues that the "primary focus" of the settlement must have been "based on the uninsured and uninsurable proceeds of *knowing fraud*" because the underlying Anti-Kickback Statute violation "required proof that the defendant acted 'knowingly and willfully.'" See 42 U.S.C. § 1320a–7b(b).

Broadly speaking, this argument overlooks the difference between a potential claim for fraud and a remedy demanding restitution for the proceeds of that fraud as distinct from compensatory relief. See *Level 3*, 272 F.3d at 911 (discussing scenarios where remedy for fraud would not be restitutionary). More fundamental, Federal's argument confuses an (implied) allegation of fraud with conclusive proof of such fraud.

a. *Whether Allegations of Fraud Under the False Claims Act and Anti-Kickback Statute Suffice to Bar Coverage*

An ultimate finding of liability under the False Claims Act requires proof of knowing fraud. 31 U.S.C. § 3729(a)(1)(A) (requiring "knowingly present[ing] … a false or fraudulent claim"). The Anti-Kickback Statute requires proof of a knowing and willful "false statement or representation of a material fact." 42 U.S.C. § 1320a-7b(a). The fact that these statutes, operating together, require intentional, knowing, and willful fraud does *not* mean that any party accused of violating them who settles a civil claim against it must have acted with fraudulent scienter. The claim or charge cannot alone prove the (insurer's) case.

Beyond this general point, we are particularly wary of Federal's scienter argument in the context of the False Claims Act. Regardless of the scienter needed to prove an underlying violation of the Anti-Kickback Statute, the False Claims Act's scienter standard is broad. It reaches reckless conduct. Moreover, the line between reckless conduct and merely negligent conduct can be fuzzy, especially where inferences from circumstantial evidence are often critical.

Civil liability under the False Claims Act requires proof that the defendant "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).[4] As amended in 1986, the False

[4] A "claim" encompasses both "direct requests to the Government for payment" and "reimbursement requests made to the recipients of federal funds under federal benefits programs[ ]" like Medicare. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 182 (2016). And the "false or fraudulent claim" element may be satisfied by proving a

Claims Act has a broad definition of "knowing." The Act's "scienter requirement defines 'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 182 (2016), quoting 31 U.S.C. § 3729(b)(1)(A)(i)–(iii). A "specific intent to defraud" is not required. 31 U.S.C. § 3729(b)(1)(B).

Complicating matters further for classifying a settlement reached in 2019, the scienter standard under the False Claims Act is a moving target. In light of a circuit split on that standard, the Supreme Court recently heard argument in two cases from this circuit. See *United States ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455 (7th Cir. 2021), cert. granted, No. 21-1326 (Jan. 13, 2023); *United States ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649 (7th Cir. 2022), cert. granted, No. 22-111 (Jan. 13, 2023).

In short, the fact that a party has been accused of (let alone just investigated for) violating the False Claims Act or the Anti-Kickback Statute falls well short of establishing that its payment to settle such an accusation or investigation is uninsurable.

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violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(g) ("In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.").

b. *Whether the Evidence Supports a Reasonable Inference of Fraud Without a Final Adjudication*

At best, for Federal, whether Astellas actually committed fraud depends on the evidence. With no underlying litigation, Federal's burden is high. Illinois law does not allow an insurer to try fully the merits of the settled claim to prove that the insured's loss is uninsurable. Indeed, "requiring that insureds" litigate in an insurance action "the entire case which was to be offered against them" would likely "have a chilling effect on settlements." *United States Gypsum*, 643 N.E.2d at 1239–42, 1244 (reviewing only the record from the underlying action). Rather, Federal must rely solely on the existing record evidence. See *Commonwealth Edison*, 752 N.E.2d at 563–65 (noting that "the nature of the pleadings, the pretrial discovery, evidence and testimony presented during the trial prior to settlement would be relevant to establish" whether the claim would have likely been covered or not if it had proceeded to a final adjudication), quoting *United States Gypsum*, 643 N.E.2d at 1244.

Like the Illinois courts, therefore, we "must consider the facts and circumstances" of the particular case to determine whether a settlement payment violates public policy. See *Gulliver's East, Inc. v. California Union Ins. Co.*, 118 Ill. App. 3d 589, 74 Ill. Dec. 234, 455 N.E.2d 264, 265 (1983) (discussing whether a contract clause, rather than a settlement payment, violated public policy). This is an objective inquiry.[5]

[5] Federal is correct that this objective inquiry does not depend on whether the insured expressly admits liability. It would make little sense if it did. All of the cases giving rise to the "primary focus" standard involved an *insured* trying to prove that it *reasonably thought it might be found liable* if the underlying action had resulted in a final judgment instead of a

When Illinois courts apply this "primary focus" test, they may analyze the evidence upon which the claim could have been adjudicated. See *United States Gypsum*, 643 N.E.2d at 1245–47 (reviewing physical evidence, deposition, trial, and expert witness testimony, and reports and recommendations by federal and state health and environmental agencies); *Commonwealth Edison*, 752 N.E.2d at 565 (considering allegations in pleadings and evidence presented in both underlying and coverage actions, including depositions, corroborating witnesses, and party stipulations); *Binney & Smith*, 913 N.E.2d at 48–54 (accounting for factual allegations in underlying complaint and affidavits from parties and their counsel); *Rosalind Franklin University*, 8 N.E.3d at 39–43 (reviewing underlying complaint's factual allegations and requests for relief irrespective of legal theories).[6]

Whether Federal can show that Astellas would have been found liable for fraud under the False Claims Act and the Anti-Kickback Statute if those claims had been litigated depends "on the quality and quantity of proof" that would have

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settlement. See *United States Gypsum*, 643 N.E.2d at 1244–47 (insured trying to show that it reasonably anticipated liability for property damage); *Edison*, 752 N.E.2d at 564–65 (same for wrongful death and related damages); *Binney & Smith*, 913 N.E.2d at 47–53 (same for deceptive trade practices and warranty breach); *Santa's Best*, 611 F.3d at 348, 352 (same for "slogan infringement").

[6] While we suggested in *Santa's Best* that the district court could, on remand, supplement the record evidence with further briefing or "an evidentiary hearing," 611 F.3d at 352, decisions of the courts of Illinois do not invite such expansion of the record. Allowing such expansion would trend more and more toward requiring that insureds litigate "the entire case" that might have been offered against them. *United States Gypsum*, 643 N.E.2d at 1244.

been "offered against [Astellas] in the underlying action." See *United States Gypsum*, 643 N.E.2d at 1245.

To avoid the need to show objective evidence of fraud, Federal relies on our statement in *Ryerson* that if the insured there could have obtained reimbursement from Federal, it would "have gotten away with fraud," for "if [the] claim that [the insured] agreed to settle was not completely meritless, some portion of the [settlement payment] was proceeds of fraud." 676 F.3d at 612. Federal tries to reframe this statement as a binding command for all settlements paid after fraud is alleged.

We read that comment differently, as a case-specific observation grounded in the facts in that case. In *Ryerson*, we *knew* from the underlying litigation—lasting more than three years—that the adverse party in the underlying action had actively sought restitutionary relief based on fraudulent concealment. 676 F.3d at 612. And we *knew* from the settlement agreement itself that the insured had made partial restitution, restoring to the other party funds that the insured had obtained in the allegedly fraudulent transaction. *Id*. We did not infer fraud from the fact of settlement, nor did we make any finding of fraud. All we did in *Ryerson* was see that the settlement payment there was clearly restitutionary in nature and confirm that it was uninsurable. In the portions of the opinion upon which Federal relies, we were explaining the public policy justifications for treating restitution as uninsurable.

Ryerson was a relatively straightforward case where we saw restitution and called it restitution. This case is not as straightforward. Here, Federal wants to support an inference that the settlement was restitutionary by arguing that Astellas would have been liable for fraud under the False Claims Act

and Anti-Kickback Statute. That is, Federal tries to show that Astellas settled the potential claims against it in "reasonable anticipation of liability." See *United States Gypsum*, 643 N.E.2d at 1244. Federal must point to evidence in the record to support that inference. Federal's evidence on this point is, however, too weak to avoid summary judgment. We summarize Federal's evidence and then the contrary evidence, and then we explain why room for debate about Astellas' actions does not preclude summary judgment.

(1) *Federal's Evidence of Reasonably Anticipated Liability for Fraud*

Federal relies first on declarations by Astellas' lawyer handling the investigation. He said that the government's investigation "focused primarily on Medicare Part D payments" for Xtandi. The Department of Justice believed that Astellas was using patient assistance programs "as conduits to funnel impermissible copay assistance to Xtandi patients in violation of the Anti-Kickback Statute … , thereby causing Medicare beneficiaries to submit false claims" in violation of the False Claims Act.

Second, Federal relies on the proffer made by the Astellas marketing executive. The executive made clear that he "understood that the majority of patients prescribed Xtandi would be covered by Medicare," that a significant number of them would be unable to afford their co-pays, and that oncologists had recommended contributing to patient assistance programs to ensure broader access to Xtandi.

Third, Federal describes how Astellas chose to structure its contributions. In May 2013, the marketing executive talked with the Chronic Disease Fund and the Patient Network

Foundation about setting up new funds to provide co-pay assistance to patients being treated with androgen receptor inhibitors. Only Xtandi and a few other medications would be covered. According to one Astellas lawyer helping with the investigation, the Department of Justice thought Astellas chose to make these charitable donations because doing so might "generate revenue."

The Department of Justice theorized that the supposedly charitable donations violated the Anti-Kickback Statute, in part, due to the 2005 guidance issued by the Office of the Inspector General. The guidance was "concerned that, in some cases, charities may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor's particular products." 70 Fed. Reg. at 70627. Examples included defining disease categories "by reference to specific symptoms, severity of symptoms, or the method of administration of drugs, rather than by diagnoses or broadly recognized illnesses or diseases." *Id.* But Anti-Kickback Statute concerns would be at a minimum where the patient assistance program does not "function as a conduit for payments by the pharmaceutical manufacturer to patients and [does] not impermissibly influence beneficiaries' drug choices." *Id*. at 70626–27. Suspecting that Astellas' arrangement of and contributions to the androgen receptor inhibitor funds ran contrary to this guidance, the government investigated.

On its own, this evidence shows what we already know—the government suspected that Astellas might be in violation of the False Claims Act and the Anti-Kickback Statute, and it investigated Astellas based on those suspicions. This evidence does not support the inference Federal asks us to accept.

(2) *Astellas' Evidence Against Reasonably Anticipated Liability for Fraud*

Even if Federal's evidence were stronger, there are also countervailing facts that further lessen the evidence's probative value. For example, in his proffer, the Astellas executive maintained that while he had "hoped" there would be a financial benefit to Astellas, the "primary purpose of the donations … was charitable," regardless of any "expected or anticipated" profits. To be sure, when the executive learned that more patients were switching to Xtandi, he exclaimed in an e-mail, "Hooray! The system is working as we promised!!" And donations to the funds would remain high so long as Astellas' "trend line is increasing." But the executive was also clear that Astellas made no efforts to "quantify the number of switches," or to "calculate[ ] a return on investment." He said there were just too many "variables that made any financial benefit uncertain." Federal has not offered evidence directly disputing his testimony.

(3) *Why the Evidence Does Not Preclude Summary Judgment.*

Counterbalanced by contrary evidence in the record, Federal's evidence falls well short of proof of the requisite scienter for the intentional, knowing, and willful fraud the False Claims Act and Anti-Kickback Statute require. It cannot, therefore, support an inference that Astellas would have been liable if the government had litigated the potential claims. Even if the funds were erroneously structured and Astellas' donations to them were improper, to meet the False Claims Act's scienter standard as this court currently construes it, the government would have had to show that Astellas' approach to providing subsidies was objectively unreasonable and

contrary to the regulatory guidance. See *SuperValu*, 9 F.4th at 464 (establishing current circuit law), citing *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47, 70 (2007).

In this case, undisputed evidence shows that, before the funds were created or any donations were made, both patient assistance plans consulted independent outside counsel. Counsel for both foundations determined that the funds were "appropriate" under the government's guidance. Astellas' counsel conferred with the foundations' outside lawyers, who had "each independently approved" the funds. And only after obtaining legal advice from regulatory experts at an outside law firm, who thought the funds would meet the requirements in the guidance, did Astellas' in-house counsel give its approval as well. Federal has not called into question Astellas' good faith in seeking legal advice before proceeding with the patient assistance program contributions. Given the absence of stronger evidence of fraudulent scienter and the undisputed evidence of the legal advice Astellas, the Chronic Disease Fund and the Patient Network Foundation obtained in structuring the funds and making the charitable donations, Federal has not come forward with evidence that would allow a reasonable jury to find that Astellas acted with fraudulent intent, let alone that the settlement of the potential claims was entirely restitutionary.

Nor is it clear that the arrangement was contrary to the regulatory guidance. The Astellas executive's "understanding was that 'a fund could not classify a disease area too narrowly.'" That understanding accords with the guidance. The guidance discussed many factors other than just narrow classification, but classification was a critical factor. The guidance was specifically concerned with "artificially" defining

"disease categories" too narrowly and included examples that, importantly, did not include how the drug functions, which is how the two foundations here defined the androgen receptor inhibitor funds. See 70 Fed. Reg. at 70627.

In sum, it is far from clear from the record that Astellas' conduct would meet the scienter requirements of both the False Claims Act and the Anti-Kickback Statute if the Department of Justice had elected to litigate rather than to settle. It is one thing to suspect fraud. It is another thing to prove it.

In this insurance dispute, we need not decide whether Astellas could have won a hypothetical motion for summary judgment on False Claims Act and Anti-Kickback Statute claims if the government had actually filed any. Nor do we need to decide whether the government could have won a motion for summary judgment. The point here is that the parties agreed to settle those potential claims rather than litigate them to a final judgment. Each side would have had some evidence favoring its position, and each side preferred to agree to the settlement rather than litigate. In this insurance dispute, the burden is on Federal to show that the settlement was (entirely) restitutionary in nature, and it has not offered evidence sufficient to show that.

On this point, the Illinois Appellate Court's decision in *Gulliver's East, Inc. v. California Union Insurance* is instructive. In *Gulliver's East*, the defendant insurer had issued a fire insurance policy to an Illinois restaurant. 455 N.E.2d at 265. The policy provided that the insurer could not raise arson as a defense to coverage absent "an indictment and conviction" for arson. *Id*. After the restaurant was destroyed by fire, the insurer investigated and found that the fire had been set intentionally by someone acting on behalf of the restaurant. The

insurer denied coverage. Gulliver's East sued for a declaratory judgment that the indictment and conviction requirement was enforceable and not, as the insurer argued, contrary to Illinois public policy. *Id*.

The appellate court affirmed the trial court's decision to enforce the exclusion's requirement for indictment and conviction. The appellate court rejected the insurer's argument that the clause encouraged arson, reasoning that the "parties did not agree to indemnify unconvicted arsonists, but rather agreed in advance to the manner in which [the insurer] could raise and establish the arson defense." *Id.* While Illinois public policy "discourage[ed] the intentional burning of property for profit," the arson clause "delegate[d] the arson assessment to a disinterested party, the prosecuting authorities." *Id.* The insurer's opinion that the fire was the result of arson was not sufficient to defeat coverage based on Illinois public policy. *Id*. "Once there was a conviction," however, not only could the insurer contractually raise the defense of arson, but that defense would align "with the public policy against arson and the general policy of preventing wrongdoers from profiting from their intentionally wrongful acts." *Id.* at 266. Those found guilty of arson would be prevented from unjustly profiting from their crimes, *id*., but mere allegations or suspicions would not suffice. Rejecting a lesser showing or suspicion was not contrary to Illinois public policy.

Just as the parties in *Gulliver's East* agreed to "final adjudication" exclusions and thereby "delegate[d] the arson assessment to a disinterested party, the prosecuting authorities," 455 N.E.2d at 265, so here Federal and Astellas agreed to the "final adjudication" exclusions discussed above. They delegated assessment of possible "illegal remuneration,"

"deliberate fraudulent act[s]," or "willful violation[s] of law" to a third-party adjudicator in an action brought by a third party. As in *Gulliver's East*, where the insurer's opinion regarding the insured's culpability was insufficient to deny coverage under the contract, so here Federal's belief that Astellas committed fraud and profited from it because Astellas was investigated for fraud and paid to settle potential claims is likewise insufficient to deny coverage. See also *USA Gymnastics v. Liberty Ins. Underwriters, Inc.*, 27 F.4th 499, 520–22, 534 (7th Cir. 2022) (applying Indiana law to similar "final adjudication" exclusion in directors-and-officers policy, denying insurance coverage for 10 claims of criminal sexual conduct where an insured had been adjudicated "formally guilty," but ordering coverage for 115 settled claims based on same type of alleged criminal conduct).[7]

To reiterate, an insurance coverage dispute is not a forum for trying the merits of the potential claims against the insured. Demanding that insureds litigate "the entire case" that might have been offered against them would "have a chilling effect on settlements." *United States Gypsum*, 643 N.E.2d at 1239–42, 1244.

[7] Nor can we, as Federal suggests, draw a reasonable inference against Astellas simply because the company chose to settle with the government for $100 million. This was not a mere nuisance settlement, cf. *Level 3*, 272 F.3d at 911–12, but $100 million was well below the government's initial damages estimate without statutory multipliers ($460 million) and much less than the nearly $1.4 billion the government might have sought with the False Claims Act's damages multiplier.

c. *Whether the Settlement Payment was Entirely Restitutionary*

Even if Federal had offered stronger evidence of scienter, that would not be enough to show that the settlement payment was restitutionary. Proving fraud does not necessarily prove restitution. *Level 3*, 272 F.3d at 911 ("We can imagine situations in which there would be a covered loss" even though the insured was found liable for fraudulent conduct.). The critical question under Illinois public policy is whether the payment was restitutionary. Federal has not shown that it was, and certainly not that it was entirely restitutionary. See *Santa's Best*, 611 F.3d at 352 ("the proper inquiry is whether the claims were *not even potentially covered* by the insurance policy") (emphasis in original). The False Claims Act does not provide for restitutionary damages, and Federal has not offered sufficient evidence to find either fraud or disgorgement of profits.

(1) *The False Claims Act's Remedies*

Federal might show that the settlement payment was restitutionary if it could show that violations of the False Claims Act and Anti-Kickback Statute are necessarily remedied via restitution rather than compensation. The district court found the opposite: the False Claims Act "allows only for civil penalties and compensatory damages, not for restitution." *Astellas*, 566 F. Supp. 3d at 900. We agree.

The False Claims Act provides that anyone who has violated the Act "is liable to the United States Government for a civil penalty … plus 3 times the amount of *damages* which the Government sustains" because of such violation. 31 U.S.C. § 3729(a)(1) (emphasis added). The Supreme Court "has

explained many times over many years that, when the meaning of the statute's terms is plain, our job is at an end." *Bostock v. Clayton County*, 140 S. Ct. 1731, 1749 (2020). The False Claims Act speaks in terms of "damages."

Still, as discussed above, labels cannot always be taken at face value in this context of public policy and insurability. The Supreme Court has also said that "the chief purpose" of the False Claims Act's civil penalties "was to provide for *restitution* to the government of money taken from it by fraud." *United States v. Bornstein*, 423 U.S. 303, 314 (1976), quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551 (1943) (emphasis added). This observation might settle the matter were it not for both the statutory text and the inconsistent use of the word "restitution," *Raintree Homes*, 807 N.E.2d at 444, as well as the Court's later statement in *Bornstein* "that the device of [multiplied] damages … was chosen to make sure that the government would be made completely whole." 423 U.S. at 314, quoting *Hess*, 317 U.S. at 551–52. Making the government whole is the language of compensatory damages. *Bornstein* went on to discuss only compensatory damages and to hold that "in computing the [multiplied] damages authorized by the Act, the Government's actual damages are to be [multiplied] before any subtractions are made for compensatory payments previously received by the Government." 423 U.S. at 315–16. The Court's passing use of the word "restitution" in *Bornstein*, which addressed how to calculate damages under the Act, did not address, let alone resolve, our inquiry about the nature of Astellas' settlement payment.

Where a statutory term is undefined, "we ask what that term's 'ordinary, contemporary, common meaning' was when Congress enacted" the statute. *Food Marketing Institute*

v. Argus Leader Media, 139 S. Ct. 2356, 2362 (2019), quoting *Perrin v. United States*, 444 U.S. 37, 42 (1979). Toward that end, it can sometimes be helpful to consider dictionary definitions from the time of the statute's enactment "because they are evidence of what people at the time of a statute's enactment would have understood its words to mean." *Bostock*, 140 S. Ct. at 1766, citing John F. Manning, *Textualism and the Equity of the Statute*, 101 Colum. L. Rev. 1, 109 (2001). But dictionaries offer many definitions, both broad and narrow, without reliable guides for choosing among them for particular legal purposes. See generally *Jordan v. De George*, 341 U.S. 223, 234 (1951) (Jackson, J., dissenting) (describing dictionaries as "the last resort of the baffled judge"); Frank H. Easterbrook, *Text, History, and Structure in Statutory Interpretation*, 17 Harv. J.L. & Pub. Pol'y 61, 67 (1994) ("the choice among meanings [of words in statutes] must have a footing more solid than a dictionary—which is a museum of words, an historical catalog rather than a means to decode the work of legislatures").

When the False Claims Act was enacted in 1863, "damages" meant "[t]he value, estimated in money, of something lost or withheld; the sum of money claimed or adjudged to be paid in compensation for loss or injury sustained." *Damage*, 4 The Oxford English Dictionary 224 (2d ed. 1989). That definition aligns with the statute's text, which speaks of "damages which the Government sustains." 31 U.S.C. § 3729(a)(1). Injuries are sustained by victims. So are losses and damages. Profits or proceeds for a wrongdoer are not. The context of the word "damages" in the False Claims Act supports reading the word according to its "ordinary, contemporary, [and] common meaning" in 1863. That is, "damages" points in the direction of "compensation" rather than "restitution."

As we have said, however, we have to be careful about the slippery uses of words like "damages." *Raintree Homes*, 807 N.E.2d at 444; Murphy, *Misclassifying Monetary Restitution*, 55 SMU L. Rev. 1577 (2002). But "where a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it." *Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11, 19 (1979); see also *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010) (recognizing "the risks created by an excessively broad interpretation" of False Claims Act).

"The presumption that a remedy was deliberately omitted from a statute is strongest when Congress has enacted a comprehensive legislative scheme including an integrated system of procedures for enforcement." *Massachusetts Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 147 (1985), quoting *Northwest Airlines, Inc. v. Transport Workers*, 451 U.S. 77, 97 (1981); see also *Mortgages, Inc. v. United States Dist. Court*, 934 F.2d 209, 213 (9th Cir. 1991) (declining to create "additional federal common law" because False Claims Act "includes comprehensive procedures for enforcement"). "This approach is especially appropriate in this case where the Government can pursue other remedies (such as administrative proceedings and common law unjust enrichment claims) if it so chooses." *United States ex rel. Taylor v. Gabelli*, No. 03 CIV 8762(PAC), 2005 WL 2978921, at *8 (S.D.N.Y. Nov. 4, 2005) (thoroughly analyzing availability of restitution under False Claims Act and finding that only compensatory damages are available); see also *Call One Inc. v. Berkley Ins. Co.*, 587 F. Supp. 3d 706, 716–17 (N.D. Ill. 2022) (canvassing cases on False Claims Act remedies to find that Illinois analogue "provides for compensatory damages or actual loss, not disgorgement, as a remedy"); *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719,

732 (N.D. Ill. 2007) ("Disgorgement of profits is not a remedy recoverable" under False Claims Act). As best we can tell, no court has ever interpreted the False Claims Act as allowing restitutionary remedies. See *Taylor*, 2005 WL 2978921, at *8 (surveying case law). We are not persuaded that we should be the first to treat "damages" under the False Claims Act as restitutionary rather than compensatory, particularly in the context of a dispute over insurance coverage for claims that were never even formally asserted.

(2) *Whether the Government Obtained Restitution*

Federal argues further that the settlement payment here is restitutionary because it "*both* disgorges some of the proceeds Astellas realized from its fraud scheme *and* uses the disgorgement to return funds to the victim of the scheme." That is, Federal contends that the settlement payment "required Astellas to return a subset of its fraud proceeds to the government in repayment for false" Medicare claims.

Federal starts with the fact that the settlement agreement itself labeled half of the payment as "restitution to the United States." Federal argues that this "restitution" label shows that the settlement payment "expressly encompassed" the proceeds of fraud. We are not persuaded, for two reasons beyond our skepticism about labels. See *Ryerson*, 676 F.3d at 613 ("the label isn't important").

First, we have undisputed evidence about the tax reasons for that designation. Money paid to the government "in relation to … [an] investigation" by the government "into the potential violation of any law" is not tax deductible unless the amount "constitutes restitution" and "is identified as restitution" in a "settlement agreement." 26 U.S.C. § 162(f), as

amended by the Tax Cuts and Jobs Act of 2017; see also *Astellas*, 566 F. Supp. 3d at 898 (district court's explanation of tax reasons for settlement language).

Astellas' lead counsel in the government's investigation testified that, since the Tax Cuts and Jobs Act amended the tax code in 2017, the Department of Justice has incorporated this "restitution to the United States" language into all settlement agreements. During settlement negotiations, the government told the lawyer that "the purpose of identifying $50 million as restitution to the United States was to comply" with the Tax Cuts and Jobs Act. The lawyer had suggested that the settlement agreement specifically acknowledge the tax purposes of the "restitution" label, but the Department of Justice rejected that proposal because of its "long-standing policy" against modifying its standard settlement template. We are not persuaded that the label for federal tax purposes is probative of Illinois public policy on moral hazard and insurability.

Second, even if the restitution label were probative for our question, the label applied to only half of the settlement. The half that was not subject to that label far exceeded Federal's policy limit of $10 million. It is Federal's burden to show that the payment was "not even potentially covered." *Santa's Best*, 611 F.3d at 352. The label does not help Federal make this showing.

(3) *Whether Alleged Profits Require Restitutionary Payment*

Federal also asserts that Astellas actually came into possession of some "ill-gotten gain," some form of fraudulent proceeds, that it returned to the government in the settlement. Federal asks us to assume that Astellas benefited from the

alleged scheme, but it has not offered evidence that would allow a reasonable inference that Astellas actually benefited from the alleged scheme. Federal argues that any "kickback-tainted payments for Xtandi" that Medicare paid out "*necessarily* accrued to Astellas through the ordinary operation of the pharmaceutical distribution and payment chain, generating revenues to which Astellas was not entitled." But why "necessarily"? Federal argues that this "kind of payment is *inherently* restitutionary." Why "inherently"? There must be some evidence of profit, benefit, or proceeds for this argument to work, and Federal has not offered any.

Federal points to the Astellas executive's statements that he "expected or anticipated" Astellas to benefit financially from the charitable donations, that the donations would "have a positive impact on business," that Astellas would keep donating while the "trend line is increasing," and that "it was 'obvious'" that Astellas would lose revenue without the donations. This evidence does not establish as undisputed, as Federal contends, that Astellas actually received substantial proceeds from the scheme.

As Federal points out, Astellas never calculated any profits. More to the point, neither has Federal. Federal says this is irrelevant. We disagree, at least to the extent that Federal is trying to prove the settlement was restitutionary based on supposed disgorgement of profits. Federal asserts that "nobody needs to know" Astellas' total profit to recognize that the settlement forced Astellas "to return money it took by fraud and never should have had in the first place." We disagree. Without evidence, Federal asks us to assume both fraudulent proceeds and disgorgement of those proceeds. We cannot make that assumption. Recall again that Federal wrote a

policy promising coverage to the limits of law and public policy. It has the burden of showing that a public policy exclusion applies.[8]

On this point, Federal's reliance on *Level 3* and *Ryerson* is misplaced. Federal asserts that, as in those cases, the settlement payment here represented a return of part or maybe all of the profit that Astellas had obtained. See *Ryerson*, 676 F.3d at 612; *Level 3*, 272 F.3d at 911. In both of those cases, however, there were more specific reasons to think that the payments were restitutionary. Unlike the primary underlying claim here, which allows only for compensatory damages, the underlying claim in *Level 3* was for securities fraud, where the "standard damages relief … is restitutionary in character." 272 F.3d at 910. And in *Ryerson*, we knew that the settlement payment partially refunded a purchase price that had been inflated by the insured's fraudulent concealment. 676 F.3d at 612.

The False Claims Act is different, as we have explained, and the focus in litigation is on damages the government sustained. Still, Federal insists that because a False Claims Act violation that incorporates an Anti-Kickback Statute violation requires that all of the government's loss be paid back, Astellas' gains were necessarily returned to the government. This argument misconstrues the rationale for the False Claims

[8] To be clear, we do not mean to suggest that Federal's theory that the settlement was restitutionary required it to prove that Astellas profited in a technical or accounting sense. We are saying that Federal needed to offer some evidence that would allow a reasonable inference of benefits to Astellas that were returned to the government in the settlement, and that the benefits were large enough such that *any* insurance coverage would amount to coverage of restitution. Federal did not meet that burden.

Act's remedial measures. As we observed in *United States v. Rogan*, through Medicare, the "government offers a subsidy … with conditions. When the conditions are not satisfied, nothing is due[ ]" from the government, so when false claims have been made, "the entire amount that" was paid out "must be paid back." 517 F.3d 449, 453 (7th Cir. 2008). Regardless of whether a drug manufacturer like Astellas accrues profits or losses via false claims, the government will receive the same amount in damages, its total potential losses, with the multiplier acting "to make sure that the government [is] made completely whole." *Bornstein*, 423 U.S. at 314, quoting *Hess*, 317 U.S. at 551–52. Federal would have us infer from this legal fiction of "total compensation" that any profits are necessarily encompassed by the settlement payment.

The opposite inference prevails. The False Claims Act's remedial scheme does not depend at all on the defendant's (potential) profits or losses. In the absence of any evidence of profits or proceeds, we must assume that the settlement payment was measured not against disgorgement of (not-yet-alleged) fraudulent gains but against making the government "completely whole." *Bornstein*, 423 U.S. at 314, quoting *Hess*, 317 U.S. at 552. In negotiations here, the government based its damages estimates on the number of Medicare subsidies for Xtandi that were paid on behalf of patients receiving assistance from the androgen receptor inhibitor funds. That is, accounting for neither Astellas' potential profits nor for the government's actual losses, the government sought the undiminished compensation available to it under the False Claims Act. For all we know on the evidence before us, Astellas may have *lost* money. Federal has the burden, ultimately to prove, but on summary judgment to offer evidence, that an exclusion applies. Again, this lack of evidence is decisive.

And again, even if we could find that $50 million was probably restitutionary, the other $50 million would remain compensatory and insurable. In other words, Federal would still have to show that the $10 million Astellas seeks to recover under the insurance policy applies to an *uninsurable* portion of the settlement payment. Even in cases where settlement payments unquestionably included some restitution, Illinois courts have given the benefit of the doubt to the insureds. In *Rosalind Franklin University*, the settlement "disposed of all of the underlying plaintiffs' claims, including" some claims that clearly required disgorgement. 8 N.E.3d at 39. The Illinois Appellate Court found that the settlement payment *as a whole* "did not represent disgorgement." *Id.*

In sum, we agree with the district court that the undisputed facts show that the settlement payment here was not restitutionary, so insurance coverage is available. If the Illinois courts disagree on the broader issues, they of course have "the last word." *Erie Railroad Co.*, 304 U.S. at 79. The judgment of the district court is AFFIRMED.