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Eli Lilly Verdict Offers Insight Into FCA Scienter Battle

By **Leah Judge and Marlene Koury** (August 30, 2022, 6:10 PM EDT)

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Earlier this month, a Chicago jury in the U.S. District Court for the Northern District of Illinois returned a $61 million verdict for the relator in the False Claims Act case U.S. v. Eli Lilly and Co.[1]

It took the jurors only five hours to decide that Eli Lilly had cheated the Medicaid Drug Rebate Program out of tens of millions of dollars by reporting false drug pricing data.

Although the size of the verdict is significant, perhaps more important is that the relator's allegations made it to a jury at all, beating back Eli Lilly's challenge under the U.S. Court of Appeals for the Seventh Circuit's controversial 2021 decision in U.S. v. SuperValu Inc.[2]

The SuperValu court held that a defendant does not possess the requisite scienter to submit false claims where it can offer a post-hoc, objectively reasonable interpretation of the law that justified its prior behavior, and no authoritative guidance warned the defendant away from its course of action.

In doing so, the SuperValu court stripped from the trier of fact the quintessential determination of a defendant's intent and created a scienter loophole that appears likely to significantly curtail FCA liability. However, the recent Eli Lilly verdict suggests that courts might yet be able to limit SuperValu's reach.

SuperValu

In SuperValu, a divided three-judge panel seismically shifted — some might say rewrote — the FCA scienter standard. To make out a claim under the FCA, the plaintiff must show that the defendant knowingly defrauded the government.[3]

Since Congress overhauled the statute in 1986, the FCA has expressly defined knowingly to "mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information."[4]

It does not require proof of specific intent to defraud.[5]

The 1986 FCA amendments modernized the statute and were intended to expand, not contract, the government's ability to use the FCA to fight fraud.[6] Congress unequivocally broadened the FCA's scienter provision by drafting one of the most detailed definitions in the federal code, clearly laying out three distinct mental states sufficient for liability.[7]

Nonetheless, the SuperValu majority excised two-thirds of the FCA's statutory scienter definition, reading out the two subjective prongs. The decision grafts onto the FCA the U.S. Supreme Court's interpretation of the Fair Credit Reporting Act's scienter standard, articulated in the 2007 Safeco Insurance Company of America v. Burr decision.[8]

Unlike the FCA, which is a fraud statute, the FCRA — a consumer protection statute — imposes liability on those who act "willfully" and provides no further definition of the term.

The Safeco court concluded that the FCRA's use of "willfully" included both "knowing and reckless disregard of the law,"[9] and held that an FCRA defendant did not act with reckless disregard if its interpretation of the relevant law was objectively reasonable, albeit incorrect, and no authoritative guidance warned it away from its incorrect interpretation.[10]

In a footnote, the court explained that "reckless disregard" encompasses "knowing" and rejected the argument that "evidence of subjective bad faith must be taken into account in determining whether a company acted knowingly or recklessly for purposes of [the FCRA]."[11]

The SuperValu majority held that Safeco applied equally to the FCA, concluding that "a failure to establish the Safeco standard as a threshold matter precludes liability under any of [the FCA's three scienter] definitions."[12] Seizing on Safeco's footnote, the majority further held that a defendant's subjective intent is irrelevant, stating, "it is not enough that a defendant suspect or believe that its claim was false."[13]

In other words, SuperValu permits an FCA defendant to avoid liability by offering a reasonable interpretation of the rule it broke to justify its behavior, regardless of whether the defendant actually believed its own justification at the time it submitted the false claims. The fact-specific, at times messy question of intent can be disposed of by a judge on summary judgment or even a motion to dismiss. A jury simply does not get to hear evidence of the actions a defendant took — or did not take — that shed light on its understanding of the law and whether its actions complied with it.

The SuperValu case itself involved compelling scienter evidence a jury never got to hear. The relators alleged that SuperValu pharmacies reported to Medicare and Medicaid knowingly false usual and customary drug prices, causing the government to reimburse SuperValu for the drugs at much higher rates than it was entitled to receive. Medicaid rules define "usual and customary" as the price a pharmacy charges the general public" for a drug.

For years, SuperValu reported its set, retail price for a given drug as the usual and customary price. But SuperValu also regularly matched the lower drug prices of its competitors, notably Walmart Inc., whose $4 monthly generic program had disrupted the industry.[14] Centers for Medicare and Medicaid Services guidance had explained this was Walmart's usual and customary price.[15] SuperValu, however, did not report these lower, matched prices to the government.

In discovery, relators adduced evidence that the price match was a matter of company policy; that

SuperValu usually charged the $4 price for many drugs; and that, in at least one year, SuperValu's usual and customary prices for more than 40 drugs were "eight to fifteen times higher than the prices it was actually charging a majority of the relevant customers" through the price match program.[16]

The relators also adduced evidence showing that SuperValu's executives understood that price matching might undermine the integrity of their usual and customary price reporting and suggested that the company take a "stealthy" approach.[17]

None of this evidence made it to a jury. Moreover, the majority dismissed CMS' guidance on Walmart's usual and customary price as insufficient to put SuperValu on notice that it was misreporting its usual and customary prices.[18]

Eli Lilly

In contrast, the Eli Lilly court rejected a SuperValu-based assault on allegations likewise implicating the so-called complex regulatory scheme controlling the government's reimbursement of prescription drugs.[19]

Eli Lilly involved the Medicaid Drug Rebate Program, which requires drugmakers to pay rebates to the federal and state governments as a condition of Medicaid reimbursement.[20] The relator alleged that Eli Lilly falsely reported to the government a lower average manufacturer price, or AMP, for certain drugs. Generally speaking, the higher the AMP, the higher the rebate owed.

A jury concluded that Eli Lilly reported intentionally lower AMPs by excluding the price-increase value of a drug from its calculations.

When Eli Lilly raised the price of a drug after a wholesaler had purchased it, its wholesaler agreements required the wholesaler to pay Eli Lilly the price-increase value, calculated as the value of any drug price increase multiplied by the number of drugs remaining in the wholesaler's inventory.[21]

At summary judgment, Eli Lilly relied almost entirely on SuperValu, arguing that the regulatory landscape was simply too unclear to unequivocally require inclusion of the price-increase value in its AMP calculations.

The court forcefully rejected Lilly's position. The court found SuperValu inapplicable, explaining:

Lilly has not proffered, nor has the Court been able to imagine, a reasonable alternative interpretation to both the mechanics and the definition of 'price increase value' to be anything other than an adjustment of price and thus within the definition of Average Manufacturer's Price.[22]

After all, the definition of AMP stated that it "must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized."[23]

The court refused to entertain Eli Lilly's well-crafted arguments designed to muddy the regulatory waters. This included Eli Lilly's assertions that its legal obligations were somehow obfuscated by the absence of a regulatory definition for price-increase values.

The court acknowledged that "[b]y requiring regulations to be too specific [courts] would be opening up large loopholes allowing conduct which should be regulated to escape regulation" and declined to allow

Eli Lilly's loophole.[24]

As a result, a jury heard the evidence of Eli Lilly's intent to manipulate its AMPs, including its maintenance of a minimally staffed government pricing department, its large financial motive to exclude price-increase value and the alteration of language in its wholesaler agreements to be more consistent with its pricing representations to the government.

What's Next

Making it to a jury was far from inevitable for Ronald Streck, the relator in the Eli Lilly case. In 2018, a U.S. Court of Appeals for the Third Circuit panel had already agreed with nearly identical assertions of regulatory ambiguity raised by pharmaceutical manufacturers in the FCA suit, U.S. v. Allergan Inc., also brought by Streck.[25]

Indeed, other courts squarely confronted with SuperValu and Safeco challenges concerning a defendant's subjective intent have sided with defendants. Five months after the Seventh Circuit decided SuperValu, a likewise split U.S. Court of Appeals for the Fourth Circuit panel adopted the Safeco standard to throw out another case challenging manipulation of the Medicaid Drug Rebate Program.

In U.S. v. Allergan Sales LLC, the majority affirmed dismissal of allegations that the defendant intentionally reported a higher "best price" to the government by failing to aggregate stacked discounts — discounts provided for the same drug to different entities along the supply distribution chain.[26]

The Medicaid Drug Rebate Program's best-price requirement is the AMP's companion provision and is likewise designed to reduce government drug spending.[27] A lower best price, like a higher AMP, increases the government's costs by increasing the reimbursement paid to drug producers.

The Fourth Circuit Allergan majority — deciding the issue on a motion to dismiss — found the defendant's exclusion of stacked rebates from best-price calculations objectively reasonable, disregarding specific allegations that the defendants knew they should report the stacked rebates and intentionally concealed them from the government.[28]

Tellingly, the majority openly decried the "vast power" of the "administrative state" in adopting the defendant's regulatory interpretation.[29] The Fourth Circuit has agreed to rehear the case en banc in September.

A few months after the Fourth Circuit decided Allergan, the Seventh Circuit again applied SuperValu to dispose of another case with detailed evidence of a knowing scheme to artificially lower usual and customary drug pricing by concealing widespread price matching.[30] In U.S. v. Safeway Inc., the majority itself acknowledged that the defendant appeared to have implemented a program it knew subverted the usual and customary pricing rules and simply disguised it as a something that did not.[31]

At least two district courts have also explicitly applied SuperValu to end cases, giving short shrift to allegations and evidence of subjective intent to defraud.[32] Earlier this year, in U.S. v. Wisconsin Bell Inc., the U.S. District Court for the Eastern District of Wisconsin granted summary judgment to defendants after significant discovery without even mentioning the scienter evidence adduced by relator. The Northern District of Illinois similarly applied SuperValu in 2021 to a motion to dismiss in Lupinetti v. Exeltis USA Inc.[33]

Despite the success of Streck in the Eli Lilly case, the past year suggests that defendants will continue to invoke SuperValu and its progeny to beat back allegations of fraud that involve complex regulatory or statutory schemes. That is, if SuperValu remains the law.

The relators in both SuperValu and Safeway have filed petitions for certiorari, asking the Supreme Court to read subjective intent back into the FCA's scienter standard.[34] Sen. Charles Grassley, the principal sponsor of the 1986 FCA amendments, has weighed in with an amicus brief in support of the SuperValu relators. And the Supreme Court has recently invited the solicitor general to provide its views on SuperValu, dramatically increasing the likelihood that cert will be granted.

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Disclosure: Constantine Cannon represents Grassley on his amicus brief in support of the SuperValu cert petition.

[1] U.S. et al. v. Eli Lilly and Co. et al., case number 1:14-cv-09412, N.D. Ill.

[2] U.S. ex rel. Schutte v. SuperValu Inc., 9 F.4th 455 (7th Cir. 2021), rehearing and rehearing en banc denied.

[3] 31 U.S.C. § 3729(a)(1).

[4] 31 U.S.C § 3729(b)(1)(A).

[5] 31 U.S.C § 3729(b)(1)(B).

[6] See H.R.Rep. No. 99–660, p. 18 (1986) (the FCA "is ... the primary vehicle by the Government for recouping losses suffered through fraud").

[7] Congress did so in part to address the issue of government contractors intentionally choosing to remain ignorant of their legal obligations in order to avoid liability. See H. Rep. 99-660, at 21 (1986) (explaining that the statute imposes liability on persons "who ignore 'red flags' that the information may not be accurate or those persons who deliberately choose to remain ignorant of the process through which their company handles a claim.").

[8] 551 U.S. 47 (2007).

[9] 551 U.S. at 52, 59.

[10] Id. at 68.

[11] Id. at 70 n.20 (emphasis added).

[12] U.S. ex rel. Schutte, 9 F.4th at 459.

[13] Id. at 475, 470.

[14] Id. at 461-62.

[15] 9 F.4th at 472.

[16] Id. at 472-74 (Hamilton, J., dissenting).

[17] Id. at 475 (Hamilton, J., dissenting).

[18] Id. at 472.

[19] Id. at 459.

[20] U.S. ex rel. Streck, No. 14 C 9412, 2022 WL 595308 (N.D. Ill. Feb. 28, 2022).

[21] Id. at *3.

[22] Id. at *13.

[23] Id. at *12.

[24] Id.

[25] U.S. ex rel. Streck v. Allergan Inc., 746 F. App'x 101 (3d Cir. 2018) (ignoring relevant regulatory and contractual language to conclude there was no definite requirement to include a subsequent price increase in the AMP). Another court, however, had allowed Streck's allegations to proceed against Bristol-Myers Squibb, concluding that, at a minimum, "available administrative and judicial guidance" had warned the company that price-increase values should be included in AMPs. U.S. ex rel. Streck v. Bristol-Myers Squibb Co., 370 F.Supp.3d 491, 497 (E.D. Pa. 2019).

[26] 24 F.4th 340, 343-44 (4th Cir. 2022),reh'g en banc granted, No. 20-2330, 2022 WL 1467710 (4th Cir. May 10, 2022).

[27] 24 F.4th at 373-74 (Wynn, J., dissenting).

[28] Id. at 351; id. at 377-78 (Wynn, J., dissenting).

[29] Id. at 356. Soon thereafter, another split Fourth Circuit panel disposed of a case, this time at summary judgment, on the grounds that an objectively reasonable interpretation of a Medicaid rule permitted the conduct at issue. U.S. ex rel. Gugenheim v. Meridian Senior Living, LLC, 36 F.4th 173 (4th Cir. 2022). Although the court suggested that evidence of subjective intent might be relevant to the scienter inquiry, id. at 181-82, it nonetheless declined to let that evidence go to a jury. Id. at 190 (Traxler, J. dissenting).

[30] U.S. ex rel. Proctor v. Safeway, Inc., 30 F.4th 649 (7th Cir. 2022). Scienter evidence included an email from a Safeway executive acknowledging that the company might "have some issues with U&C and state medicaids with price matching," because "if you [match a] price offer, that becomes your usual

and customary for that day and that pricing needs to be extended to Medicaid." Id. at 667 (Hamilton, J., dissenting).

[31] Id. at 660.

[32] U.S. ex rel. Heath v. Wisconsin Bell, Inc., No. 08-CV-0724, 2022 WL 860621 (E.D. Wis. Mar. 23, 2022) (summary judgment; applying SuperValu to end case alleging violations of the "lowest corresponding price" rule in the federal E-rate program); Lupinetti v. Exeltis USA, Inc., No. 19 C 825, 2021 WL 5407424 (N.D. Ill. Nov. 19, 2021) (motion to dismiss; applying SuperValu to dismiss allegations that prenatal vitamin makers falsely labeled their products as "prescription only" to ensure Medicaid reimbursement).

[33] No. 08-CV-0724, 2022 WL 860621 (E.D. Wis. Mar. 23, 2022).

[34] U.S. ex rel. Schutte v. SuperValu Inc., 9 F.4th 455 (7th Cir. 2021), cert. filed (Apr. 1, 2021) (No. 21-1326); U.S. ex rel. Proctor v. Safeway, Inc., 30 F.4th 649 (7th Cir. 2022), cert. filed (Aug. 3, 2022) (No. 22-111).