Doc. 702767940

Case: 15-1502 Document: 59 Filed: 05/27/2016 Pages: 23

## In the

## United States Court of Appeals For the Seventh Circuit

No. 15-1502

United States of America ex rel. James Garbe,

Relator-Appellee,

v.

KMART CORPORATION,

Defendant-Appellant.

Appeal from the United States District Court for the Southern District of Illinois.

No. 3:12-cv-00881-NJR-PMF — Nancy J. Rosenstengel, Judge.

100. 5.12-cv-00001-1011(1-11011) — 10alicy J. Roselisi

 ${\tt Argued\ October\ 28,2015-Decided\ May\ 27,2016}$ 

Before Wood, *Chief Judge*, and Easterbrook and Hamilton, *Circuit Judges*.

WOOD, *Chief Judge*. James Garbe, an experienced pharmacist, began working at Kmart pharmacy in Ohio in 2007. One day, Garbe picked up a personal prescription at a competitor pharmacy. When he reviewed his receipt, Garbe got a surprise: the competitor pharmacy had charged his Medicare Part D insurer far less than Kmart ordinarily charged it for the same prescription. Curious to see whether his discovery was

2 No. 15-1502

a one-off, he started inspecting Kmart's pharmacy reimbursement claims. His amateur detective work revealed that Kmart routinely charged customers with insurance—whether public or private—higher prices than customers who paid out of pocket. Not all cash customers were charged the same price: people in Kmart's "discount programs" paid much less. But the ensuing investigation revealed that nearly all cash customers received the lower "discount program" prices. Meanwhile, those "discount program" sales were ignored when Kmart calculated its "usual and customary" prices for its generic drugs for purposes of Medicare reimbursement. Garbe shared his discovery with the government and filed a *qui tam* suit on July 12, 2008. The government has not intervened.

According to the accepted definition of "usual and customary," Garbe says, Kmart's "usual and customary" prices should be based on the prices Kmart charged the majority of its cash customers, meaning those participating in its generic drug "discount programs"—not the higher prices it imposed on a small fraction of those buyers or those with third-party insurance. After a flurry of motions, the district court granted partial summary judgment in Garbe's favor on some issues and denied it to Kmart on others.

We accepted an interlocutory appeal from these rulings under 28 U.S.C. § 1292(b). Before us are several questions: (1) whether the amendments to 31 U.S.C. § 3729(a)(2) (now 31 U.S.C. § 3729(a)(1)(B)) in the Fraud Enforcement and Recovery Act (FERA) apply to all *cases* "pending on or after June 7, 2008," or just all *claims* as of that date; (2) whether Medicare Part D Pharmacy Benefit Managers and Plan Sponsors are "officers or employees of the United States" for purposes of the

No. 15-1502

FCA; (3) whether Garbe has satisfied the materiality requirement under the FCA for his Medicare Part D claims; and (4) whether Kmart's "discount" prices were offered to the "general public." We conclude that the district court erred when it found that the Pharmacy Benefit Managers and Plan Sponsors are "officers or employees of the United States," but we otherwise affirm the district court's rulings.

Ι

A

Garbe's allegations cover Kmart programs that stretch back 12 years. In 2004, Kmart introduced a program meant to compete with online, mail-order pharmacies: the "Kmart Maintenance Program" (KMP). The KMP offered specified generic drugs to customers with 90-day prescriptions at a discount price of \$15 per prescription.

Congress added the Part D prescription benefit to Medicare, a federally funded health insurance program, in 2006. Part D allows beneficiaries to opt in to prescription drug benefits by enrolling in a private insurance plan. The program provides insurance coverage, up to a certain amount, for beneficiaries' prescription drug costs. Above that amount, beneficiaries are responsible for additional costs up to another set dollar value, where Part D's "catastrophic coverage" kicks in. (This coverage gap is known as the "donut hole.")

The Part D program is overseen by the federal Centers for Medicare and Medicaid Services (CMS). CMS does not administer the program; instead, it uses Plan Sponsors, which are private entities that compete for the opportunity to manage Part D beneficiaries' claim submissions and payment pro-

4 No. 15-1502

cesses. Most Plan Sponsors subcontract with Pharmacy Benefit Managers, which are other private entities that work directly with retail pharmacies to provide prescriptions to Part D beneficiaries. CMS pays Plan Sponsors fixed monthly payments according to certain benchmarks. At the end of each year, it conducts "reconciliation" with the sponsors. The reconciliation process determines, based on Plan Sponsor records and a complex subsidy system, whether individual Plan Sponsors should receive additional funds.

CMS thus does not directly pay or reimburse any individual prescriptions through the program. It does control prices, however, insofar as it requires retail pharmacies to charge Medicare Part D beneficiaries the "usual and customary" price, an administratively defined term, for each prescription. See 42 C.F.R. §§ 423.100, 447.512(b). The district court found that the "usual and customary" price is generally understood to mean the "cash price offered to the general public."

В

Kmart saw the Part D program as an attractive potential source for new revenue. But Kmart had a problem: the program was leading to increased competition among retail pharmacies, which were developing their own discount generic-drug programs. This competition, Kmart feared, would drive down the prices for prescriptions reimbursed by third-party payers, and therefore revenue.

In late 2005, as the Part D program was rolling out, Kmart revamped the KMP. The key reform was a new pricing system. According to Kmart internal documents (from which we take all of the following quotes), Kmart recognized that it was "financially beneficial to maintain the Usual and Customary

No. 15-1502 5

price higher than reimbursement rates." Kmart set out to accomplish this goal by instituting a policy of setting low "discount" prices for cash customers who signed up for one of its programs, while charging higher "usual and customary" prices to non-program cash customers, "to drive as much profit as possible out of [third-party] programs." Kmart's second step was simple: it changed the program's name. In order to put it at as "long a[s] possible arms length from [Kmart's] U&C pricing," the KMP was relabeled as the "Retail Maintenance Program," or "RMP."

To strengthen Kmart's "firewall" between RMP and its "usual and customary" prices, Kmart hired Agelity, a thirdparty processor, to administer RMP. According to Garbe's evidence, however, Agelity's participation was a sham. In reality, Kmart decided which drugs were in the RMP formulary, the prices for those drugs, and which customers were eligible for those prices. In 2008, Kmart expanded RMP to include additional drugs and expanded its discount programs to many 30- and 60-day prescriptions. Yet Kmart pharmacists routinely overrode official program pricing to match competitor prices. In 2009 Kmart retooled RMP by introducing the "Prescription Savings Club," under which Kmart officially offered its low cash prices on 30-, 60-, and 90-day prescriptions. The programs underwent other modifications along the way. But according to Garbe, each version of Kmart's "discount programs" was the same old wine, in new bottles: Kmart offered low prices to discount-program cash customers, while submitting higher "usual and customary" prices for prescriptions reimbursed by third-party insurers and some non-program cash customers.

6 No. 15-1502

C

As Garbe sees it, Kmart's real "usual and customary" prices were not the high ones paid by non-program cash customers or those submitted to third parties for reimbursement, but the low ones it offered to the cash customers participating in one of its "discount programs." These programs, he charges, were nothing but a sham allowing it to manipulate its "usual and customary" cash price.

Garbe retained a pharmaceutical economist, Dr. Joel Hay, to analyze mountains of reimbursement data. Dr. Hay's work revealed that Kmart charged nearly all its cash customers "discount program" prices. Garbe also hired an auditor, who testified that, under industry practice and the terms of over 1,000 contracts between Kmart and Medicare Part D Benefit Managers and Plan Sponsors, Kmart should have based its reimbursement requests to the insurance companies handling Medicare Part D on its "discount program" prices. Dr. Hay's examination revealed that Kmart instead used significantly higher prices when submitting those requests, and was thus reimbursed at a much higher level.

At the close of discovery, Kmart filed four motions for partial summary judgment. Relevant to this appeal, it challenged Garbe's assertion that Kmart's "discount programs" were its actual "usual and customary" prices, and therefore that it made a false statement in requesting reimbursement based on allegedly inflated "usual and customary" prices. It also argued that Garbe's claims failed for lack of presentment and materiality on the theory that the government never actually received or paid any of its reimbursement requests. Related to its second challenge, it argued that FERA, which amended the FCA, applied retroactively only to *claims* pending on or

No. 15-1502 7

after June 7, 2008. (Garbe filed his initial complaint on July 16, 2008.) According to Kmart, this meant that the post-FERA FCA applied only to a tiny portion of the payments on which Garbe focused.

The district court rejected all Kmart's arguments. It found as a matter of law that transactions under Kmart's "discount programs" represented the "usual and customary" price. It held that the FERA amendments retroactively covered *cases* pending on June 7, 2008, and therefore they applied to all of transactions Garbe had identified. It also found that Garbe's evidence raised at least a genuine dispute of material fact about Kmart's liability under 31 U.S.C. § 3729.

After some adjustments in response to its motion for reconsideration, Kmart asked the district court to certify its summary judgment order for interlocutory appeal under 28 U.S.C. § 1292(b). The court obliged and identified three pivotal issues: (1) whether the retroactivity provision relevant to 31 U.S.C. § 3729(a)(2) [now 31 U.S.C. § 3729(a)(1)(B)] applies to all *cases* "pending on or after June 7, 2008," as opposed to all *payments* after that date; (2) whether Medicare Part D Pharmacy Benefit Managers and Plan Sponsors are "officers or employees of the United States" for purposes of the FCA; and (3) whether Garbe satisfied the FCA materiality requirement for his Medicare Part D claims. We granted Kmart's petition and added the question whether the district court correctly identified the "usual and customary" price.

II

We consider *de novo* the district court's rulings on partial summary judgment, construing the facts in the light most favorable to the non-moving party—in this case, Garbe. *Jaburek* 

8 No. 15-1502

v. Foxx, 813 F.3d 626, 630 (7th Cir. 2016). Summary judgment is appropriate when there is no dispute of material fact, and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a).

## Α

Kmart opens with its retroactivity argument, which if successful would knock out almost all of Garbe's case. It urges that § 3729(a)(1)(B) of the 2009 FERA Amendments covers only requests for reimbursement that were pending on or after June 7, 2008 (four days before Garbe filed his suit). Garbe reads the statute more expansively, to cover all *cases* pending on or after that date. Kmart also argues that it cannot be liable under the False Claims Act because (it contends) Garbe has failed to present evidence that (1) he properly presented the pre-FERA False Claims Act to the government and (2) the false claims were "material."

1

Since 2009, the FCA has said that "any person who ... (1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable under the False Claims Act. 31 U.S.C. § 3729(a)(1) (2009). But the section did not always read that way. Before the enactment of FERA, 31 U.S.C. § 3729, it provided for liability for "[a]ny person who ... (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;" or "(2) knowingly makes, uses, or causes to be made or used, a false record or

No. 15-1502

statement to get a false or fraudulent claim paid or approved by the Government." Id. § 3729(a) (1994) (emphasis added).

The change occurred because of a Supreme Court decision. In 2008, the Court held that FCA § 3729(a)(1) requires a defendant's direct presentment of the false claim to an officer or employee of the government. *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 668 (2008). The Court further held that for liability under § 3729(a)(2) to attach, there had to be proof that the defendant had a specific intent to defraud the government. *Id.* 

Congress responded the next year by enacting FERA. FERA excised the language requiring that the claim be presented "to an officer or employee of the United States Government or a member of the Armed Forces of the United States." It also struck from § 3729(a)(2) the words "to get a false or fraudulent claim paid or approved by the Government," which the Supreme Court had interpreted to require a specific intent to defraud the government. See *Allison Engine*, 553 U.S. at 668–69. The revised law imposed only the less onerous requirement that the "false record or statement" be "material to a false or fraudulent claim."

FERA also clarified the statutory definitions for "claim" and "material." It defined "claim" to mean, in relevant part, "any request or demand ... for money or property, that ... is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest" and to which the government either "provides or has provided any portion of the money or property" or "will reimburse such contractor, grantee, or other recipient for any portion of the money or property." 31 U.S.C. § 3729(b)(2) (2009). The new

10 No. 15-1502

language underscored Congress's intent that FCA liability attach to any false claim made to an entity implementing a program with government funds, regardless of whether that entity was public or private. FERA defines "material" to mean "having the natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4). Notably missing from this definition is any requirement that the false statement or record be material to the government program.

Whether we call the changes made by FERA clarifications or changes, the end result is clear: as amended, the FCA contains no presentment requirement. For any transactions to which FERA applies, Garbe is thus not required to show that any statement or record was delivered to any government employee, official, or entity. FCA liability attaches to any false claim to any entity—public or private—implementing a government program or a program using government funds.

2

Kmart's materiality arguments are similarly mistaken. Kmart contends that Garbe has not raised a genuine issue of fact on materiality because he offered no evidence that the alleged overcharges were capable of affecting the *government's* payment decision. But FERA's materiality rule requires only that the false record or statement influence the "payment *or receipt* of money or property"—no government decision is required. 31 U.S.C. § 3729(b)(4) (emphasis added). Garbe is required to show only that Kmart's allegedly false claims were material to Kmart's receipt of more money than it should have gotten. In other words, Kmart's misstatements had to be "capable of influencing[] the decisionmaking body to which [they were] addressed." *Neder v. United States*, 527 U.S. 1, 16

No. 15-1502

(1999) (noting, for tax fraud statute with same materiality definition, that numerous courts have found "any failure to report income is material"). Dr. Hay's report shows that, to the extent Kmart made false claims, they were material: those claims were the basis of the federal monies Kmart received.

Kmart argues that there must be a "causal chain" between a false claim and a CMS payment, but it offers no support for such a rule. FERA had the effect of bringing within the FCA's ambit false claims to intermediaries or other private entities that either implement government programs or use government funds. See 31 U.S.C. § 3729(b)(2) (2009). There is little doubt that much of the money paid to Kmart under Medicare Part D came from government coffers. See, e.g., 2014 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds 103 (funds from U.S. Treasury made up 73.1% of total revenue disbursed by Medicare Part D trust fund in fiscal year 2013). Garbe is not required to trace the movement of currency from the U.S. Treasury through the Medicare Part D funding structure; Kmart's argument in this respect is just presentment in materiality clothing. Kmart is not entitled to summary judgment for lack of either presentment or materiality for any claims to which FERA applies.

3

Having found that Garbe's claims satisfy the post-FERA version of the FCA, we now consider whether that version applies to them. In FERA § 4(f), Congress said that the amendments were effective "as if [subsection (a)(1)(B) had been] enacted on June 7, 2008," and that they "apply to all claims under the False Claims Act that are pending on or after that date." 123 Stat. at 1625 (not codified). Kmart argues that the

12 No. 15-1502

"claims" to which this refers are demands for payment, not FCA cases. Garbe takes the broader view.

We have held before that the word "claims" in  $\S 4(f)(1)$  refers to cases, not to individual requests for payment. See United States ex rel. Yannacopoulos v. Gen. Dynamics, 652 F.3d 818, 822 n.2 (7th Cir. 2011) ("[S]ection 3729(a)(1)(B) ... applies to cases, such as this, that were pending on or after June 7, 2008."); United States v. Sanford-Brown, Ltd., 788 F.3d 696, 701 n.1 (7th Cir. 2015) (same); Thulin v. Shopko Stores Operating Co., LLC, 771 F.3d 994, 998 (7th Cir. 2014) (same). The majority of our sister circuits take the same position. See Sanders v. Allison Engine Co., 703 F.3d 930, 942 (6th Cir. 2012) (holding that "claim' in § 4(f)(1) refers to a civil action or case"); United States ex rel. Kirk v. Schindler Elevator Corp., 601 F.3d 94, 113 (2d Cir. 2010) (holding § 3729(a)(1)(B) retroactive as to lawsuits), rev'd on other grounds, 563 U.S. 401 (2011); United States ex rel. Rigsby v. State Farm Fire & Cas. Co., 794 F.3d 457, 465 (5th Cir. 2015) (same).

This is the interpretation that best reflects the text and structure of the statute. Construing "claims" to mean "requests for payment" makes no sense. There is no such thing as a request or demand for payment under the False Claims Act. Rather, a claim "under the [FCA]" is a legal action by the government or a relator to recover fraudulently obtained funds. See 123 Stat. at 1625; *Sanders*, 703 F.3d at 938.

Construing the FERA amendments as retroactive only for requests or demands for payment is also in tension with Congress's stated goal of changing *Allison Engine*'s interpretation of § 3729(a). Congress specified that the FERA provision codified as § 3729(a)(1)(B) should be applied "as if ... enacted on June 7, 2008." 123 Stat. at 1625. That date is two days before

No. 15-1502

June 9, 2008, the date when the Supreme Court handed down *Allison Engine*, and a Saturday (June 9, 2008, was a Monday). It seems no accident that Congress picked Saturday, June 7, 2008, as the date of retroactivity: by choosing that date, it could eliminate the approach taken in *Allison Engine* without reopening judgments that were already final when *Allison Engine* was decided.

Interpreting § 4(f)(1)'s "claims" to mean "cases" accomplishes this goal. Interpreting it as "any request or demand, whether under a contract or otherwise, for money or property" does not. Kmart offers no reason why, under its theory, Congress would have chosen June 7, 2008, for the effective date. Worse, Kmart's reading would render meaningless what is arguably § 4(f)(1)'s most important element—the date of retroactivity—and thus violate the "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." See *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (internal quotation marks omitted); *Stone v. I.N.S.*, 514 U.S. 386, 397 (1995) ("When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect.").

Kmart argues that because the FCA provides a statutory definition of "claim," that definition should control. It is true that "[s]tatutory definitions control the meaning of statutory words ... in the usual case." *Burgess v. United States*, 553 U.S. 124, 129 (2008). And § 3729(b)(2)(A) defines "claim" as "any request or demand ... for money or property." Kmart argues that the retroactivity provision therefore applies only to *demands for payment* that were pending on June 7, 2008, not lawsuits. But this argument does not survive closer examination:

14 No. 15-1502

section 3729(b) specifies that the statutory definition of "claim" is only "for purposes of this section." Because § 4(f) of FERA is not mentioned in § 3729(b), the latter section dictates that its definition does not apply to § 4(f).

Kmart argues that its interpretation is reinforced by other parts of the FERA. It is true that "[c]ontext, not just literal text, will often lead a court to Congress' intent in respect to a particular statute." *United States v. Webber*, 536 F.3d 584, 593 (7th Cir. 2008). And § 4(f)(2)—the adjacent provision—specifies that certain other amendments to the FCA would "apply to *cases* pending on the date of enactment." 123 Stat. at 1625 (emphasis added). This juxtaposition, Kmart says, implies that Congress knew how to refer to "cases" when it intended to, but chose not to do so in § 3729(a)(1)(B).

But the presumption that "disparate inclusion or exclusion" is purposeful is weakened when, as here, the provisions were not joined together or considered simultaneously. Sanders, 703 F.3d at 937; cf. Lindh v. Murphy, 521 U.S. 320, 330 (1997) ("[N]egative implications raised by disparate provisions are strongest when the portions of a statute treated differently had already been joined together and were being considered simultaneously when the language raising the implication was inserted."). Sections 4(f)(1) and 4(f)(2) were drafted by different chambers of Congress, at different times. See Sanders, 703 F.3d at 936–37; Matthew Titolo, Retroactivity and the Fraud Enforcement and Recovery Act of 2009, 86 IND. L.J. 257, 298 (2011); S. 386, 111th Cong. § 4(b) (as reported in Senate, March 5, 2009); S. 386, 111th Cong. § 4(f) (House engrossed amendment, May 6, 2009).

Moreover, the "presumption that identical words used in different parts of the same act are intended to have the same

No. 15-1502

meaning ... is not rigid and readily yields whenever there is such variation in the connection in which the words are used as reasonably to warrant the conclusion that they were employed in different parts of the act with different intent." *Gen. Dynamics Land Sys., Inc. v. Cline,* 540 U.S. 581, 595 (2004) (quoting *Atl. Cleaners & Dyers v. United States,* 286 U.S. 427, 433 (1932)). The presumption is especially weak when the word "has several commonly understood meanings." *Cline,* 540 U.S. at 595–96. "Claim" is just such a word.

Congress's free use of "claim" (along with "action") to mean "civil action" throughout the FCA further supports the argument that § 4(f)(1) was not meant to incorporate the definition in § 3729(b)(2)(A). See, e.g., 31 U.S.C. §§ 3730(c)(5) (the government "may elect to pursue its claim through any alternate remedy available"); 3731(c) (repeated references to the government's "claims" in describing procedure for intervention in FCA lawsuit); 3732(b) (referring to "[c]laims under state law" in conveying district courts' jurisdiction over "any action brought under the laws of any State"); see also Sanders, 703 F.3d at 939 (noting same in discussing issue).

Finally, Kmart maintains that three other courts of appeals, albeit in footnotes, have agreed with it. See *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318 n.1 (11th Cir. 2009) (interpreting "claim" in § 4(f)(1) to mean "any request or demand ... for money or property"); *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 475 n.4 (5th Cir. 2012) (noting approvingly that the district court held that FERA did not apply to conduct occurring before its enactment); *United States ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1051 n.1 (9th Cir. 2011) (citing *Hopper* in holding that FERA did not apply to

16 No. 15-1502

case). None of these cases, however, addressed the question with any analysis, and so they give us little pause.

All things considered, we have no trouble concluding that the word "claims" does not mean "request[s] or demand[s] for ... money or property." It means "cases," and thus § 4(f)(1) applies to FCA cases pending on or after June 7, 2008.

В

With the broader point established, the practical impact of Kmart's next point, which relates to its liability under the pre-FERA version of the Act, is greatly diminished. This issue is relevant only to the extent that any of the transactions about which Garbe is complaining are not covered by the amended version of § 3729(a)(1)(B). (Whether there are any such transactions is a matter yet to be resolved by the district court.) As we have noted, none of Garbe's allegations involve false claims submitted directly to the government. Kmart contends that Garbe may rely on the former § 3729(a)(1) (1994) only if § 3729(a)(1)(A) is construed to be retroactive "clarifying" legislation rather than a "substantive" amendment.

Although retroactive application of statutes "is not favored," a statute will be construed "to have retroactive effect" where its "language requires this result." *Republic of Austria v. Altmann*, 541 U.S. 677, 692 (2004) (citations omitted). In deciding whether an amendment is clarifying rather than substantive, we consider "[1] whether the enacting body declared that it was clarifying a prior enactment; [2] whether a conflict or ambiguity existed prior to the amendment; and [3] whether the amendment is consistent with a reasonable interpretation of the prior enactment and its legislative history." *Middleton v.* 

No. 15-1502

City of Chicago, 578 F.3d 655, 663–64 (7th Cir. 2009). The Supreme Court has emphasized the importance of the first and second factors. See, e.g., Cherokee Nation of Oklahoma v. Leavitt, 543 U.S. 631, 646–47 (2005) (statute not clarifying where earlier "statutes ... were not ambiguous" despite legislative history evincing intent to clarify); Rivers v. Roadway Exp., Inc., 511 U.S. 298, 307 (1994) (requiring "clear expression of congressional intent" for retroactive effect despite evidence that Congress intended to disapprove a judicial interpretation).

There are several problems with interpreting § 3729(a)(1)(A) to be retroactive to a time before the stated effective date. It is a stretch, first, to say that the earlier version of the law was ambiguous. Presentment of a claim "for payment or approval" to "an officer or employee of the United States Government or a member of the Armed Forces of the United States" was an important part of § 3729(a)(1). The sounder conclusion, we believe, is that § 3729(a)(1)(A) follows the normal presumption that statutes do not have retroactive effect.

Garbe argues that even if the amendments are not retroactive and the presentment requirement applies to some claims, the intermediaries that actually reimbursed Kmart's allegedly fraudulent claims should be considered to be "officer[s] or employee[s] of the United States Government" under § 3729(a)(1) (1994). He points to *Bodimetric Health Services Inc. v. Aetna Life & Casualty*, 903 F.2d 480, 488 (7th Cir. 1990), which found that certain intermediaries' acts were covered by an exclusive remedy prescribed by the Medicare Act because those intermediaries performed a "public function" under the Act. *Id.* But *Bodimetric* did not find that the intermediaries stood in for "the government" for the purpose of the exclusive remedy

18 No. 15-1502

provision, let alone for FCA presentment. *Id.* In addition, finding that they did so would be inconsistent with our holding in *Juhong v. Boeing Co.*, 792 F.3d 805, 808–10 (7th Cir. 2015) (addressing who is an officer of the United States for purposes of removal under 28 U.S.C. § 1442). Finally, deeming any contractor implementing a government program to be "the government" would functionally eliminate the presentment requirement. To the extent Garbe's suit covers pre-FERA transactions that do not rely on § 3729(a)(1)(B), he cannot rely upon § 3729(a)(1)(A).

C

Finally, we address Kmart's contention that the term "general public," as found in the definition of "usual and customary" pricing, excludes persons participating in its "discount programs."

Unless state regulations provide otherwise, the "usual and customary" price is defined as the "cash price offered to the general public." Garbe alleges that Kmart's actual "usual and customary" prices are the prices it charges through several generic-drug discount programs. If he is correct, Kmart misrepresented its "usual and customary" prices by charging Medicare Part D participants far in excess of those prices—sometimes as much as 30 times more. Kmart argues that because the participants in its discount programs were not the "general public," those prices were not its "usual and customary" charges. Although the district court decided that the definition of "usual and customary" raised a question of law, it nonetheless took expert evidence on the industry definition of the term. It resolved the meaning of "general public" without taking evidence.

No. 15-1502

1

Kmart argues that the ordinary meaning of "general public" excludes customers who join a discount program. It points to two definitions of "general public" from online dictionaries: first, "ordinary people in society, rather than people who are considered to be important or who belong to a particular group," Macmillan Dictionary Online, http://www.macmillandictionary.com/dictionary/british/the-general-public (visited May 18, 2016); and second, "ordinary people, especially all the people who are not members of a particular organization or who do not have any special type of knowledge." Cambridge Dictionaries Online, http://dictionary.cambridge.org/us/dictionary/english/the-general-public?q=general+public (visited May 18, 2016). It argues that because members of its discount programs "belong to a particular group" or "organization" that represents a subset of its customer base, they are not members of the general public and the price they were charged is not the usual and customary price.

Saying that someone is a member of a "particular" organization, however, does not make it so. We are given no reason to think that there was any meaningful selectivity for the people who joined Kmart's programs, and thus that they could be distinguished in any way from the "general public." Few of Kmart's customers would consider themselves as "belong[ing] to a particular group" or "members of a particular organization" just because they accepted Kmart's offer of a discount. Even if the prices were offered only to members of its "discount programs"—and it is disputed whether this was the case—the programs themselves were offered to the gen-

20 No. 15-1502

eral public. Kmart's programs typically offered its "discounts" in return for nothing more than assent, demographic data the pharmacy already needed to fill a prescription, and a nominal fee.

The evidence submitted shows that the barriers to joining the Kmart "programs" were almost nonexistent, to the extent they were enforced at all. Cash customers walking into Kmart do not cease to be members of the general public the minute they are offered—or pushed into—"membership" in Kmart's "discount program." The program's most robust version allowed customers to obtain its "benefits" immediately for ten dollars. (For those people, the program fee is part of the cash price: for example, if the fee was \$10 and the program drug price was \$15, the customer paid \$25 for her first prescription. For people who fill more than one prescription, the \$10 fee would need to be allocated in some sensible way.) Garbe's expert indicated that most of Kmart's cash customers received its "discount" prices.

Our reading of "general public" is consistent with the regulatory structure that gave rise to the "usual and customary" price term. Under 42 C.F.R. § 423.100, the "[u]sual and customary (U&C) price means the price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug." The term is included in state regulations, plans, and contracts related to Medicare Part D because the Medicare and Medicaid regulations demand that it be. *Id.* § 447.512(b). Its meaning in many state regulations, plans, and contracts is lifted from the federal regulations without significant modification.

No. 15-1502 21

Medicare, Medicaid, and their corresponding regulations mandate that state plans ensure that "payments for services be consistent with efficiency, economy, and quality of care." *Id.* § 447.200 (citing 42 U.S.C. § 1396a(a)(30)). Under 42 C.F.R. § 50.503, "[i]t is the policy of the Secretary that program funds which are utilized for the acquisition of drugs be expended in the most economical manner feasible." The Medicare regulations mandate that payments for drugs under the program must not exceed "the lower of the[] (1) [Estimated Acquisition Cost] plus reasonable dispensing fees established by the agency; or (2) Providers' usual and customary charges to the general public." Id. § 447.512(b). The Estimated Acquisition Cost is "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." Id. § 447.502.

Taken together, "[t]he purpose of these regulations is clear: state agencies are not to pay more for prescribed drugs than the prevailing retail market price." *United States v. Bruno's, Inc.*, 54 F. Supp. 2d 1252, 1257 (M.D. Ala. 1999) (interpreting 42 C.F.R. § 447.512(b), then numbered 42 C.F.R. § 447.331(b)). Regulations related to "usual and customary" price should be read to ensure that where the pharmacy regularly offers a price to its cash purchasers of a particular drug, Medicare Part D receives the benefit of that deal. See generally *Arkansas Pharmacists Ass'n v. Harris*, 627 F.2d 867, 869 n.4 (8th Cir. 1980) (noting that "[t]he [Maximum Allowable Cost]," relevant only if lower than the usual and customary price, "is basically the lowest price at which a drug is widely and consistently available.").

22 No. 15-1502

An agency's interpretation of its own regulation is given "controlling weight unless it is plainly erroneous or inconsistent with the regulation." Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (quoting Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945)); cf. United Student Aid Funds, Inc. v. Bible, No. 15-861, cert. denied, May 16, 2016 (raising question whether Auer v. Robbins, 519 U.S. 452 (1997), should be overruled). The CMS Manual has long noted that "where a pharmacy offers a lower price to its customers throughout a benefit year" the lower price is considered the "usual and customary" price rather than "a one-time 'lower cash' price," even where the cash purchaser uses a discount card. CENTERS FOR MEDICARE & MEDICAID SERVS., Chapter 14 – Coordination of Benefits, in Medicare Prescription Drug Benefit Manual 19 n.1 (2006), https://perma.cc/MW6A-H4P6. Kmart offered its "discount" prices to customers continuously, throughout multiple benefit years.

Allowing Kmart to insulate high "usual and customary" prices by artificially dividing its customer base would undermine a central purpose of the statutory and regulatory structure. The "usual and customary" price requirement should not be frustrated by so flimsy a device as Kmart's "discount programs." Because Kmart offered the terms of its "discount programs" to the general public and made them the lowest prices for which its drugs were widely and consistently available, the Kmart "discount" prices at issue represented the "usual and customary" charges for the drugs.

2

Kmart argues that even if it is not entitled to summary judgment on whether its discount prices were its "usual and customary" charges, the issue is one of fact and appropriate

No. 15-1502 23

for a jury. But the interpretation of contractual and regulatory terms is generally a question of law. See *Hanover Ins. Co. v. N. Bldg. Co.*, 751 F.3d 788, 791 (7th Cir. 2014) ("[C]ontract interpretation is a question of law."); *Urso v. United States*, 72 F.3d 59, 60 (7th Cir. 1995) ("[T]he meaning of a regulation is a question of law for the court, not of fact for the jury."). No special consideration prevents this question from being resolved at summary judgment.

## III

FERA § 4(f) made 31 U.S.C. § 3729(a)(1)(B) (2009) retroactive with respect to *cases*, not just requests for payment. The current version of § 3729(a)(1)(B) therefore applies to (almost) all of Garbe's claims. Because Garbe has presented evidence sufficient to create a genuine dispute of material fact, his § 3729(a)(1)(B) claims survive summary judgment. FERA was not, however, mere clarifying legislation with regard to the pre-FERA § 3729(a)(1). Thus, if and to the extent any of Garbe's claims rely on the earlier law, they fail for lack of presentment. Finally, participants in Kmart's "discount programs" qualify as the "general public" for the purpose of determining the relevant "usual and customary" prices. We therefore AFFIRM in part and REVERSE in part, and REMAND for proceedings consistent with this opinion.