United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 17, 2012 Decided January 4, 2013

No. 11-5350

COALITION FOR COMMON SENSE IN GOVERNMENT PROCUREMENT,
APPELLANT

v.

UNITED STATES OF AMERICA AND UNITED STATES DEPARTMENT OF DEFENSE,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:08-cv-00996)

Lisa S. Blatt argued the cause for appellant. With her on the briefs were *Jeffrey L. Handwerker*, *Kara L. Daniels*, and *R. Stanton Jones*. *Daniel G. Jarcho* entered an appearance.

Sarang Vijay Damle, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Stuart F. Delery*, Acting Assistant Attorney General, *Ronald C. Machen, Jr.*, U.S. Attorney, and *Mark B. Stern*, Attorney.

Before: HENDERSON and TATEL, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* TATEL.

TATEL, *Circuit Judge*: Seeking to curb the rising cost of prescription drugs for military families, Congress enacted section 703 of the National Defense Authorization Act for Fiscal Year 2008, which subjects all prescriptions purchased at retail pharmacies by service members to the same price caps as drugs procured directly by the Department of Defense. Pursuant to this provision, the Secretary of Defense issued a regulation requiring pharmaceutical manufacturers to refund to the federal government the difference between the retail price and the price cap. This case presents two questions: May the Secretary impose price caps without obtaining the voluntary written agreements required in the procurement process? Has the Secretary impermissibly imposed retroactive rebate liability on pharmaceutical manufacturers? For the reasons given below, we conclude that the Secretary reasonably interpreted section 703 to impose involuntary price caps and hold that the statute itself imposes retroactive rebate liability on pharmaceutical manufacturers.

I.

The Department of Defense provides medical benefits to current and retired service members and their families through the TRICARE health care program. TRICARE beneficiaries receive prescription drugs through three "points of service" relevant to this case: military treatment facilities; TRICARE's mail-order pharmacy; and within-network retail pharmacies, like Walgreens or CVS. For prescriptions filled at military treatment facilities and TRICARE's mail-order pharmacy, the Department procures the drugs from manufacturers and then distributes them to beneficiaries. Since 1992, this procurement process has been governed by 38 U.S.C. § 8126, which requires the Department and manufacturer to "enter

into a master agreement . . . under which the price charged during the one-year [contract] may not exceed 76 percent of the non-Federal average manufacturer price." *Id.* § 8126(a)(2). In other words, these written agreements mandate a price—known as the "federal ceiling price"—discounted by at least twenty-four percent from the retail price.

For many years, by contrast, when a TRICARE beneficiary filled a prescription at the third "point of service"—a within-network retail pharmacy—the Department paid the full retail price for the drug. The reason was simple: unlike in the case of military treatment facilities and TRICARE's mail-order pharmacy, the Department did not procure the drug. Instead, the drug was distributed through commercial supply chains, and the TRICARE beneficiary purchased the drug from the retail pharmacy. The Department thus had no written agreement with the manufacturer through which it could limit the cost of a drug to the federal ceiling price.

Over the past decade, the government has made several attempts to close the twenty-four percent price differential between prescription drugs procured by the Department and those purchased by TRICARE beneficiaries at retail pharmacies. In October 2004, the Department of Veterans Affairs issued a "Dear Manufacturer letter" that required pharmaceutical manufacturers to refund to the Defense Department the difference between the retail price and the federal ceiling price. In a lawsuit filed by the Coalition for Common Sense in Government Procurement—a multi-industry interest group that represents pharmaceutical companies—the Federal Circuit invalidated the rebate requirement, finding that it constituted a substantive regulation that had to be promulgated via notice and comment

rulemaking, a process the Secretary had tried to circumvent by issuing the Dear Manufacturer letter. *See Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs*, 464 F.3d 1306 (Fed. Cir. 2006).

While that case was pending, the Defense Department announced the creation of a voluntary rebate program whereby manufacturers would give the Department refunds for drugs purchased at retail pharmacies in exchange for increasing the prospects that the particular drug would be placed on TRICARE's uniform formulary—prescription drugs with lower co-payments for beneficiaries. *See* 32 C.F.R. §§ 199.21(a)–(g). As an additional incentive, the Department indicated that it might waive its written preauthorization requirement for beneficiaries seeking these drugs. *See id.* § 199.21(k). The Department chose a rebate system because the drugs were distributed via private supply chains, which meant that pharmaceutical manufacturers had no way of knowing in advance what percentage of their drugs would be purchased by TRICARE beneficiaries. Thus, rather than involving downstream actors or adjusting the wholesale price, the Department required participating manufacturers to refund the money. This voluntary rebate program was not linked to the federal ceiling price.

In fiscal year 2007, the voluntary rebate program recouped only $28 million. At the same time, TRICARE costs continued to soar. As detailed in a Government Accountability Office report, the Defense Department's "prescription drug spending more than tripled from $1.6 billion in fiscal year 2000 to $6.2 billion in fiscal year 2006. Retail pharmacy spending drove most of this increase, rising from $455 million to $3.9 billion and growing from 29 percent of [the Defense Department's] overall drug spending to 63 percent." U.S. Government Accountability Office,

GAO-08-327, DOD Pharmacy Program: Continued Efforts Needed to Reduce Growth in Spending at Retail Pharmacies 3–4 (2008). The report found the cost increase attributable to "federal pricing arrangements . . . not appl[ying] to drugs dispensed at retail pharmacies" and to "increased use of retail pharmacies" by TRICARE beneficiaries. *Id.* at 4.

Concerned about the spiraling cost of TRICARE's prescription drug program and seeking to close the cost gap between prescriptions procured by the Department and those purchased at retail pharmacies, Congress enacted section 703 of the National Defense Authorization Act for Fiscal Year 2008, Pub. L. 110-181, 122 Stat. 3, 188, which, as amended, provides:

> With respect to any prescription filled after January 28, 2008, the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126.

10 U.S.C. § 1074g(f); *see also* National Defense Authorization Act for Fiscal Year 2010, Pub. L. No. 111-84, 123 Stat. 2190, 2474 (2009) (making a technical amendment to section 703 to replace the words "on or after the date of enactment of the [statute]" with "after January 28, 2008"). In short, section 703 subjects all prescriptions filled in the TRICARE retail pharmacy program to section 8126 requirements "to the extent necessary to ensure" that those drugs "are subject to [section 8126] pricing standards." 10

U.S.C. § 1074g(f). Section 703 also includes an express delegation of rulemaking authority to the Secretary of Defense. *See id.* § 1074g(h) ("The Secretary of Defense shall . . . prescribe regulations to carry out this section.").

Almost immediately after section 703's enactment, on February 1, 2008, the Defense Department issued its own "Dear Manufacturer letter" informing pharmaceutical companies that the voluntary rebate program would be "used for the initial implementation" of section 703. The Department then published a proposed rule that would have required manufacturers to enter into written agreements to abide by the federal ceiling price before their drugs could be included on the uniform formulary. *See* 73 Fed. Reg. 43,394 (July 25, 2008). Diverging from the proposed rule, the final rule, issued on March 17, 2009, directs manufacturers to refund to the Department the difference between the federal ceiling price and the retail price for all prescriptions filled at TRICARE retail pharmacies. *See* 74 Fed. Reg. 11,279 (Mar. 17, 2009); 32 C.F.R § 199.21(q). Thus, price caps apply regardless of whether manufacturers have signed a voluntary written agreement, though such agreements remain a prerequisite for both uniform formulary status and preauthorization. *See* 32 C.F.R. § 199.21(q)(2). Additionally, the final rule requires manufacturers to refund to the Department the price differential for any prescription filled after January 28, 2008, the date of section 703's enactment. *See id.* § 199.21(q)(1)(i). According to the Coalition, this "retroactive" requirement will likely cost the pharmaceutical industry in excess of $500 million. Under the final rule, however, the Secretary may waive or reduce the refund amount. *See id.* § 199.21(q)(3)(iii)(A). Manufacturers, moreover, can escape the federal ceiling price altogether by removing a drug from TRICARE coverage. *See id.* § 199.21(q)(3).

In the meantime, the Coalition, which had also sued the Defense Department in the United States District Court for the District of Columbia, amended its complaint to challenge the Secretary's authority to impose price caps without written agreements. On cross-motions for summary judgment, the district court remanded the final rule to the Department because the Secretary had failed to explain why he imposed the rebate requirement on drug manufacturers rather than another actor in the supply chain. *See Coalition for Common Sense in Government Procurement v. United States*, 671 F. Supp. 2d 48 (D.D.C. 2009). At *Chevron* step one, the district court reasoned that "the statute does not establish a particular regulatory scheme. Congress has not dictated that manufacturers must pay the costs associated with the Federal Ceiling Prices, or that they must refund proceeds in excess of this price on retail pharmacy program transactions." *Id.* at 54. But the district court declined to defer to the Secretary at *Chevron* step two because the Secretary had simply assumed that section 703 itself mandated that manufacturers rebate the twenty-four percent discount to the government. *See id.* at 55–56. Accordingly, the district court instructed the Secretary to consider other alternatives, such as requiring retail pharmacies to bear the burden of refunding the price differential to the Department. *See id.* at 54–56, 61.

Responding to the district court on October 15, 2010, the Secretary issued a supplemental rule explaining his rationale for requiring manufacturers to refund the price differential. *See* 75 Fed. Reg. 63,383 (Oct. 15, 2010). The Secretary interpreted section 703's text, structure, purpose, and legislative history as strongly indicating that the federal ceiling price applies to manufacturers, not some other entity in the supply chain such as wholesalers or retail pharmacies. *See id.* at 63,386–88. After addressing alternative mechanisms, the Secretary re-adopted the requirement that

pharmaceutical manufacturers refund the price differential to the Department. *See id.* at 63,388–91.

The Secretary also reiterated his position on the two main issues in this appeal. First, he defended his view that section 703's rebate program cannot be dependent on a voluntary written agreement. *See id.* at 63,391–93. Second, regarding retroactivity, the Secretary emphasized that he lacked discretion to impose a different implementation date. According to the Secretary, the statute's text and legislative history made clear that Congress intended that any prescription filled after the enactment date would be subject to the federal ceiling price. *See id.* at 63,391.

The 2010 rule fared better in the district court. Finding section 703 ambiguous as to the question of whether the federal ceiling price could be imposed on pharmaceutical manufacturers absent section 8126 written agreements, the district court upheld the Secretary's rule as a reasonable interpretation of the statute. The district court also rejected the Coalition's retroactivity argument, concluding that section 703 itself determines when prescriptions become subject to the federal ceiling price. *See Coalition for Common Sense in Government Procurement v. United States*, 821 F. Supp. 2d 275 (D.D.C. 2011).

Echoing its position in the district court, the Coalition raises two arguments on appeal. First, it contends that the Secretary has no authority to impose federal ceiling prices on manufacturers without obtaining their consent. Specifically, the Coalition believes that section 703 incorporates section 8126's written agreement requirement. Second, the Coalition argues that the rule impermissibly imposes retroactive rebate liability. The Coalition has abandoned its argument that other

entities, such as retail pharmacies, should reimburse the Defense Department.

We review a district court's grant of summary judgment de novo. *See Holcomb v. Powell*, 433 F.3d 889, 895 (D.C. Cir. 2006). In considering the Secretary's interpretation of section 703, we engage in the familiar *Chevron* two-step analysis. *See Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842–43 (1984).

II.

As always, we begin by examining the statute's text. Distilled to its core, section 703 provides:

> With respect to any prescription filled after January 28, 2008, the TRICARE retail pharmacy program shall be treated as an element of . . . section 8126 . . . to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense . . . are subject to [section 8126] pricing standards . . . .

10 U.S.C. § 1074g(f).

Section 703 unambiguously requires price caps. It directs the Secretary to "*ensure* that pharmaceuticals paid for by the Department of Defense . . . are subject to [section 8126] pricing standards." *Id.* (emphasis added). According to the Coalition, the statute also unambiguously requires procurement-type contracts to achieve those price caps. In addressing this argument, we ask "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. It has not. As the Secretary points out, Congress's use of the words "to the extent necessary" signals that not every jot and tittle of section 8126's procurement regime had

to be imposed on TRICARE's retail pharmacy program. The Coalition nonetheless advances several reasons why it believes that section 703 clearly requires written agreements between pharmaceutical manufacturers and the federal government. Only three merit serious attention.

First, the Coalition contends that section 703 "folds TRICARE[']s retail pharmacy sales into the pre-existing statutory scheme of federal ceiling prices under Section 8126" and "leaves no discretion for [the Secretary] to bypass the consensual underpinnings of the ceiling prices of Section 8126." Appellant's Br. 26–27. As the Coalition sees it, manufacturers cannot be forced to refund the price differential absent section 8126 procurement-type contracts. But as we see it, the Coalition's statutory interpretation risks creating a two-tiered regime in which only some prescriptions filled would be subject to federal ceiling prices. The Coalition offers no explanation for how a voluntary contract requirement, by itself, would fulfill section 703's mandate that "*any* prescription filled" be subject to the federal ceiling price. 10 U.S.C. § 1074g(f) (emphasis added). And at *Chevron* step one, the Coalition "must show that the statute *unambiguously* forecloses the [Secretary's] interpretation." *Village of Barrington v. Surface Transportation Board*, 636 F.3d 650, 661 (D.C. Cir. 2011). Given the statute's discretion-enhancing language, the Coalition has failed to meet its "heavy burden" of demonstrating that section 703 precludes the Secretary's method for achieving price caps. *Id.*

Second, pointing to other statutory schemes, such as the Medicaid Drug Rebate Program, *see* 42 U.S.C. § 1396r-8, the Coalition argues that "Congress without exception has required the government to enter into contracts with drug manufacturers to obtain their consent to price discounts in connection with federal healthcare programs." Appellant's Br.

32. The Coalition also asserts that when Congress imposes price caps, it speaks clearly and expressly. *See, e.g.*, Emergency Petroleum Allocation Act of 1973, Pub. L. No. 93-159, § 4, 87 Stat. 627, 629 ("The President shall promulgate a regulation providing for the mandatory allocation of [petroleum products] . . . at prices specified in (or determined in a manner prescribed by) such regulation . . . ."). This may well be true. But our job is to interpret *this* statute—section 703—and *this* statute gives the Secretary discretion as to how to ensure that prescriptions filled at retail pharmacies are subject to the federal ceiling price. Section 703's evolution reinforces this point. Congress enacted the provision in the wake of the Defense Department's creation of the very type of voluntary rebate program the Coalition insists the statute now requires. Despite that reform and its incentives for reducing prescription drug prices, Congress remained concerned about the rapidly rising cost of TRICARE's retail pharmacy program and passed section 703 to give the Secretary discretionary authority to solve this problem.

Third, the Coalition argues that because pharmaceutical manufacturers sell prescription drugs to wholesalers or retail pharmacies and have "no way of knowing where drugs end up," Appellant's Br. 28, they cannot predict their potential liability and should therefore not be forced, absent agreement, to refund unforeseeable sums of money to the government. Although the opt-out provision allows pharmaceutical companies to escape federal ceiling prices by removing their drugs from TRICARE, the Coalition believes that Congress could never have intended to put military service members' access to prescription drugs at risk. *See* Appellant's Br. 6. It is certainly true that the logistical issues associated with commercial supply chains raise questions about precisely how the federal ceiling price can be extended to prescriptions filled

at within-network retail pharmacies. But the question before us at this stage of *Chevron* analysis is whether section 703 unambiguously requires the Secretary to resolve these issues through procurement-type contracts. As explained above, it does not.

Turning to *Chevron* step two, we ask whether the Secretary's rule represents a "permissible construction" of section 703. *Chevron*, 467 U.S. at 843. Other than repeating the *Chevron* step one arguments we have already rejected, the Coalition claims that the Secretary's regulation is unreasonable because most pharmaceutical companies have now entered into prospective section 703 agreements. This, the Coalition believes, demonstrates that a voluntary contract regime could work. The *Chevron* step two question, however, is not whether the Coalition's proposed alternative is an acceptable policy option but whether the Secretary's rule reflects a reasonable interpretation of section 703.

The rule easily satisfies *Chevron* step two. It accomplishes Congress's objectives and does so in a way that accounts for market realities. Section 703 requires that "any prescription filled" be subject to section 8126 "pricing standards." 10 U.S.C. § 1074g(f). The rule achieves this goal through a universal requirement on all pharmaceutical manufacturers that participate in TRICARE—that is, the rule imposes involuntary price caps "to the extent necessary" to guarantee compliance with section 8126 "pricing standards." Moreover, the rule furthers Congress's primary goal of ensuring price parity across TRICARE's three points of service. And finally, the rule capitalizes on the logistical convenience of imposing refund liability on manufacturers rather than lowering retail prices or seeking refunds from downstream actors.

III.

The Coalition also contends that the regulation—promulgated in 2010 but requiring refunds for prescriptions filled after January 28, 2008—impermissibly imposes retroactive rebate liability. In the legal sense of the term, retroactivity occurs when a statute or rule "takes away or impairs vested rights acquired under existing law, or creates a new obligation, imposes a new duty, or attaches a new disability in respect to transactions or considerations already past." *National Mining Association v. Department of Labor*, 292 F.3d 849, 859 (D.C. Cir. 2002) (internal quotation marks omitted). Characterizing January 28, 2008, as nothing more than section 703's effective date, the Coalition argues that the " 'mere promulgation of an effective date for a statute does not provide sufficient assurance that Congress specifically considered the potential unfairness that retroactive application would produce.' " Appellant's Br. 47 (quoting *INS v. St. Cyr*, 533 U.S. 289, 317 (2001)). As a result, the Coalition claims it was the 2010 regulation, not the statute, that imposed retroactive liability on pharmaceutical manufacturers. Because the Secretary lacks retroactive rulemaking authority, the argument goes, the regulation's retroactive application must fail. *See Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988) (explaining that a "statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms").

We disagree with the Coalition's premise. As the district court explained, "it was the passing of the *statute*, not the promulgation of a *regulation*, that determined when prescriptions became subject to [federal ceiling prices]." *Coalition for Common Sense*, 821 F. Supp. 2d at 288 (emphases added). As the Supreme Court has instructed, a

"statute may not be applied retroactively . . . absent a clear indication from Congress that it intended such a result." *St. Cyr*, 533 U.S. at 316. Thus, the question is whether Congress intended section 703 to impose rebate liability for prescriptions filled after its date of enactment.

Section 703 could hardly be clearer: "With respect to *any* prescription *filled after* January 28, 2008, the TRICARE retail pharmacy program *shall* be" subject to section 8126's "pricing standards." 10 U.S.C. § 1074g(f) (emphases added). This language leaves no doubt that Section 703's effective date is the date of enactment—January 28, 2008—and that the triggering event for rebate liability is the filling of a prescription.

The Coalition nonetheless insists that because the district court ruled in 2009 that section 703 was ambiguous as to *who* should pay the rebate, it was in fact the 2010 regulation that imposed refund liability on pharmaceutical manufacturers. As the Coalition understands the law-of-the-case doctrine, the district court's ruling binds this Court. This is incorrect. The law-of-the-case doctrine bars us from reconsidering only questions decided by *this* Court in this case. *See LaShawn A. v. Barry*, 87 F.3d 1389, 1393 (D.C. Cir. 1996) (en banc) (explaining that under the law-of-the-case doctrine "the same issue presented a second time in the same case in the *same court* should lead to the same result" (emphases omitted)).

The only question, then, is whether section 703 unambiguously imposes price caps on *manufacturers*. Although section 703 nowhere mentions manufacturers, it cross-references section 8126's pricing standards—standards that apply to manufacturers and expressly exclude "wholesale distributors of drugs or a retail pharmacy." 38 U.S.C. § 8126(h)(4)(B). In other words, federal ceiling prices apply

to manufacturers, not other entities. Congress, moreover, enacted section 703 against a regulatory backdrop that presumed manufacturers would bear the burden of refunding the price differential to the Defense Department. The 2004 Dear Manufacturer letter mandated manufacturer liability, and the Defense Department's voluntary rebate program focused on signing deals with manufacturers, not retail pharmacies. We therefore conclude that section 703 not only clearly imposed rebate liability on January 28, 2008, but also put pharmaceutical manufacturers on notice that they would bear the burden of closing the gap between the retail price and the federal ceiling price.

The Coalition marshals one final argument. Invoking the realities of supply chains, it contends that the final rule makes pharmaceutical manufacturers liable for drugs that entered the marketplace well before section 703's enactment. Put differently, the Coalition claims Congress could not have intended that a drug sold by a manufacturer to a wholesaler before the statute's effective date could trigger refund liability when purchased by a TRICARE beneficiary after that date. That, however, is precisely what Congress intended: section 703 applies price caps to "any prescription *filled after*" the effective date, not to any drug sold to a wholesaler after that date. 10 U.S.C. § 1074g(f) (emphasis added). Given the logistics of pharmaceutical supply chains, which Congress obviously understood, some drugs would inevitably be in the distribution stream on section 703's enactment date.

Furthermore, although the final regulation allows the Secretary to waive refund liability, no pharmaceutical manufacturer has yet sought a waiver. *See* Appellees' Br. 27–28. Given that Congress clearly imposed refund liability for any prescription filled after section 703's effective date, pharmaceutical manufacturers who believe they should not

have to pay for drugs already in the supply chain on January 28, 2008, should seek a waiver from the Department, not this Court.

IV.

For the foregoing reasons, we affirm.

So ordered.