PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 20-2330

UNITED STATES EX REL. DEBORAH SHELDON, Executrix of the Estate of Troy Sheldon, United States of America, ex rel.,

Plaintiff – Appellant,

v.

ALLERGAN SALES, LLC,

Defendant – Appellee.

UNITED STATES OF AMERICA; TAXPAYERS AGAINST FRAUD EDUCATION FUND,

Amici Supporting Appellant.

WASHINGTON LEGAL FOUNDATION; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Amici Supporting Appellee.

Appeal from the United States District Court for the District of Maryland, at Baltimore. Ellen L. Hollander, Senior District Judge. (1:14-cv-02535-ELH)

Argued: October 28, 2021 Decided: January 25, 2022

Before WILKINSON, WYNN, and RICHARDSON, Circuit Judges.

Affirmed by published opinion. Judge Wilkinson wrote the opinion, in which Judge Richardson joined. Judge Wynn wrote a dissenting opinion.

ARGUED: Joshua Yrion Dos Santos, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Joseph M. Callow, Jr., KEATING, MUETHING & KLEKAMP PLL, Cincinnati, Ohio, for Appellant. John Patrick Elwood, ARNOLD & PORTER KAYE SCHOLER LLP, Washington, D.C., for Appellee. **ON BRIEF:** Gregory M. Utter, Paul R. Kerridge, Collin L. Ryan, KEATING MUETHING & KLEKAMP PLL, Cincinnati, Ohio; Joel D. Hesch, THE HESCH FIRM, LLC, Lynchburg, Virginia, for Appellant. Michael A. Rogoff, Paula R. Ramer, New York, New York, Jeffrey L. Handwerker, Christian D. Sheehan, ARNOLD & PORTER KAYE SCHOLER LLP, Washington, D.C., for Appellee. Brian M. Boynton, Acting Assistant Attorney General, Michael S. Raab, Charles W. Scarborough, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Amicus United States of America. Jacklyn De Mar, TAXPAYERS AGAINST FRAUD EDUCATION FUND, Washington, D.C.; John W. Black, Samuel J. Buffone, Jr., BLACK & BUFFONE PLLC, Washington, D.C., for Amicus Taxpayers Against Fraud Education Fund. John M. Masslon II, Cory L. Andrews, WASHINGTON LEGAL FOUNDATION, Washington, D.C., for Amicus Washington Legal Foundation. James C. Stansel, Melissa B. Kimmel, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Washington, D.C., for Amicus Pharmaceutical Research and Manufacturers of America. Tara S. Morrissey, Andrew R. Varcoe, UNITED STATES CHAMBER LITIGATION CENTER, Washington, D.C., for Amicus Chamber of Commerce of the United States of America. John C. O'Quinn, Matthew S. Owen, Matthew D. Rowen, Andrea R. Butler, KIRKLAND & ELLIS LLP, Washington, D.C., for Amici Pharmaceutical Research and Manufacturers of America and Chamber of Commerce of the United States of America.

WILKINSON, Circuit Judge:

Plaintiff Troy Sheldon filed a False Claims Act *qui tam* suit against his employer, Forest Laboratories, LLC. He alleged that Forest engaged in a fraudulent price reporting scheme under the Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8, by failing to aggregate discounts given to separate customers for purposes of reporting "Best Price." Because Forest's reading of the Rebate Statute was at the very least objectively reasonable and because it was not warned away from that reading by authoritative guidance, it did not act "knowingly" under the False Claims Act. As a result, we affirm the district court's dismissal of Sheldon's complaint.

We thank our friend for his thoughtful dissent. We do of course agree with him that "[t]he False Claims Act is the government's primary litigative tool for the recovery of losses sustained as the result of fraud against the government." Dissenting Op. at 32 (quoting *Avco Corp. v. U.S. Dep't of Just.*, 884 F.2d 621, 622 (D.C. Cir. 1989)). Regrettably, despite all protestations, the dissent nullifies the whole concept of scienter about which the Supreme Court has shown an especial solicitude. The FCA unquestionably has a punitive aspect, and the kinship between civil scienter and criminal mens rea in this case is closer than Sheldon or the dissent is willing to acknowledge.

Sheldon's position takes the FCA a very long step toward a strict liability statute. It conflates factual fraud and legal fraud, thereby facilitating steep liability for those whose factual representations are not alleged to be either false or duplicitous and those whose legal position is not only arguable but correct. Sheldon does not so much as allege reckless disregard or deliberate indifference or nefarious knowledge here with respect to, in the

operative word of the statute, the "information." 31 U.S.C. § 3729(b)(1)(A). Yet the relator's position instead makes sinister actors out of parties who have followed the law in every respect and sought administrative guidance where none was ever provided. Given the veritable thicket of Medicaid regulations, it is not too much to expect something more in the way of clarity and direction than was ever offered here. To reward the state with treble damages for this treatment of parties in the private sector is something no court should do.

Sheldon would disregard Judge Hollander's sound counsel that the Rebate Statute's "plain and natural reading" did not require aggregating discounts, along with her sensible conclusion that there was not "a single example where CMS explicitly state[d] that manufacturers must aggregate discounts to different customers along the supply chain in a given sale." *United States ex rel. Sheldon v. Forest Laboratories, LLC*, 499 F. Supp. 3d 184, 209, 211 (D. Md. 2020). Sheldon in addition recommends we ignore all our sister circuits which have followed the framework that the Supreme Court has set forth in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007), thus opening wide a stark circuit split. *See United States ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 459 (7th Cir. 2021); *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2018); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879–80 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 290–91 (D.C. Cir. 2015). Moreover, Sheldon proposes to disregard the Supreme Court's insistence that the concept of scienter be given "rigorous" application, *Universal Health Servs., Inc. v.*

United States ex rel. Escobar, 136 S. Ct. 1989, 2002 (2016), and the dissent dismisses as "dictum" Supreme Court guidance which it finds inconvenient, Dissenting Op. at 31. All this—at all three levels of the judicial system—Sheldon and the dissent would overturn, in deference to a view that is not sustainable under law or under any notion of notice and due process with which we are familiar.

I.

A.

Medicaid offers federal financial assistance to states that reimburse certain medical expenses for eligible individuals. *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 650 (2003). One of those expenses is prescription drugs. 42 U.S.C. § 1396d(a)(12). To make sure that Medicaid programs receive "the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser," H.R. Rep. No. 101-881, at 96 (1990), Congress enacted the Medicaid Drug Rebate Statute in 1990, *see* 42 U.S.C. § 1396r-8.

Under the Rebate Statute, manufacturers seeking to have their drugs covered by Medicaid must enter into Rebate Agreements with the Secretary of Health and Human Services and provide quarterly rebates to states on Medicaid sales of covered drugs. *Id.* § 1396r-8(a)(1), (c)(1)(A). The manufacturer reports the "Average Manufacturer Price" and the "Best Price" for its covered drugs to the Centers for Medicare & Medicaid Services (CMS); CMS then calculates the rebate amount that the manufacturer must pay to the states for each drug. *See id.* § 1396r-8(b)(3)(A). For covered drugs, the rebate amount is the greater of two numbers: (1) the statutory minimum rebate percentage, or (2) the difference

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.