No. 22-3675

In the United States Court of Appeals for the Eighth Circuit

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellant,

v.

ALAN MCCLAIN, in his official capacity as Commissioner of the Arkansas Insurance Department

Defendant-Appellee,

COMMUNITY HEALTH CENTERS OF ARKANSAS; PIGGOTT COMMUNITY HOSPITAL,

Intervenors-Appellees.

On Appeal from the United States District Court for the Eastern District of Arkansas

Civil Action No.: 4:21-cv-864-BRW

MOTION OF KALDEROS, INC. FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT'S PETITION FOR REHEARING *EN BANC*

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April 16, 2024

Counsel for Movant Kalderos, Inc.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1A of the United States Court of Appeals for the Eighth Circuit, Kalderos, Inc., states that it has no parent corporation and that no publicly held corporation owns 10% or more of any stock in Kalderos, Inc. Kalderos is a technology company that has developed an equitable, easy-to-use technology platform designed to implement the 340B program on behalf of covered entities and participating drug manufacturers.

Pursuant to Federal Rule of Appellate Procedure 27 and 29(b), and Local Rule 29A, Kalderos, Inc. respectfully moves this Court for leave to file a brief as *amicus curiae* in support of Plaintiff-Appellant's Petition for Rehearing *En Banc*. A copy of the proposed brief is attached as Exhibit A to this motion.

INTEREST OF *AMICUS CURIAE* AND REASONS WHY THE MOTION SHOULD BE GRANTED

Kalderos, Inc. is a technology company that has developed an equitable, easy-to-use technology platform designed to implement the 340B program on behalf of covered entities and participating drug manufacturers. Kalderos' platform facilitates both covered entities and manufacturers receiving benefits and meeting their respective responsibilities under the 340B statute. Kalderos seeks to assist both covered entities and manufacturers to secure the statutory benefits and protections Congress provided by enacting Section 340B.

Kalderos offers a unique perspective to this case. Kalderos' mission is to address the concerns of both covered entities and manufacturers. It does so by (1) ensuring that 340B covered entities receive the discounted price required by statute, and (2) helping manufacturers identify and reduce prohibited diversion and duplicate discounts. Importantly, diversion, in the context of a drug whose distribution must be carefully controlled for safety reasons has not just fiscal, but patient safety implications, a shared concern for both manufacturers and covered entities.

Kalderos' platform—and the equitable assistance it offers to both covered entities and manufacturers—is a function of Kalderos' receipt of data, from both sets of stakeholders, in compliance with all applicable privacy and security laws. These data include sales and pricing information from manufacturers and standard data sets from covered entities relating to the products they have purchased and for which they claim the discounted 340B price. With these data, the Kalderos platform flags potential diversion and/or duplicate discounts and ensures that the 340B price has, in fact, been extended to eligible covered entities. The platform is a "win-win" that reflects the balance at the core of the 340B program.

Given all this, Kalderos has firsthand knowledge of the 340B program and how manufacturers and covered entities meet their responsibilities under the 340B program. Kalderos' proposed brief emphasizes that the panel's decision should be reviewed en banc because (i) it reflects a mistaken picture of how the 340B program operates, (ii) its ruling that Act 1103 is not preempted undercuts proper enforcement of the 340B program by the Department of Health and Human Services ("HHS"), and (iii) its impact may extend beyond the scope of Act 1103 because other states have enacted or are considering similar laws that, like Act 1103, would alter the scope of the 340B program and undermine its proper enforcement.

The panel decision erred in holding that Act 1103 is not preempted by federal law. Kalderos is concerned that this Court's decision rests on a flawed understanding of the 340B program and therefore respectfully moves for leave to file the *amicus* brief attached as Exhibit A, hereto.

CONCLUSION

For these reasons, Kalderos respectfully requests leave to file a brief as *amicus curiae* in support of Plaintiff-Appellant's petition for rehearing en banc.

Date: April 16, 2024

Respectfully submitted,

/s/ Paul J. Zidlicky

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CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with the type-volume limitations of Federal Rules of Appellate Procedure 27(d) because the motion contains 514 words, excluding the parts of the motion exempted by Federal Rule of Civil Procedure 32(f) and the accompanying document authorized by Federal Rule of Appellate Procedure 27(a)(2)(B).

I also certify that this motion complies with the typeface requirements of Federal Rules of Appellate Procedure 27(d)(1)(E) and 32(a)(5)–(6) because this motion has been prepared using Microsoft Word 2016 in 14-point Times New Roman font.

s/ Paul J. Zidlicky
Paul J. Zidlicky

Dated: April 16, 2024

CERTIFICATE OF SERVICE

I hereby certify that on April 16, 2024, a true and correct copy of the foregoing was timely filed with the Clerk of the Court using the appellate CM/ECF system, which will send notifications to all counsel registered to receive electronic notices.

Within five days of receipt of notice that the foregoing document has been filed, Kalderos will serve each party separately represented with a paper copy of its proposed amicus brief.

I further certify that ten paper copies of Kalderos' proposed brief as *amicus curiae* will be provided to the Court within five days after receipt of notice that the foregoing document has been filed pursuant to Rule 28A(d).

/s/ Paul J. Zidlicky
Paul J. Zidlicky