United States Court of Appeals

for the

Third Circuit

Case Nos. 18-2259, 18-2656

In re: AVANDIA MARKETING, SALES PRACTICES & PRODUCTS LIABILITY LITIGATION

UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND AND J.B. HUNT TRANSPORT SERVICES, INC.,

Petitioners-Appellants,

– v. –

GLAXOSMITHKLINE, LLC,

Respondent-Appellee.

ON APPEAL FROM A JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA IN NOS. 2:07-MD-01871, 2:10-CV-2475, 2:11-CV-4013

BRIEF OF *AMICI CURIAE* COLLABORATION FOR RESEARCH INTEGRITY AND TRANSPARENCY AND PUBLIC JUSTICE IN SUPPORT OF APPELLANTS

PUBLIC JUSTICE, P.C.
475 14th Street, Suite 610
Oakland, CA 94612
(510) 622-8150
jbennett@publicjustice.net

COLLABORATION FOR RESEARCH INTEGRITY AND TRANSPARENCY
Yale Law School
jeanie.kim@yale.edu
cortelyou.kenney@yale.edu

ABRAMS INSTITUTE FOR FREEDOM OF EXPRESSION
Yale Law School
127 Wall Street, New Haven, CT 06510
christopher.morten@yale.edu
david.schulz@yale.edu

Attorneys for Amici Curiae

November 5, 2018

CORPORATE DISCLOSURE STATEMENT

The Collaboration for Research Integrity and Transparency (CRIT) is an organization within Yale University, which is a nonprofit, nonstock corporation, with no parent corporation. Yale University issues no stock, and no publicly held corporation owns 10% or more of its stock. CRIT is a non-corporate party and is an interdisciplinary initiative of Yale Law School, Yale School of Medicine, and Yale School of Public Health.

Public Justice, P.C. has no parent corporation, and no publicly held corporation owns any of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

RULES

STATEMENT OF IDENTIFICATION[1]

Amicus Collaboration for Research Integrity and Transparency (CRIT) is an interdisciplinary initiative of Yale's Law School, School of Medicine, and School of Public Health. CRIT works to improve patient outcomes, scientific knowledge, and public health by promoting the transparency and integrity of scientific research on drugs and medical devices. CRIT has a strong interest in supporting the public's right of access to court records in complex pharmaceutical tort litigation, as such records provide insight into the research, marketing, and regulation of medical products.

Amicus Public Justice is a national public interest legal organization that specializes in precedent-setting, socially significant civil litigation, with a focus on fighting corporate and governmental misconduct. As part of this work, Public Justice has a longstanding project devoted to fighting court secrecy. Through this project, Public Justice challenges unlawful sealing orders, overbroad protective orders, and confidentiality provisions in settlement agreements that have been used to hide corporate or governmental misconduct—often misconduct that continues to cause harm precisely because the evidence is hidden in sealed court records.

---

[1] No counsel for any party authored this brief in whole or part. Apart from *amici curiae*, no person or organization, including parties or parties' counsel, contributed money intended to fund the preparation and submission of this brief.

Public Justice, therefore, has a strong interest in ensuring that courts protect the common law and constitutional rights of access to court records.

Amici file this brief pursuant to Fed. R. App. P. 29(a). Appellants and Appellee consent to the filing of this amicus brief.

PRELIMINARY STATEMENT AND SUMMARY OF THE ARGUMENT

Over the past two decades, some of the most egregious practices of the pharmaceutical industry have been exposed through consumer protection and personal injury lawsuits. *See* Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. Am. Med. Ass'n 308 (2007). These cases have revealed how drug companies misrepresented research findings in scientific publications, delayed reporting safety concerns to regulators, and made misleading claims to physicians and patients. *Id*. at 309.

However, a significant amount of research, marketing, and regulatory information about drug safety and efficacy that is revealed in litigation remains hidden from the public—despite its clinical and public health significance—due to overbroad confidentiality orders. *See* Daniel J. Givelber & Anthony Robbins, *Public Health Versus Court-Sponsored Secrecy*, 69 Law & Contemp. Probs. 131, 131 (2006). In particular, sealing orders that are issued without proper assessment of the public's interests have resulted in widespread and unwarranted sealing of court records in violation of standards set forth by the Supreme Court, this Court, and other U.S. Courts of Appeals.

Amici submit this brief to urge this Court to clarify three important points essential to protecting the public's right to access court records. First, this Court should make explicit what is implicit in its previous decisions: the First

Amendment protects the public's right of access to summary judgment records. While summary judgment records are clearly subject to the common law right of access under this Court's precedent, this Court has not yet expressly ruled that summary judgment records are also subject to the First Amendment right of access. Binding precedents of this Court and the Supreme Court compel that conclusion.

Second, this Court should clarify that courts have an independent obligation to protect the public's right of access by applying the standards for sealing set forth by the common law and the First Amendment. The district court failed to fulfill this obligation. The district court first perfunctorily and improperly sealed court documents pursuant to a blanket protective order and then kept the documents under seal based on the less stringent "good cause" standard that governs unfiled discovery but does not govern court records. The district court's errors here are not isolated but are illustrative of common errors made by district courts that result in court records being sealed without adequate justification, despite rulings from this Court that such sealing is impermissible.

Finally, this Court should reiterate that where court records implicate public health and safety, as here and as in all pharmaceutical tort litigation, the public's already substantial interest in disclosure is even stronger and creates an even higher standard for sealing. This higher standard is critical because such lawsuits

play an important role in protecting public health and safety and ensuring that medical products are properly regulated.

ARGUMENT

I. THE PUBLIC HAS A WELL-SETTLED RIGHT OF ACCESS TO COURT RECORDS, INCLUDING SUMMARY JUDGMENT EXHIBITS

The public has a right of access to summary judgment records under the common law and the First Amendment. This Court has long recognized a common law right of access to "papers filed in connection with a motion for summary judgment," *Republic of Philippines v. Westinghouse Elec. Corp.*, 949 F.2d 653, 661 (3d Cir. 1991), and more generally, to "all material filed in connection with nondiscovery pretrial motions," *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 165 (3d Cir. 1993). It is also well settled that there is a constitutional right of access to civil proceedings. *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1070 (3d Cir. 1984). However, the scope of the constitutional right remains less defined in this Circuit. This Court should both reaffirm the strong common law right of access to materials attached to substantive pretrial motions and join other Courts of Appeals in holding that such documents are also subject to the constitutional right of access. *See, e.g., Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 121 (2d Cir. 2006); *Rushford v. New Yorker Magazine, Inc.*, 846 F.2d 249, 253 (4th Cir. 1988).

A. The Common Law Right of Access Applies to Summary Judgment Exhibits

The common law right of access "antedates the Constitution," and its applicability in "both criminal and civil cases[] is now 'beyond dispute.'" *Leucadia*, 998 F.2d at 161 (quoting *Littlejohn v. BIC Corp.*, 851 F.2d 673, 677-78 (3d Cir. 1988)). Noting the importance of "[a] citizen's desire to keep a watchful eye on the workings of public agencies," the Supreme Court has explained that the public has a right "to inspect and copy public records and documents, including judicial records and documents," regardless of "a proprietary interest in the document" or "a need for it as evidence in a lawsuit." *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597-98 (1978). This right "promotes public confidence in the judicial system." *Westinghouse*, 949 F.2d at 660 (quoting *Littlejohn*, 851 F.2d at 678).

This Court has specifically ruled that the common law right of access attaches to "papers filed in connection with a motion for summary judgment." *Westinghouse*, 949 F.2d at 661; *see also Leucadia*, 998 F.2d at 165 (the right of access extends to "all material filed in connection with nondiscovery pretrial motions, whether these motions are case dispositive or not"). Summary judgment proceedings can "shape[] the scope and substance of litigation." *Westinghouse*, 949 F.2d at 660. In such proceedings, access to the underlying evidence provides "an opportunity to assess the correctness of the judge's decision." *Id*. at 661

(citation omitted). Access also "helps to impart legitimacy to the pronouncements of [the] rather insulated federal judiciary." *Id*. at 664.

B. The Stronger Constitutional Right of Access Also Applies

The public also has a right of access grounded in the First Amendment's "core purpose of assuring freedom of communication on matters relating to the functioning of government." *Richmond Newspapers, Inc. v. Virginia*, 448 U.S. 555, 575 (1980). This Court should rule, consistently with other Courts of Appeals, that summary judgment materials are subject to the constitutional right of access, which "requires a much higher showing" to overcome than its common law counterpart. *In re Cendant Corp.*, 260 F.3d 183, 198 n.13 (3d Cir. 2001) (citing *Publicker*, 733 F.2d at 1070).

In *Richmond Newspapers*, the Supreme Court first articulated the public's right of access to judicial proceedings that is "implicit in the guarantees of the First Amendment." 448 U.S. at 580. To give meaning to "the explicit, guaranteed rights to speak and publish concerning what takes place at a trial," *id*. at 576-77, the Supreme Court recognized the First Amendment "as protecting the right of everyone to attend trials," *id*. at 575. Accordingly, the Court held that "arbitrary interference with access to important information" is an abridgment of the freedoms of speech and press. *Id*. at 583 (Stevens, J., concurring).

Although *Richmond Newspapers* first recognized the constitutional right of access in the context of a criminal trial, *id*. at 575-77, the Supreme Court has held that the right extends more broadly to other proceedings. Courts determine whether the First Amendment applies to a particular proceeding by examining two factors: (1) experience—"whether the place and process have historically been open to the press and general public," and (2) logic—"whether public access plays a significant positive role in the functioning of the particular process in question." *Press-Enter. Co. v. Superior Court of Cal., Riverside Cnty.*, 478 U.S. 1 (1986) ("*Press-Enterprise II*").

Both the Supreme Court and this Court have treated the experience factor flexibly—placing equal or greater emphasis on logic—in determining whether the constitutional right of access extends to a particular government proceeding. *Press-Enterprise II*, 478 U.S. at 10 & n.3, 13; *United States v. Criden*, 675 F.2d 550, 555 (3d Cir. 1982). In *Press-Enterprise II*, for example, the Supreme Court concluded that the First Amendment provides a right of access to pretrial criminal proceedings. *Press-Enterprise II*, 478 U.S. at 10. Addressing both experience and logic, the Supreme Court referenced the history of "preliminary hearings [held] in open court," *id.*, and reasoned that preliminary hearings are "sufficiently like a trial" such that public access is "essential to the proper functioning of the criminal justice system," *id*. at 12. The Court also noted approvingly that several state

courts had applied the constitutional access right to pretrial proceedings—even when those specific proceedings had "no historical counterpart"—because of "the importance of the pretrial proceeding to the criminal trial." *Id*. at 10 n.3.

Similarly, in *Criden*, when considering whether there is a constitutional right of access to a pretrial hearing on a motion to suppress evidence, this Court deemphasized "historical analysis" because "the relative importance of pretrial procedure to that of trial has grown immensely in the last two hundred years." 675 F.2d at 555. While *Criden* predated *Press-Enterprise II*, *Criden* also focused on the logic of public access, stressing that access to a pretrial criminal hearing would serve the criminal trial process by (1) "promot[ing] informed discussion of government affairs," (2) "assur[ing] that the proceedings were conducted fairly to all concerned," (3) "provid[ing] an outlet for community concern, hostility, and emotion," (4) "serv[ing] as a check on corrupt practices by exposing the judicial process to public scrutiny," (5) "enhanc[ing] the performance of all involved" in criminal proceedings, and (6) "discourag[ing] perjury." *Id*. at 556 (citing the "six societal interests" identified in *Richmond Newspapers*) (internal quotation marks omitted).

Applying experience and logic, this Court and every other Circuit to address the issue have held that the constitutional right of access extends to civil

proceedings.[2] *Rushford*, 846 F.2d at 253; *Publicker*, 733 F.2d at 1068, 1070; *Westmoreland v. CBS, Inc.*, 752 F.2d 16, 22-23 (2d Cir. 1984); *In re Cont'l Ill. Sec. Litig.*, 732 F.2d 1302, 1308 (7th Cir. 1984). In *Publicker*, this Court held that the constitutional right of access attaches to a hearing on a motion for preliminary injunction. 733 F.2d at 1070, 1073-74. In determining the scope of the First Amendment right, the Court found no basis to distinguish between civil and criminal proceedings. *Id.* at 1070 ("Public access to civil trials, no less than criminal trials, plays an important role in the participation and the free discussion of governmental affairs."). *Publicker* observed that the history of "open trials . . . whether civil *or* criminal" can be traced back to the Nation's founding. *Id*. at 1069 (citations and internal quotation marks omitted). The Court then described several ways that public access to civil proceedings benefits the judicial process, such as "the proper administration of justice," "security for testimonial trustworthiness," and "a better understanding of the operation of the government." *Id*. at 1069, 1070 (citations omitted).

[2] In *Richmond Newspapers* itself, the Supreme Court observed that "historically both civil and criminal trials have been presumptively open." 448 U.S. at 580 n.17.

Contrary to GSK's contention that the constitutional right of access exists "in civil cases only in the context of access to trials, hearings, and transcripts,"[3] this Court has cited *Publicker* to affirm that the First Amendment broadly "protects the public's right of access to the *records* of civil proceedings." *Westinghouse*, 949 F.2d at 659 (citing *Publicker*, 733 F.2d at 1070) (emphasis added); *accord Leucadia*, 998 F.2d at 161 n.6.

While this Court has not yet determined whether summary judgment records are "records of civil proceedings" to which the First Amendment right of access applies, other Courts of Appeals have. *See, e.g.*, *Rushford*, 846 F.2d at 253; *Lugosch*, 435 F.3d at 121. For example, following *Publicker*'s reasoning that the constitutional right must apply to civil proceedings, the Fourth Circuit held that "the more rigorous First Amendment standard" applies to documents submitted with summary judgment motions. *Rushford*, 846 F.2d at 253 (citing *Publicker*, 733 F.2d at 1067-71). The Fourth Circuit found no basis to distinguish between civil trial and summary judgment for First Amendment purposes "[b]ecause summary judgment adjudicates substantive rights and serves as a substitute for a

[3] Response of Appellant GlaxoSmithKline, LLC, at 5-6 n.3, *In re Avandia Mktg., Sales Practices, and Prods. Liab. Litig.*, No. 18-1010 (3d Cir.) (July 6, 2018) ("GSK's July 6 Response").

trial." *Id*. at 252. Attachments to a summary judgment motion, therefore, are subject to the constitutional right of access. *Id*. at 253.

Similarly, the Second Circuit held that "documents submitted to a court for its consideration in a summary judgment motion are—as a matter of law—judicial documents to which a strong presumption of access attaches, under both the common law and the First Amendment." *Lugosch*, 435 F.3d at 121. Access to summary judgment records, the Second Circuit explained, promotes the integrity of and public confidence in judicial process. *Id*. Agreeing with "other circuits that have addressed the question," the Second Circuit held broadly that the constitutional right of access applies "to written documents submitted in connection with judicial proceedings that themselves implicate the right of access." *Id*. at 124 (alterations and internal citations omitted).

It is important for this Court to articulate the First Amendment right here, even if the Court finds that Appellants should prevail under the common law right. Previously, this Court has avoided the First Amendment question when it has found that the common law right suffices to warrant public access. *See Cendant*, 260 F.3d at 192, 197; *Leucadia*, 998 F.2d at 161 n.6; *Westinghouse*, 949 F.2d at 659. This Court's lack of an explicit statement that there is a First Amendment right of access to summary judgment records has led some district courts to improperly confine the constitutional access right, resulting in sealing orders that

violate the First Amendment. For example, in a case cited by GSK,[4] one district court wrongly stated that "[w]hen the Third Circuit does examine the parallel [access] right as it exists under the First Amendment, it does so only when a civil action to have a transcript unsealed is brought (or intervened in) by a member of the public." *Eisai Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-cv-4168, 2015 WL 1138400, at *3 n.3 (D.N.J. Mar. 11, 2015) (citing *Publicker*, 733 F.2d 1059). GSK relies on *Eisai*'s incorrect interpretation to support the contention that the First Amendment right of access does not apply to civil "briefing and exhibits to motions."[5]

The Court should join the Second and Fourth Circuits and expressly hold that the constitutional right of access to civil proceedings and records articulated in *Publicker* applies to summary judgment materials. In previous cases, this Court has considered the scope of the First Amendment right of access—even though the case could be decided on common law grounds—to protect the freedoms guaranteed in the Constitution. *Publicker*, 733 F.2d at 1067 ("Although we could rest our decision on a common law right of access [to civil trials], the importance in guaranteeing freedoms at issue here compel us to reach the constitutional

[4] GSK's July 6 Response at 6 n.3.

[5] GSK's July 6 Response at 5-6 n.3.

issues."). It should do so again here, as other Circuits that have considered the issue have done, to ensure that district courts correctly understand—and apply—the correct standard. *See Lugosch*, 435 F.3d at 124 ("Having concluded that the common law presumption of access exists [for summary judgment materials], we may not avoid the question of whether a First Amendment presumption of access also exists, for the Newspapers ask us to impose the higher constitutional burden . . . ."); *accord Rushford*, 846 F.2d at 253.

II. THE DISTRICT COURT'S FAILURE TO RECOGNIZE THE PUBLIC'S RIGHT OF ACCESS TO COURT RECORDS IS REPRESENTATIVE OF COMMON ERRORS MADE BY DISTRICT COURTS IN THIS CIRCUIT

The district court's sealing orders illustrate two common errors that courts in this Circuit have made in violation of the public's rights of access. First, the district court initially sealed the summary judgment exhibits pursuant to a blanket protective order without applying any standard or engaging in an independent assessment as required by the common law and the First Amendment. Second, when assessing whether the summary judgment exhibits should remain under seal, the district court applied the wrong standard, adjudicating the issue on the basis of Federal Rule of Civil Procedure 26(c)'s "good cause" standard that governs *unfiled* discovery, instead of the more stringent common law and constitutional standards for court records, which are set forth below.

"[T]o protect the legitimate public interest in filed materials," this Court should reaffirm that courts have an obligation to protect the public's common law and First Amendment right to court records—that courts may not seal court records unless they have determined that the interest in secrecy outweighs those rights. *Leucadia*, 998 F.2d at 165 (common law); *see also Publicker*, 733 F.2d at 1071 (constitutional).

A. This Court Should Reaffirm the Correct Standards for Applying the Common Law And Constitutional Rights of Access to Court Records

Under both the common law and the First Amendment, "careful factfinding and balancing of competing interests is required before the strong presumption of openness" of court records "can be overcome by the secrecy interests of private litigants." *Leucadia*, 998 F.2d at 167; *see Publicker*, 733 F.2d at 1071 (party seeking secrecy must prove injury with specificity).

The common law right of access can only be overcome by a particularized showing that "disclosure will work a clearly defined and serious injury to the party seeking closure." *Cendant*, 260 F.3d at 194 (citation and internal quotation marks omitted). The party seeking "to seal any part of a judicial record bears the heavy burden of showing that 'the material is the kind of information that courts will protect' . . . ." *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (citing *Publicker*, 733 F.2d at 1071). "[S]pecificity is essential" in articulating the injury

to be prevented, and "[b]road allegations of harm, bereft of specific examples or articulated reasoning, are insufficient." *Cendant*, 260 F.3d at 194.

The constitutional right of access "requires a much higher showing than" the already-demanding common law standard. *Id.* at 198 n. 13 (citing *Publicker*, 733 F.2d at 1070). The First Amendment access right can be overcome "only by an overriding interest based on findings that closure is essential to preserve higher values." *Press-Enter. Co. v. Superior Court of Cal., Riverside Cnty.*, 464 U.S. 501, 510 (1984) ("*Press-Enterprise I*"). The party seeking closure must demonstrate that public access would create a "substantial probability" that a compelling interest will be prejudiced, that no alternatives to closure can sufficiently protect the threatened interest, that the closure is narrowly tailored to serve that interest, and that the closure will be effective in protecting the interest. *Press-Enterprise II*, 478 U.S. at 13-15. Courts cannot deny access "unless specific, on the record findings are made" that closure is essential. *Id*. at 14.

Here, GSK failed to meet its burden under either the common law or First Amendment because, as Appellants show, GSK's conclusory assertions of harm do not present a factual basis—or even an explanation—of *how* disclosure of *specific* documents would prejudice any legitimate interest. *See* Appellants' Br. at 23-51.

B. The District Court Incorrectly Applied Rule 26(c)'s Good Cause Standard, Which Applies to Discovery, not Court Records

The district court failed to apply the correct standards. Instead of applying the common law and First Amendment standards for sealing court records, the court erroneously sealed the summary judgment exhibits on the basis of Federal Rule of Civil Procedure 26(c)'s good cause standard, which governs unfiled discovery materials.

Rule 26(c) grants courts the discretion to issue protective orders that restrict the disclosure of *unfiled discovery* materials when a party seeking confidentiality demonstrates "good cause." Fed. R. Civ. P. 26(c)(1)(G). The good cause standard protects *unfiled* discovery from disclosure because, as the Supreme Court suggested in *Seattle Times Co. v. Rhinehart*, there is no established public right of access to discovery materials that are not filed with the court. 467 U.S. 20 (1984).

However, once discovery documents are filed in court with a substantive motion, they become court records, and courts are required to apply the higher common law and First Amendment standards. *Bank of Am. Nat'l Trust and Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 343-44 (3d Cir. 1986) ("[D]iscovery, . . . which is ordinarily conducted in private, stands on a different footing than does a motion filed by a party seeking action by the court. . . . [T]he court's approval of a settlement or action on a motion are matters which the public has a right to know about and evaluate.").

In fact, in *Pansy v. Borough of Stroudsburg*, the case that lays out the factors for determining whether there is good cause under Rule 26(c) ("*Pansy*" factors), this Court specifically distinguished unfiled discovery materials from court records and made clear that the standard for sealing court records is more rigorous. 23 F.3d 772, 792 n.31 (3d Cir. 1994) (finding that an unfiled settlement agreement was not a court record, and thus the good cause standard applied rather than "the standards we have articulated in our line of cases dealing with access to judicial proceedings and documents").

Other Circuits have similarly found that a showing of good cause is insufficient to justify sealing documents that are submitted for judicial review. *See, e.g.*, *Joy v. North*, 692 F.2d 880, 894 (2d Cir. 1982) (finding that a showing of good cause is "patently inadequate" once discovery documents become "part of a court record"); *accord Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135-36 (9th Cir. 2003); *Poliquin v. Garden Way, Inc.*, 989 F.2d 527, 532-33 (1st Cir. 1993); *Rushford*, 846 F.2d at 252, 254.

GSK incorrectly argued—and the district court accepted—that both Rule 26(c)'s good cause standard and the standard for abrogating the right of access to

court records should apply the same *Pansy* factors, conflating the two standards.[6] When the district court granted GSK's second motion to keep the summary judgment exhibits under seal, it failed to apply the more exacting common law and constitutional right of access standards and instead adopted GSK's erroneous argument that satisfying the *Pansy* factors suffices to deny access to court records.[7]

The district court is not alone in this Circuit in improperly sealing court records on the basis of good cause. In *In re Gabapentin Patent Litigation*,[8] for example, the district court denied a motion to modify a protective order and a motion to unseal summary judgment documents on the same basis that "[j]udicial records are to remain sealed upon such a showing [of good cause,] even if the party seeking access has a First Amendment or common law right to access the materials." 312 F. Supp. 2d 653, 664 (D.N.J. 2004). More recently, in *Mosaid Technologies Inc. v. LSI Corp.*, a magistrate judge applied the good cause standard to support redactions of a summary judgment oral argument transcript. 878 F. Supp. 2d 503, 507-08, 514 (D. Del. 2012). Other district courts have relied on

---

[6] Reply Memorandum in Support of GSK's Second Motion to Preserve Confidentiality at 2-3, *In re Avandia Mktg., Sales Practices, and Prods. Liab. Litig.*, No. 07-md-1871 (E.D. Pa.) (July 16, 2018) (Dkt. No. 5217-1).

[7] *In re Avandia Mktg., Sales Practices, and Prods. Liab. Litig.*, No. 07-md-1871 (E.D. Pa. July 24, 2018) (Dkt. No. 5220, Order), at 1-2 n.1 (applying the *Pansy* factors in the common law right of access analysis).

[8] GSK improperly relies on this case. GSK July 6 Response at 7.

Mosaid to incorrectly hold that a showing of good cause justifies redacting or sealing court records. *See, e.g.*, *Del. Display Grp. LLC v. LG Elecs.*, 221 F. Supp. 3d 495, 496 (D. Del. 2016) (relying on *Mosaid* and *Pansy* and applying good cause to grant in part a party's motion to redact items in court documents); *Eisai v. Sanofi-Aventis*, 2015 WL 1138400, at *2.[9]

Even on appeal, GSK continues to incorrectly rely on the good cause standard to argue that it has met the burden for keeping the exhibits under seal.[10] This Court should reaffirm that a showing under Rule 26(c)'s good cause standard is an insufficient basis to deny the public's common law and constitutional rights of access to court documents.

C. The District Court Erred By Sealing the Summary Judgment Exhibits Pursuant to a Blanket Protective Order

The district court also erred by sealing the summary judgment exhibits in the first place on the basis of a blanket protective order. Courts must "review any request to seal the record (or part of it)" and "may not rubber stamp a stipulation to

---

[9] Other district courts have properly refused to seal court records but have mistakenly applied the *Pansy* factors to do so. *See, e.g.*, *Securimetrics, Inc. v. Iridian Techs., Inc.*, No. 03-cv-04394, 2006 WL 827889, at *2 (D.N.J. Mar. 30, 2006) (applying the good cause standard to deny a motion to seal documents attached to briefing in connection with a motion to amend a pleading).

[10] GSK July 6 Response at 7 (claiming that "the *Pansy* balancing test weighs in favor of maintaining confidentiality of each of the challenged documents").

seal the record." *Citizens First Nat'l Bank of Princeton v. Cincinnati Ins. Co.*, 178 F.3d 943, 945 (7th Cir. 1999).

This Court has mandated that district courts "protect the legitimate public interest in filed materials from overly broad and unjustifiable protective orders." *Leucadia*, 998 F.2d at 165. Blanket protective orders allow the parties themselves to initially designate, in good faith, any discovery material as confidential.[11] *Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1122 (3d Cir. 1986). While blanket protective orders are useful for case management, they "are by nature overinclusive." *Public Citizen v. Liggett Grp., Inc.*, 858 F.2d 775, 790 (1st Cir. 1988).

This Court specifically prohibits district courts from sealing judicial records on the basis of a blanket protective order. *Leucadia*, 998 F.2d at 166. In *Leucadia*, for example, the Court held that even if there is a blanket protective order, the producing party "must make a particularized showing of the need for continued secrecy if the documents are to remain under seal." *Id.* (citations and internal quotation marks omitted).[12]

---

[11] Blanket protective orders are used to facilitate discovery in "virtually every complex case." *Zenith Radio Corp. v. Matsushita Elec. Indus. Co., Ltd.*, 529 F. Supp. 866, 872 (E.D. Pa. 1981).

[12] The Fourth Circuit has similarly held that a court must assess whether summary judgment exhibits should be sealed "at the time it grants a summary

The district court failed to require such a showing. The blanket protective order in this case, which was issued ten years ago in the multidistrict litigation for Avandia, allowed GSK to designate discovery materials as "confidential" without demonstrating good cause to the court.[13] The district court summarily sealed the summary judgment opinion without requiring GSK to meet its burden.[14] After Appellants challenged GSK's assertions of confidentiality, GSK improperly argued that the summary judgment records should remain under seal simply because GSK had designated them as confidential pursuant to the blanket protective order.[15] The district court accepted this argument when it issued a perfunctory order granting GSK's motion to keep the summary judgment exhibits under seal, punting the sealing question in a footnote.[16]

---

judgment motion and [must] not merely allow continued effect to a pretrial discovery protective order." *Rushford*, 846 F.2d at 253.

[13] *In re Avandia Mktg., Sales Practices, and Prods. Liab. Litig.*, No. 07-md-1871 (E.D. Pa. June 11, 2008) (Dkt. No. 138, Pretrial Order No. 10), at 2.

[14] *In re Avandia Mktg., Sales Practices, and Prods. Liab. Litig.*, No. 07-md-1871 (E.D. Pa. Dec. 7, 2017) (Dkt. No. 5154, Order).

[15] Memorandum in Support of the Motion of GSK to Preserve Confidentiality at 4, *In re Avandia Mktg., Sales Practices, and Prods. Liab. Litig.*, No. 07-md-1871 (E.D. Pa.) (May 4, 2018) (Dkt. No. 5192).

[16] *In re Avandia Mktg., Sales Practices, and Prods. Liab. Litig.*, No. 07-md-1871 (E.D. Pa. May 31, 2018) (Dkt. No. 5201, Order). The court did properly unseal its summary judgment opinion.

The district court failed to engage in any independent assessment of whether GSK had met the standards for sealing court records. *See Publicker*, 733 F.2d at 1074 (finding that the district court failed both to make specific findings demonstrating an interest in sealing and to consider less restrictive means of maintaining confidentiality, and that such "errors alone constitute an abuse of discretion"). The district court did not engage in "careful factfinding," as required by the common law. *Leucadia*, 998 F.2d at 167. Nor did it make "specific, on the record findings," as required by the First Amendment. *Press-Enterprise II*, 478 U.S. at 13-14. GSK's unilateral designations of confidentiality pursuant to a blanket protective order cannot substitute for a court's assessment of whether the documents should be sealed once they are filed as part of summary judgment proceedings. *See Leucadia*, 998 F.2d at 166.

The district court's reliance on the blanket protective order and failure to engage in a document-by-document assessment are particularly egregious given that blanket protective orders do not meet even the less rigorous good cause standard that governs discovery. *Cipollone v. Liggett Grp., Inc.*, 822 F.2d 335, 343 (3d Cir. 1987) (affirming a district court's conclusion that the convenience of facilitating discovery provided by a blanket protective order "is not sufficient 'good cause' under Rule 26(c)" (quoting *Cipollone v. Liggett Grp., Inc.*, 113 F.R.D. 86, 92-92 (D.N.J. 1986)); *see also Pansy*, 23 F.3d at 786-87 (holding that,

under Rule 26(c), the party invoking confidentiality bears the burden of "justifying the confidentiality of each and every document sought to be covered by [the] protective order").

This Court should reiterate that blanket protective orders are insufficient grounds for sealing court records—even when parties stipulate to the issuance of such an order.

III. THERE IS A PARTICULARLY STRONG PUBLIC INTEREST IN ACCESS TO COURT RECORDS WHERE PUBLIC HEALTH AND SAFETY ARE IMPLICATED

Even if a compelling need for confidentiality has been established (and GSK has shown none), courts cannot properly deny access to judicial records without considering "the public's interest in disclosure." *LEAP Sys., Inc. v. MoneyTrax, Inc.*, 638 F.3d 216, 222 (3d Cir. 2011) ("Having found LEAP's privacy interest significant, we now turn to the public's interest in disclosure."); *see also Westinghouse*, 949 F.2d at 663 ("turn[ing] to the public interest issue" after considering whether there was a countervailing interest in confidentiality). Here, there is a strong public interest in disclosure because the summary judgment exhibits contain information that implicates "public health and safety." *Westinghouse*, 949 F.2d at 664.

Courts have repeatedly held that the public interest in disclosure is particularly strong where court records concern public health and safety. *See, e.g.*,

In re Air Crash at Lexington, Ky., Aug. 27, 2006, No. 5:06-cv-316, 2009 WL 1683629, at *8 (E.D. Ky. June 16, 2009) (denying motion to amend a protective order to defeat public access because "the public interest in a plane crash that resulted in the deaths of forty-nine people is quite strong, as is the public interest in air safety"); *United States v. Gen. Motors Corp.*, 99 F.R.D. 610, 612 (D.D.C. 1983) (granting motion to unseal summary judgment records after noting that the case, which involved a defect in a vehicle braking mechanism, was of undisputed "public significance"). "[A]ccess to judicial records" in cases like this "promotes public health and safety by not allowing secrets hidden in court records to be shielded from public view." *Westinghouse*, 949 F.2d at 664; *cf. LEAP v. MoneyTrax*, 638 F.3d at 222 (approving the district court's weighing of "the public's interest in disclosure" and finding the interest "minimal" because the "dispute ha[d] no impact on the safety and health of the public").

"[C]ommon sense tells us that the greater the motivation a corporation has to shield its operations, the greater the public's need to know." *Brown & Williamson Tobacco Corp. v. Fed. Trade Comm'n*, 710 F.2d 1165, 1180 (6th Cir. 1983). In *Brown & Williamson*, the Sixth Circuit vacated a district court order sealing court records containing information on the testing and reporting of cigarette ingredients. *Id.* at 1180-81. The court emphasized that the court records, which documented flawed methodologies and inaccurate claims of reduced tar and nicotine levels,

"potentially involve[] the health of citizens." *Id*. at 1180. The public has a strong interest, the court held, in scrutinizing certain "inaccuracies and the possible errors" in testing tar and nicotine content, *id*. at 1776, and "in knowing how the government agency has responded to allegations of error in the testing program," *id*. at 1181.

Here, the public has a strong interest in the summary judgment records, which contain clinical, marketing, and regulatory information on a controversial drug with lingering uncertainties about its safety risks. Avandia has been the subject of intense scrutiny ever since 2007, when independent researchers alerted the public and regulators to the potential cardiovascular risks of the drug, including heart attack and death.[17] A few months after this independent study was published, the FDA added a "black-box" warning—the strictest level of warning—to Avandia's prescribing information, and for several years the FDA imposed restrictions on Avandia's use.[18] While Avandia is no longer sold in the European

[17] Steven E. Nissen & Kathy Wolski, *Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes*, 356 New Eng. J. Med. 2457, 2459 (2007).

[18] Thomas M. Burton, *FDA Removes Marketing Limits on Diabetes Drug Avandia*, Wall St. J., Nov. 25, 2013.

Union,[19] it remains on the market in the U.S. with a black box warning, although the restrictions on its use were lifted in 2015.[20]

As regulators and researchers attempted to answer clinical questions about Avandia's safety and efficacy, GSK admitted to misleading physicians about the risks and benefits of Avandia and to violating its statutory duty to report data to the FDA.[21] The summary judgment exhibits in this case contain data from early clinical studies that GSK sponsored and relied on to get regulatory approval for Avandia and to promote the drug to doctors. These documents would inform patients, physicians, and researchers about GSK's efforts to market Avandia and how it framed published research findings to omit or misrepresent the risk of heart attacks and strokes. GSK has made summaries of a *subset* of its clinical study

---

[19] European Medicines Agency, *European Medicines Agency Recommends Suspension of Avandia, Avandamet and Avaglim* (Sep. 23, 2010), https://www.ema.europa.eu/news/european-medicines-agency-recommends-suspension-avandia-avandamet-avaglim (last visited Nov. 3, 2018).

[20] U.S. Food and Drug Administration, *Avandia (Rosiglitazone Maleate) Supplement Approval* (Dec. 16, 2015), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021071Orig1s050,021410Orig1s039,021700Orig1s022ltr.pdf (last visited Nov. 3, 2018).

[21] Dep't of Justice, *GSK Pleads Guilty and Pays $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (Jul. 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report (last visited Nov. 3, 2018).

reports for Avandia available to the public,[22] but access to all of the complete clinical study reports sealed by the trial court would increase researchers' ability to evaluate accurately Avandia's risks and benefits.[23] Access to this information will allow the public to understand the extent of GSK's misconduct and to examine whether GSK might still be using misleading or fraudulent tactics. This has implications beyond the evaluation and promotion of Avandia, encompassing the large portfolio of products that are manufactured, tested, and marketed by GSK.

---

[22] GlaxoSmithKline, LLC, ClinicalStudyDataRequest.com, https://clinicalstudydatarequest.com (last visited Nov. 3, 2018).

[23] Systematic reviews and meta-analyses, which pool together data across multiple clinical trials, often form the basis of clinical practice guidelines, which are used by physicians to make treatment decisions and have wide-ranging impact on healthcare costs. However, when researchers cannot identify or do not have access to data from all relevant studies, the reviews are incomplete and potentially biased. Access to data from clinical study reports from trials of other products, including rofecoxib (anti-inflammatory drug), oseltamivir (anti-viral), and reboxetine (antidepressant) as examples, has contributed to more complete systematic reviews of these drugs and has proven critical to advancing the public health's interest. *See, e.g.*, Joseph S. Ross et al., *Pooled Analysis of Rofecoxib Placebo-Controlled Clinical Trial Data: Lessons for Postmarket Pharmaceutical Safety Surveillance*, 169 Archives Internal Med. 1976 (2009) (rofecoxib); Tom Jefferson et al., *Oseltamivir for influenza in adults and children: systematic review of clinical study reports and summary of regulatory comments*, 348 Brit. Med. J. g2545 (2014) (oseltamivir); Dirk Eyding et al., *Reboxetine for acute treatment of major depression: systematic review and meta-analysis of published and unpublished placebo and selective serotonin reuptake inhibitor controlled trials*, 341 Brit. Med. J. c4737 (2010) (reboxetine).

This Court should recognize that even if there are countervailing interests in confidentiality, the public's strong interest in obtaining information of this nature sets an even higher bar for sealing. This will help to ensure that corporate misconduct cannot continue while documentation of past misconduct remains sealed.

CONCLUSION

Amici curiae request that this Court hold in favor of Appellants that the public has a right to access the summary judgment documents at issue under both the common law and the First Amendment, vacate the district court's judgments, and unseal the documents at issue.

Dated: November 5, 2018

Respectfully submitted,

/s/ Christopher J. Morten

Jennifer D. Bennett
PUBLIC JUSTICE, P.C.
475 14th Street, Suite 610
Oakland, CA 94612
Tel: (510) 622-8150
jbennett@publicjustice.net

Christopher J. Morten
(NY State Bar No. 5428107)
Counsel of Record
David A. Schulz
MEDIA FREEDOM AND INFORMATION ACCESS CLINIC
ABRAMS INSTITUTE FOR FREEDOM OF EXPRESSION
Yale Law School
New Haven, CT 06511
Tel: (203) 432-4992
christopher.morten@yale.edu
david.schulz@yale.edu

Jeanie Kim
Cortelyou Kenney
Elizabeth Gilbert, Law Student Intern
COLLABORATION FOR RESEARCH INTEGRITY AND TRANSPARENCY
Yale Law School
157 Church Street 17th Floor
New Haven, CT 06510
jeanie.kim@yale.edu
cortelyou.kenney@yale.edu

CERTIFICATE OF BAR ADMISSION

I certify pursuant to Local Rule 28.3(d) that I am a member in good standing of the Bar of the United States Court of Appeals for the Third Circuit.

November 5, 2018

/s/ *Christopher J. Morten*
Christopher J. Morten
Yale Law School
New Haven, CT 06511
Tel: (203) 432-4992
christopher.morten@yale.edu

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a) AND LOCAL RULE 31.1

Pursuant to Fed. R. App. P. 32, I certify the following:

This brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because this brief contains 6,389 words, excluding the parts of the brief exempted by Rule 32(f) of the Federal Rules of Appellate Procedure.

This brief complies with the typeface requirements of Rule 32(a)(5) of the Federal Rules of Appellate Procedure and the type style requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedure because this brief has been prepared in a proportionally spaced typeface using the 2008 version of Microsoft Word in 14 point Times New Roman font.

This brief complies with the electronic filing requirements of Local Rule 31.1(c) because the text of this electronic brief is identical to the text of the paper copies, and the Vipre Virus Protection, version 3.1 has been run on the file containing the electronic version of this brief and no viruses have been detected.

Dated: November 5, 2018

/s/ *Christopher J. Morten*
Christopher J. Morten

CERTIFICATE OF SERVICE

I certify that on November 5, 2018, I electronically filed via CM/ECF a true and correct copy of the foregoing BRIEF OF AMICI CURIAE COLLABORATION FOR RESEARCH INTEGRITY AND TRANSPARENCY AND PUBLIC JUSTICE IN SUPPORT OF APPELLANTS. Counsel for all parties are registered to use CM/ECF and to receive service by CM/ECF. A copy of the brief was thereby served on all parties. Pursuant to Local Rule 25.1, ten (10) paper copies will be filed with the Clerk for the convenience of the Court.

November 5, 2018

/s/ *Christopher J. Morten*
Christopher J. Morten
Yale Law School
New Haven, CT 06511
Tel: (203) 432-4992
christopher.morten@yale.edu