No. 21-10305

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ARTHUR CARTEE,
Plaintiff-Appellant,

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., PFIZER, INC., and GLAXOSMITHKLINE LLC,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of Florida

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN, INC. IN SUPPORT OF APPELLANT AND REVERSAL

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April 5, 2021

CARTEE v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., No. 21-10305

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Rule 26.1-2, amicus curiae Public Citizen provides the following list of the persons and entities that have or may have an interest in the outcome of this case and have not been identified in the earlier-filed briefs:

- Nelson, Scott L. – counsel for Amicus Curiae
- Public Citizen, Inc. – Amicus Curiae
- Public Citizen Litigation Group – law firm for Amicus Curiae
- Zieve, Allison M. – counsel for Amicus Curiae

Pursuant to Federal Rule of Appellate Procedure 26.1, the undersigned counsel certifies that amicus curiae Public Citizen is a nonprofit, non-stock corporation. It has no parent corporations, and no publicly traded corporations have an ownership interest in it.

/s/ Allison M. Zieve
Allison M. Zieve

Attorney for Public Citizen

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INTEREST OF AMICUS CURIAE[1]

Public Citizen is a non-profit consumer advocacy organization with members and supporters in every state, including Illinois. Since its founding in 1971, Public Citizen has assessed the safety and efficacy of drugs, provided information on drug safety to the public, and advocated before the Food and Drug Administration (FDA) for product labeling and regulation to reduce safety risks. In June 2013, a Public Citizen report compiled a list of drugs for which black-box warnings—the most serious contraindications and warnings—were added after a generic equivalent entered the market. Looking at a five-year period, the report identified 53 drugs for which a black-box warning calling attention to serious or life-threatening risks was added after generic market entry. The data underscore the public-health imperative of requiring pharmaceutical companies to maintain active surveillance of safety, even after a drug is also marketed in generic form.[2]

Public Citizen has participated as an amicus in many cases brought by patients injured by drugs that carried inadequate warnings, including *PLIVA, Inc. v. Mensing*,

[1] No party's counsel authored this brief in whole or in part, and no party or party's counsel made a monetary contribution specifically intended to fund the preparation or submission of this brief. No person or entity other than amicus curiae made such a monetary contribution. All parties have consented to the filing of this brief.

[2] The report is available at www.citizen.org/documents/2138.pdf.

564 U.S. 604 (2011), and *T.H. v. Novartis*, 407 P.3d 18 (Cal. 2017). In *PLIVA*, the U. S. Supreme Court held that federal law preempts failure-to-warn claims against generic drug manufacturers because FDA regulations prohibit generic manufacturers from updating labeling except to mimic brand-name labeling changes or as ordered by the FDA. Public Citizen responded by petitioning the FDA to allow generic drug manufacturers to revise product labeling through the procedures already available to brand-name manufacturers. In November 2013, the FDA announced that, to advance product safety, it would grant Public Citizen's petition in part by issuing a proposed rule. *See* 78 Fed. Reg. 67985 (2013). Following significant industry pressure, however, the FDA eventually withdrew the proposed rule. *See* 83 Fed. Reg. 64299 (2018). Consequently, at this time, generic drug manufacturers, unlike brand-name manufacturers, cannot initiate safety updates to product labeling. Patients and physicians therefore depend on brand-name manufacturers to provide adequate warnings for both brand-name and generic drugs. Allowing patients to pursue tort claims against brand-name manufacturers for injuries caused by inadequate warnings is important both as an incentive for those manufacturers to be vigilant about product safety and as a means to hold them accountable to patients. For this reason, this case has important implications that go well beyond the interests of the parties.

INTRODUCTION AND SUMMARY OF ARGUMENT

The issue presented in this case—whether a brand-name drug manufacturer can be held liable for injuries caused by inadequately labeled generic drugs—is of significant and growing importance to patients. Following passage of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Amendments, sales of generic drugs have grown dramatically, fundamentally reshaping the pharmaceutical market. The increased availability of generic drugs has made many prescription drugs more affordable for patients. In 1983, only 35 percent of top-selling drugs with expired patents had generic equivalents; by 1998, nearly all did.[3] And when generics compete, they typically capture a significant share of the market and of profits.[4] In 2010, generics captured more than 80 percent of the market within six months of expiration of a brand-name's patent (as compared to 55 percent in 2006).[5] As of 2016, 89 percent of drug prescriptions were filled with generics rather than brand-

[3] Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at xii (1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

[4] *See* Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, at 16–17 (2006), https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf.

[5] Katherine Hobson, *What Drug Did Doctors Prescribe Most Last Year?*, Wall St. J.: Health Blog, Apr. 19, 2011.

name drugs[6]—a development spurred by state laws authorizing pharmacists to substitute generic drugs when filling prescriptions.[7] Many states have gone further and now mandate generic substitution where available.[8]

Despite these market changes, the law places responsibility for labeling firmly on brand-name manufacturers. Generic drug manufacturers cannot initiate labeling updates; the labeling of generic drugs must mirror that of the brand-name products. Thus, the regulatory scheme assumes a patient's reliance on the brand-name labeling, regardless of whether the patient took the branded or the generic version of the drug. In light of this unusual fact—that one manufacturer is required to copy the safety information provided by another—patients should be able to hold brand-name drug manufacturers accountable for injuries resulting from misrepresentations about the safety of their drugs, even if those injuries are caused by a generic version of the drug. As discussed below, allowing patients to do so makes sense under traditional tort law principles and as a matter of policy.

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[6] Ass'n for Accessible Medicines, *Generic Drug Access & Savings in the U.S.*, at 16 (2017), https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.

[7] *See* Thomas P. Christensen, et al., *Drug Product Selection: Legal Issues*, 41 J. Am. Pharm. Ass'n 868 (2001).

[8] William H. Shrank, et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 Health Affairs 1383 (July 2010).

ARGUMENT

I. Safety concerns often do not come to light until years after a drug first comes on the market, and only brand-name manufacturers can promptly update labeling in light of newly discovered risks.

Before a manufacturer can market a drug in the United States, it must obtain FDA marketing approval. 21 U.S.C. § 355. Although the FDA evaluates the drug's safety and effectiveness for its intended use before granting approval, the importance of post-approval monitoring for ensuring drug safety is well-recognized. As an article in the *Journal of the American Medical Association* explained:

> Even though the evaluation of new drugs and devices is technically rigorous, the current approach of basing drug approval decisions on clinical trials of efficacy that include relatively small numbers of patients virtually guarantees that the full risks and complete safety profile of these drugs will not be identified at the time of approval. Rather, the full safety profile and effectiveness only manifest as each drug is used in the wider population of patients who are less carefully selected than participants in clinical trials.[9]

The limitations in pre-approval testing are especially salient when a drug's significant adverse effects are relatively rare or have long latency periods—forms of risk that the FDA approval process is not designed to uncover. Examples of drugs whose substantial risks were only discovered post-approval abound in the medical

[9] Catherine D. DeAngelis & Phil B. Fontanarosa, *Prescription Drugs, Products Liability, and Preemption of Tort Litigation*, 300 J. Am. Med. Ass'n 1939, 1939 (2008).

literature.[10] A 2013 article authored jointly by three FDA staff members and two academics reported that "[t]he most critical safety-related label changes, boxed warnings and contraindications, occurred a median 10 and 13 years after drug approval (and the range spanned from 2 to 63 years after approval)."[11] This conclusion is consistent with an earlier study's finding that "[o]nly half of newly discovered serious [adverse drug reactions] are detected and documented in the *Physicians' Desk Reference* within 7 years after drug approval."[12]

Because safety risks are commonly not identified until years after a drug comes on the market, and even after generic versions of the drug come on the market, ongoing monitoring and labeling updates are crucial for safe use of medications. Yet as the Supreme Court recognized in *Wyeth v. Levine*, 555 U.S. 555 (2009), "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." *Id*. at 578–79 (footnote omitted). It has therefore been "a central premise of federal drug regulation that the manufacturer

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[10] *See*, *e.g.*, Brief of the Am. Med. Ass'n et al. as Amici Curiae Supporting Resp'ts, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), 2011 WL 794118, at 12–17 (discussing examples of fenfluramine, propoxyphene, ibuprofen, terbutaline sulfate, and metoclopramide).

[11] Jean Lester, et al., *Evaluation of FDA safety-related drug label changes in 2010*, 22 Pharmacoepidemiology and Drug Safety 302, 304 (2013).

[12] Karen E. Lasser, et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J. Am. Med. Ass'n 2215, 2218 (2002).

bears responsibility for the content of its label at all times … [and for] ensuring that its warnings remain adequate as long as the drug is on the market." *Id*. at 570–71. The need for manufacturers to play a significant role is heightened by funding and staff shortages at the FDA that have prompted the Government Accountability Office (GAO) repeatedly to express concern about post-approval drug safety monitoring.[13]

To ensure the post-approval safety of their drugs, manufacturers must "promptly review all adverse drug experience information obtained or otherwise received by the [manufacturer] from any source, foreign or domestic, including information derived from commercial marketing experience, post-marketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the

[13] *See*, *e.g.*, GAO, *High-Risk Series: An Update*, at 271 (Feb. 2015), http://www.gao.gov/assets/670/668415.pdf (expressing concern that FDA lacks resources to adequately inspect drug manufacturing facilities); GAO, *High-Risk Series: An Update*, at 116–17 (Feb. 2011), https://www.gao.gov/assets/files.gao.gov/assets/gao-11-278.pdf ("FDA staff have expressed concern about their ability to meet a growing postmarket workload, with some maintaining that their premarket responsibilities are considered a higher priority."); GAO, *Drug Safety: FDA Has Begun Efforts to Enhance Postmarket Safety, But Additional Actions Are Needed* (Nov. 2009), http://www.gao.gov/assets/300/298135.pdf; GAO, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* (Mar. 2006), https://www.gao.gov/assets/gao-06-402.pdf; *see also* David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461, 485 (2008) (noting that "[r]esource constraints have been especially acute with the agency's post-marketing surveillance efforts" and that two-thirds of FDA doctors and scientists "worry that the FDA is not adequately monitoring the safety of drugs once they are on the market").

scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b). To ensure that labeling is kept up to date as information accumulates, FDA regulations require that the labeling of both brand-name and generic drugs "must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." *Id.* § 201.57(c)(6)(i) (implementing 21 U.S.C. § 352(f)(2), which provides that a drug that lacks "adequate warnings" is misbranded). At the same time, FDA restrictions on the ability of generic manufacturers to make such revisions largely absolve those manufacturers of responsibility for labeling updates and reinforce the brand-name manufacturers' responsibility.

More specifically, brand-name manufacturers, who market drugs approved through the new drug application (NDA) process, may seek review and approval of revised labeling by filing a supplemental application. 21 C.F.R. § 314.70. A supplemental application must satisfy all regulatory requirements that apply to original applications. *See id.* § 314.71(b). Although some label changes require prior FDA approval—obtained through a "prior approval supplement," *id.* § 314.70(b)—other changes are brought to the FDA's attention at the time the applicant makes the change through a "changes being effected" (CBE) supplement, *id.* § 314.70(c). CBE supplements are authorized for, among other things, "[c]hanges in the labeling to

reflect newly acquired information … [t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which" there is reasonable evidence of a causal association. *Id*. § 314.70(c)(6)(iii)(A).

Generic manufacturers, however, have neither the power nor the responsibility to provide new safety updates. The United States Supreme Court, deferring to the FDA's interpretation of the existing regulation, has held that the CBE process is not available to generic manufacturers. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 614–15 (2011). Instead, in most cases, generic drug manufacturers can make safety updates only after approval of a CBE supplement submitted by the brand-name manufacturer for that product or when ordered to by the FDA.[14] This restriction follows from the general rule that the labeling of the generic product must be "the same as the labeling of" the corresponding brand-name drug. 21 C.F.R. § 314.94(a)(8)(iii); *see also id*. § 314.105(c). As a result, brand-name manufacturers—and only brand-name manufacturers—have the responsibility for updating labeling to provide adequate warnings, even after generic versions of the brand-name drug are on the market.

[14] FDA, *Guidance for Industry, Revising ANDA Labeling Following Revision of the RLD Labeling*, at 5 (May 2000), https://www.fda.gov/media/71488/download; *see also* FDA, *Draft Guidance, Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn* (July 2016), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510240.pdf.

II. Brand-name manufacturers can easily foresee that physicians and patients will rely on the brand-name labeling, regardless of whether a patient's prescription is filled with a generic drug.

As explained above, current FDA regulations allow the brand-name company to make safety updates without prior FDA approval, but prohibit the generic company from making safety updates except to mimic the brand-name labeling update or as instructed by the FDA. *See* 78 Fed. Reg. 67985, 67988 (2013). Indeed, the brand-name manufacturer, *even after generics come on the market*, has an "ongoing obligation to ensure [its] labeling is accurate and up-to-date," *id*. at 67987, while the generic manufacturer's obligation is only to ensure that its labeling matches the brand-name labeling, *id*. at 67988. Amicus Public Citizen has advocated that this system should be changed to allow generic companies to initiate safety updates. However, as the regulatory scheme currently exists, the responsibility for safety labeling remains squarely with the brand-name manufacturer. For this reason, a patient's (and physician's) reliance on the brand-name labeling is not only foreseeable—whether the patient takes the brand-name or the generic form of the drug—it is inevitable and expected. And in light of the brand-name manufacturer's responsibility for maintaining the adequacy of the drug's labeling, it is not surprising that patients who suffered injury after taking a generic drug that had inadequate safety warnings have sometimes sought to hold the brand-name manufacturer accountable.

Whether alleged in the form of a strict products liability claim or, as here, a negligence claim, a failure to warn of known risks that foreseeably leads to physical harms is the essence of a long-recognized tort. Thus, the Restatement (Third) of Torts § 18(a) (2010), provides that a defendant may fail to exercise reasonable care by failing to warn of a risk if "(1) the defendant knows or has reason to know: (a) of that risk; and (b) that those encountering the risk will be unaware of it; and (2) a warning might be effective in reducing the risk of harm." And the Restatement (Second) of Torts § 311(1)(b) (1965), explained that "one who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results … *to such third persons as the actor should expect to be put in peril by the action taken*" (emphasis added). The Restatement (Second) further explained that "the liability of one who is under a public duty to give the information extends to loss suffered by any of the class of persons for whose benefit the duty is created, in any of the transactions in which it is intended to protect them." Restatement (Second) of Torts § 552(3) (1977). This rule "may apply to private individuals or corporations who are required by law to file information for the benefit of the public." *Id*., comment to subsection (3).

Brand-name drug manufacturers are subject to just such a requirement: FDA regulations require that drug "labeling must be revised to include a warning about a

clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.57(c)(6)(i). Thus, traditional principles of tort law provide strong support for Appellant's position.

The issue of tort liability for the brand-name manufacturer's failure to warn is, of course, one of state law, and six state supreme courts have authoritatively addressed the issue under the laws of their states. Four have recognized a claim against brand-name manufacturers, and two have rejected the claim. In *T.H. v. Novartis*, 407 P.3d 18 (Cal. 2017), for example, the California Supreme Court held that, "[b]ecause the same warning label must appear on the brand-name drug as well as its generic bioequivalent, a brand-name drug manufacturer owes a duty of reasonable care in ensuring that the label includes appropriate warnings, regardless of whether the end user has been dispensed the brand-name drug or its generic bioequivalent." *Id*. at 22. Likewise, in *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014), the Supreme Court of Alabama rejected the notion that a misrepresentation claim requires privity between the parties, and held that the brand-name manufacturer could be held liable in an action brought by a patient who was injured by the generic version of its drug. *Id*. at 670, 675; *see id*. at 674 (noting that "Wyeth's argument completely ignores the nature of prescription medication").[15] *See also*

[15] After intense lobbying by the pharmaceutical industry, the State of Alabama later enacted a statute superseding that decision, *see* Ala. Code § 6-5-530 (2015).

Rafferty v. Merck & Co., 479 Mass. 141, 157 (2018) (disallowing negligence claims but holding "that a brand-name manufacturer that controls the contents of the label on a generic drug owes a duty to consumers of that generic drug not to act in reckless disregard of an unreasonable risk of death or grave bodily injury"); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010) (holding that brand-name manufacturer can be held liable for injury caused by generic drug under Vermont law because manufacturer owes duty of care to patients who ingest generic equivalent). In *Huck v. Wyeth, Inc*., 850 N.W.2d 353, 369, 371 (Iowa 2014), and *McNair v. Johnson & Johnson*, 241 W. Va. 26, 37 (2018), however, the courts held that a patient's failure-to-warn claim was a products liability claim under state law, and that under Iowa and West Virginia law, respectively, products liability claims may be brought only against the product seller or supplier.

Although the state supreme courts have reached different results in different states, Mr. Cartee's negligent failure-to-warn claim fits comfortably within the scope of Illinois law in light of the regulatory scheme: He alleged "facts that establish the existence of a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach." *Simpkins v. CSX Transp., Inc*., 965 N.E.2d 1092, 1096 (Ill. 2012); *see* Appellant's Br. 39 (citing additional Illinois cases). In considering the legal question whether a duty existed, in light of the regulatory scheme, "the foreseeability of Plaintiff's injury as a result of such

negligence should not be controversial." *Dolin v. SmithKline Beecham Corp*., 62 F. Supp. 3d 705, 714 (N.D. Ill. 2014) (recognizing a duty of ordinary care under Illinois law), *rev'd on other grounds sub nom*. *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803 (7th Cir. 2018). Indeed, it is beyond dispute that "[a] brand-name manufacturer could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug." *Weeks*, 159 So. 3d at 670. The foreseeability of harm caused by a defendant's failure to warn is the essence of an Illinois state-law failure-to-warn claim. Accordingly, a brand-name manufacturer can be held liable for negligent failure to warn under Illinois law.

III. Defendants-Appellees' position, if adopted, would put patients at risk.

As the Supreme Court has recognized, state-law remedies further consumer protection and patient health "by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Wyeth v. Levine*, 555 U.S. at 574. Yet, as the FDA has recognized, federal law currently gives generic drug manufacturers little incentive to comply with current requirements to conduct robust postmarketing surveillance, evaluation, and reporting, and even less ability to ensure that the labeling for their drugs is accurate and up to date. *See* 78 Fed. Reg. at 67988–89. Currently, "[f]ederal law explicitly conveys to the brand-name manufacturer—*and only that manufacturer*—the responsibility to provide an adequate warning label

for both [a] generic [drug] and its brand-name equivalent." *T.H. v. Novartis*, 407 P.3d at 22 (emphasis added). Under the current regulatory scheme, only the brand-name manufacturer can ensure that adequate warnings are provided.

For this reason, the brand-name manufacturers' plea to be exempt from accountability for labeling for which they are responsible would, if accepted, exacerbate a dangerous safety gap. "[M]ost critical safety-related label changes" are made years after the drug's initial approval, "underscoring the importance of persistent and vigilant postmarket drug safety surveillance." Jean Lester, *Evaluation of FDA safety-related drug label changes in 2010*, *supra* note 11, at 304. And the majority of labeling changes are initiated by the brand-name manufacturers, not the FDA. *Id*. at 303. Because critical safety information may come to light after entry of the generic onto the market, and because the generic manufacturer is limited to mimicking the brand-name labeling, if the brand-name manufacturer does not continue actively to monitor and propose safety updates, patients are at risk.

Courts that have rejected recognition of a state-law failure-to-warn or negligence claim in this context have failed to appreciate the unique elements of drug regulation—such as the requirement that generics use the brand-name labeling, the bar against generic manufacturers updating labeling except in response to a brand-name update or FDA order (and, on the flip side, the brand-name manufacturers' ability to update safety warnings promptly, without prior FDA

approval), and state substitution laws permitting or requiring pharmacists to fill prescriptions with generic versions where available, unless the physician specifically indicates the need for the brand-name product. *See*, *e.g.*, 225 Ill. Comp. Stat. 85/25.

The regulatory scheme is critical to consideration of the issue presented here. And the regulatory scheme supports Mr. Cartee. As explained in *Wyeth v. Levine*:

> State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that *manufacturers*, not the FDA, *bear primary responsibility for their drug labeling at all times*.

555 U.S. at 579 (emphasis added). State-law remedies thus "further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id*. at 574. The brand-name manufacturers' position would leave no manufacturer accountable for failure to warn of hazards, thus eliminating a crucial bulwark against unsafe pharmaceuticals in the marketplace.

CONCLUSION

The decision below should be reversed.

Dated: April 5, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), I certify that the foregoing brief is proportionately spaced, has a typeface of 14 points, and as calculated by my word processing software (Microsoft Word), contains 3,834 words, less than half the number of words permitted by the Court for the parties' briefs. The electronic version of the foregoing brief has been scanned for viruses and is virus-free according to the anti-virus program.

/s/ Allison M. Zieve
Allison M. Zieve

CERTIFICATE OF SERVICE

I hereby certify that this brief has been served through the Court's ECF system on counsel for all parties required to be served on April 5, 2021.

/s/
Allison M. Zieve