EXHIBIT A

2019 WL 2605789
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UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

UNPUBLISHED
Court of Appeals of Michigan.

Morris DAVIS, Emmy Gillen, Joshua Markowski, Lindsay Matthews, Gabriella Pagan, Laura Rayson, Shannon Smith, Neil Meddaugh, Stephan Barber, Devin Brown, Dominique Harrison, Georgia Hornbrook, Tiffany Humphries, Timothy Jackson, Thomas Lockett, Anthony Magahee, Mark Miller, Aretha Ware, Shareta Watson, Latice Willis, Adam Young, and Emeka Agu, also known as Emeka Egu, Plaintiffs-Appellants,
v.
BOYDELL DEVELOPMENT CO., INC., Dennis Kefallinos, also known as Dionysios Keffalinos, Fort Rosa Properties, LLC, Iron Street Properties, LLC, Grand Lofts, LLC, Lafayette Lofts, Inc., and Woodward Building Plaza, Inc., Defendants-Appellees.
Michael Byrd, Mark Camaj, Norma Dickerson, Danielle Hargo, Chryssa Hunlock, Richard Jordan, Kevin Riedel, Kimberly Fisher, Twoquala Stevens, Kennard Goforth, Dionne McKissack, Jennee Pippen, and Bennie Scott, Jr., Plaintiffs-Appellants,
v.
Boydell Development Co., Inc., Dennis Kefallinos, also known as Dionysios Keffalinos, Boydell Building, LLC, Boydell Company, Inc., Woodward Building Plaza, Inc., Grand Lofts, LLC, Iron Street Properties, LLC, Grand Holdings, LLC, Fort Rosa Properties, LLC, and Lafayette Lofts, Inc., Defendants-Appellees.
Charles Alongi, Namir Armstrong, William Barksdale, Randi Brandt, Duane Croons, Kenneth Green, Robert Howinski, Nico Krohn, Brandon Patton, Shanee Landfair, Lawrence Martin, Christopher Ratcliff, Jeffrey Richardson, Brenda Shelton, Angela Thornton, Daryl Thornton, Bogdan Vespan, Edwanna White, and Edith Woolen, Plaintiffs-Appellants,
v.
Boydell Development Co., Inc., Dennis Kefallinos, also known as Dionysios Keffalinos, Boydell Building, Inc., Boydell Company, Inc., Woodward Building Plaza, Inc., Grand Lofts, LLC, Iron Street Properties, LLC, Grand Holdings, LLC, Fort Rosa Properties, LLC, and Lafayette Lofts, Inc., Defendants-Appellees.

No. 344284, No. 344729, No. 344731
|
June 25, 2019

Wayne Circuit Court, LC No. 16-011635-CZ, 16-015807-CZ, 17-005162-CZ

Before: Sawyer, P.J., and O'Brien and Letica, JJ.

Opinion

Per Curiam.

*1 In Docket Nos. 344284, 344729, and 344731, plaintiffs [1] appeal by leave granted [2] the trial court's order granting summary disposition to defendants. [3] On appeal, plaintiffs argue that the trial court erred by granting summary disposition to defendants because the trial court erroneously held that the Michigan Consumer Protection Act (MCPA), MCL 445.901 *et seq.*, barred plaintiffs' claims. Plaintiffs also argue that the trial court erred by failing to give plaintiffs an opportunity to amend their complaints after it granted summary disposition to defendants under MCR 2.116(C)(8). We affirm.

Plaintiffs were tenants and former tenants in defendants' residential rental buildings located in Detroit, Michigan beginning in 1997. Plaintiffs allege that defendants violated the MCPA by fraudulently entering into residential leases with plaintiffs without obtaining certificates of compliance that would permit them to do so. Docket Nos. 344284, 344729, and 344731 were consolidated at the trial court level and defendants moved for summary disposition under MCR 2.116(C)(8) and (C)(10) on the ground that the MCPA did not apply. Plaintiffs responded and argued that the MCPA did apply and that if the trial court granted summary disposition to defendants it should also permit plaintiffs to amend their complaints. The trial court granted summary disposition to

defendants under MCR 2.116(C)(8) and refused to consider plaintiffs' request to amend their complaints because plaintiffs failed to file a written motion to amend and proposed amended complaints. This appeal followed.

Plaintiffs first argue that the MCPA applies to their residential leases with defendants. We disagree.

A trial court's summary disposition ruling is reviewed de novo. *Walters v. Nadell*, 481 Mich. 377, 381; 751 N.W.2d 431 (2008).

> A motion under MCR 2.116(C)(8) tests the legal sufficiency of the complaint. All well-pleaded factual allegations are accepted as true and construed in a light most favorable to the nonmovant. A motion under MCR 2.116(C)(8) may be granted only where the claims alleged are so clearly unenforceable as a matter of law that no factual development could possibly justify recovery. When deciding a motion brought under this section, a court considers only the pleadings. [*Maiden v. Rozwood*, 461 Mich. 109, 119-120; 597 N.W.2d 817 (1999) (quotation marks and citations omitted).]

***2** "Issues of statutory interpretation are reviewed de novo." *City of Riverview v. Sibley Limestone*, 270 Mich. App. 627, 630; 716 N.W.2d 615 (2006). When the language of a statute is clear and unambiguous, this Court "will apply the statute as written and judicial construction is not permitted." *Driver v. Naini*, 490 Mich. 239, 246-247; 802 N.W.2d 311 (2011).

"The MCPA prohibits certain unconscionable, deceptive or unfair acts, practices, or methods in the conduct of trade or commerce." *De Bruyn Produce Co. v. Romero*, 202 Mich. App. 92, 110; 508 N.W.2d 150 (1993). The MCPA defines "trade or commerce," in relevant part, as "the advertising, solicitation, offering for sale or rent, sale, lease, or distribution of a service or property." MCL 445.902(g). Thus, the MCPA applies to the rental of real property. See *id*; *De Bruyn Produce*, 202 Mich. App. at 110 (holding that the MCPA "defines 'trade or commerce' to include the rental of real property."). The MCPA does not apply, however, to "[a] transaction or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States." MCL 445.904(1)(a). When determining whether this exception applies to a particular case, "the relevant inquiry is whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited." *Liss v. Lewiston-Richards, Inc.*, 478 Mich. 203, 210; 732 N.W.2d 514 (2007) (quotation marks omitted). When broken down into its individual parts, " '[s]pecific' means 'having a special application, bearing, or reference; explicit or definite,' " and " '[a]uthorize' means 'to give authority or formal permission for; sanction.' " *Id.* at 212-213 (footnotes omitted). Finally, "[t]he party claiming the exemption bears the burden of proving its applicability." *Id.* at 208.

The Housing Law of Michigan, MCL 125.401 *et seq.*, states that "[u]nits in multiple dwellings or rooming houses shall not be occupied unless a certificate of compliance has been issued by the enforcing agency." MCL 125.529. The Housing Law of Michigan also grants municipalities the authority to "designate a local officer or agency which shall administer the provisions of the act." MCL 125.523. The Housing Law of Michigan additionally states that it "does not preempt, preclude, or interfere with the authority of a municipality to protect the health, safety, and general welfare of the public through ordinance, charter, or other means." MCL 125.534(8). Thus, the Housing Law of Michigan permits municipalities to designate an officer or agency to administer its provisions and it does not interfere with a municipality's ability to pass its own ordinances to protect the health, safety, and general welfare of the public. See MCL 125.523 and MCL 125.534(8).

Detroit Ordinances § 9-1-35(d)(11) provides, in relevant part, that "[t]he director of the buildings and safety engineering department, or his or her authorized local officials or designees, shall conduct inspections to obtain compliance with this article based upon" the Housing Law of Michigan and "any other applicable law or provision in the 1984 Detroit City Code regulating the maintenance, occupancy, and use of buildings, premises, or structures." The city of Detroit has also passed ordinances regulating when landlords of residential buildings must obtain certificates that permit them to rent their properties to tenants after inspection by the Buildings and Safety Department. See Detroit Ordinances, § 9-1-81 ("The owners or agents of rental property shall register

all such dwellings with the buildings and safety engineering department and obtain a certificate of registration as provided for in this section."); Detroit Ordinances, § 9-1-82 ("It shall be unlawful for a rental property required to be registered pursuant to section 9-1-81 of the 1984 Detroit City Code to be occupied without a certificate of compliance issued by the buildings and safety engineering department ...."). Detroit Ordinances §§ 9-1-19 and 9-1-20 control the penalties a landlord incurs for violations of the Detroit Property Maintenance Code, which encompasses Detroit Ordinances §§ 9-1-81 and 9-1-82. See Detroit Ordinances, §§ 9-1-19 and 9-1-20. Thus, the city of Detroit has passed ordinances, through the authority granted to it by the Housing Law of Michigan in MCL 125.523 and MCL 125.534(8), governing the certificates landlords must obtain before they can rent residential property and means to address violation of the regulations.

*3 Plaintiffs claim that defendants violated the MCPA by failing to disclose to plaintiffs that defendants did not have certificates of compliance for their residential rental properties.[4] The city of Detroit, however, passed ordinances governing when landlords of residential rental properties must obtain certificates of compliance and the penalties a landlord faces for failing to do so. See Detroit Ordinances, §§ 9-1-19, 9-19-20, 9-1-81, and 9-1-82. Landlords in Detroit are not permitted to rent residential property without a certificate of compliance. See Detroit Ordinances, § 9-1-82(b) (establishing that residential rental property must have a certificate of compliance before it can be occupied). Furthermore, the Housing Law of Michigan grants municipalities, like Detroit, the authority to enforce its provisions through such ordinances. See MCL 125.523 and MCL 125.534(8). Thus, the general transaction of whether a landlord in Detroit may rent his or her residential property without a certificate of compliance is specifically addressed by Detroit's ordinances. See *Liss*, 478 Mich. at 212-213. Finally, as stated above, when determining whether the MCPA's "specifically authorized" exception applies to a given case "the relevant inquiry is whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited." *Id.* at 210. The general transaction of a landlord leasing residential property in Detroit is specifically authorized by Detroit's ordinances and, therefore, the MCPA does not apply to the circumstances of this case even though "the specific misconduct alleged," leasing residential rental property without first obtaining certificates of compliance, is prohibited by Detroit's ordinances. See *id.* The trial court, therefore, did not err by granting summary disposition to defendants because the MCPA does not apply in the circumstances of this case. See MCL 445.904(1)(a); *Liss*, 478 Mich. at 212-213.

Finally, plaintiffs argue that MCL 455.902(g), which defines "trade or commerce" under the MCPA, and MCL 445.904(1)(a), which establishes the MCPA's "specifically authorized" exception discussed above, show that the Legislature intended for the MCPA to apply to plaintiffs' claims. The Legislature is "presumed to intend the meaning that the statute plainly expresses." *Universal Underwriters Ins. Group v. Auto Club Ins. Assn.*, 256 Mich. App. 541, 544; 666 N.W.2d 294 (2003) (quotation marks and citation omitted). Additionally, the statutory interpretation canon of *in pari materia* "provides that laws dealing with the same subject ... should if possible be interpreted harmoniously." *SBC Health Midwest, Inc. v. City of Kentwood*, 500 Mich. 65, 74 n. 26; 894 N.W.2d 535 (2017) (citation and quotation marks omitted; alteration in original). MCL 455.902(g) and MCL 455.904(1)(a) are both parts of the MCPA and, therefore, should be interpreted harmoniously when possible. See *id.* As discussed above, MCL 455.902(g) establishes the scope of the MCPA by defining "trade or commerce." This Court has previously held that "trade or commerce" under the MCPA applies to the rental of real property, *De Bruyn Produce*, 202 Mich. App. at 110. As similarly discussed above, however, MCL 445.904(1)(a) establishes that the MCPA does not apply to "specifically authorized" transactions and conduct. See MCL 445.904(1)(a). This Court has applied the "specifically authorized" exception from MCL 445.904(1)(a) to conduct covered by MCL 455.902(g) in the past. See *Liss*, 478 Mich. at 212-215 (holding that residential home builders are included in "trade or commerce" for purposes of the MCPA, but that the MCPA did not apply because the defendants' conduct was specifically authorized). Thus, MCL 455.902(g) and MCL 445.904(1)(a) do not conflict, but instead work together to define the scope of the MCPA.

Finally, plaintiffs alleged that defendants committed fraud by failing to disclose their alleged lack of certificates of compliance when renting their properties to plaintiffs. When a plaintiff alleges fraud, he or she must meet the heightened pleadings standards of MCR 2.112(B)(1), which provides that "in allegations of fraud or mistake, the circumstances constituting fraud or mistake must be stated with particularity." "Generally, fraud is not to be presumed lightly, but must be clearly proved, and must be proved by clear, satisfactory and convincing evidence[.] It is for

these reasons that our court rules create an enhanced burden to plead fraud with particularity." *State ex rel Gurganus v. CVS Caremark Corp.*, 496 Mich. 45, 63 n. 40; 852 N.W.2d 103 (2014) (citations and quotation marks omitted). When determining the claims a plaintiff has actually alleged in his or her complaint, however, "[i]t is well settled that the gravamen of an action is determined by reading the complaint as a whole, and by looking beyond mere procedural labels to determine the exact nature of the claim." *Adams v. Adams*, 276 Mich. App. 704, 710-711; 742 N.W.2d 399 (2007).

***4** Plaintiffs alleged in their complaints that defendants committed fraud by failing to disclose their alleged failure to obtain certificates of compliance before renting their properties to plaintiffs. Plaintiffs' complaints, however, failed to include additional specific information or allegations. Accordingly, plaintiffs' complaints failed to meet the heightened pleading requirements to allege fraud. See *Gurganus*, 496 Mich. at 63 n. 40. Additionally, when read as a whole, the gravamen of plaintiffs' complaints was not that defendants committed fraud. Rather, the gravamen of plaintiffs' complaints was that defendants failed to obtain certificates of compliance, not that they committed fraud by failing to disclose this alleged failure to plaintiffs. See *Adams*, 276 Mich. App. at 710-711. Plaintiffs' fraud allegations amount to nothing more than creative pleading and an attempt to have the MCPA apply to their claims against defendants. As such, plaintiffs' fraud allegations are unpersuasive and were not sufficiently pleaded. See *Gurganus*, 496 Mich. at 63 n. 40; *Adams*, 276 Mich. App. at 710-711.

Plaintiffs' second argument is that the trial court erred by refusing to consider their request to amend their complaints. We disagree.

"The grant or denial of leave to amend pleadings is within the trial court's discretion" and "[t]his Court will not reverse a trial court's decision regarding leave to amend unless it constituted an abuse of discretion that resulted in injustice." *PT Today, Inc. v. Comm'r of Office of Fin. & Ins. Servs.*, 270 Mich. App. 110, 142; 715 N.W.2d 398 (2006) (citation omitted). "An abuse of discretion occurs when the decision resulted in an outcome falling outside the range of principled outcomes." *Hayford v. Hayford*, 279 Mich. App. 324, 325-326; 760 N.W.2d 503 (2008). "A trial court necessarily abuses its discretion when it makes an error of law." *Jawad A. Shah, MD, PC v. State Farm Mut. Auto Ins. Co.*, 324 Mich. App. 182, 208; 920 N.W.2d 148 (2018), oral argument on the application gtd 503 Mich. 882 (2018). Additionally, the interpretation and application of court rules present questions of law to be reviewed de novo using the principles of statutory interpretation. *Lamkin v. Engram*, 295 Mich. App. 701, 707; 815 N.W.2d 793 (2012).

As an initial matter, defendants' argument that plaintiffs waived the issue of whether they should be permitted to amend their complaints is unpersuasive. "A waiver is a voluntary and intentional abandonment of a known right." *Braverman v. Granger*, 303 Mich. App. 587, 608; 844 N.W.2d 485 (2014) (citation and quotation marks omitted). Plaintiffs requested leave to amend the complaints in their response to defendants' motion for summary disposition. As such, they did not waive the issue of whether they could amend their complaints. See *id.*

When a trial court grants a motion for summary disposition under MCR 2.116(C)(8), (C)(9), or (C)(10), it "must give the parties an opportunity to amend their pleadings pursuant to MCR 2.118, unless the amendment would be futile." *Shah*, 324 Mich. App. at 209 (quotation marks and citation omitted); see also MCR 2.116(I)(5) ("If the grounds asserted are based on subrule (C)(8), (9), or (10), the court shall give the parties an opportunity to amend their pleadings as provided by MCR 2.118, unless the evidence then before the court shows that amendment would not be justified."). An amendment to a pleading "is futile if it merely restates the allegations already made or adds allegations that still fail to state a claim." *Lane v. KinderCare Learning Ctrs., Inc.*, 231 Mich. App. 689, 697; 588 N.W.2d 715 (1998).

Under MCR 2.118(A)(2), a party may amend a pleading by leave of the court and such "[l]eave shall be freely given when justice so requires." *Shah*, 324 Mich. App. at 209 (quotation marks and citation omitted; alteration in original). Motions to amend should only be denied for "the following particularized reasons: (1) undue delay, (2) bad faith or dilatory motive on the part of the movant, (3) repeated failure to cure deficiencies by amendments previously allowed, (4) undue prejudice to the opposing party by virtue of allowance of the amendment, or (5) futility of the amendment." *Lane*, 231 Mich. App. at 697. Delay alone, however, "does not warrant denial of a motion to amend." *Weymers v. Khera*, 454 Mich. 639, 659; 563 N.W.2d 647 (1997).

> ***5** [A] trial court may find prejudice when the moving party seeks to add a new claim or a new theory of recovery

> on the basis of the same set of facts, after discovery is closed, just before trial, and the opposing party shows that he did not have reasonable notice, from any source, that the moving party would rely on the new claim or theory at trial. [*Id.* at 659-660 (footnote omitted).]

"The trial court must specify its reasons for denying leave to amend, and the failure to do so requires reversal unless the amendment would be futile." *PT Today*, 270 Mich. App. at 143.

Under MCR 2.118(A)(4), a motion to amend a complaint must be made "in writing." MCR 2.118(A)(4). This Court examined the writing requirement of MCR 2.118(A)(4) in *Lown v. JJ Eaton Place*, 235 Mich. App. 721; 598 N.W.2d 633 (1999). In *Lown*, the defendant moved for summary disposition under MCR 2.116(C)(10) and, the "plaintiff anticipated that she would be seeking leave to amend her complaint" in her response to the defendant's motion for summary disposition. *Lown*, 235 Mich. App. at 725. The plaintiff orally requested leave to amend her complaint at the hearing on the defendant's motion for summary disposition, but the trial court denied the plaintiff's request at the same hearing and granted summary disposition to the defendant. *Id.* This Court affirmed the trial court's denial of the plaintiff's request to amend the complaint because the plaintiff's "request to amend was oral, and [the] plaintiff never offered any written amendments." *Id.* at 726. As such, the plaintiff failed to comply with MCR 2.118(A)(4), which requires amendments to be in writing. MCR 2.118(A)(4); *Lown*, 235 Mich. App. at 726. Furthermore, by characterizing the plaintiff's request to amend the complaint as oral, this Court implicitly held that the plaintiff's statement in her response to the defendant's motion for summary disposition that she would seek leave to amend did not fulfill MCR 2.118's requirements. See *Lown*, 235 Mich. App. at 725-726. The importance of the submission of a written proposed amended complaint has since been reiterated in *Anton, Sowerby & Assoc., Inc. v. Mr. C'S Lake Orion, LLC*, 309 Mich. App. 535, 551; 872 N.W.2d 699 (2015), in which this Court held that "[i]f a plaintiff does not present its proposed amended complaint to the court, there is no way to determine whether an amendment is justified."

The trial court granted summary disposition to defendants under MCR 2.116(C)(8). In such a situation, a trial court *must* give a party an opportunity to amend its pleadings. *Shah*, 324 Mich. App. at 209. Plaintiffs, however, failed to file proposed amended complaints or written motions to amend their complaints. Instead, like the plaintiff in *Lown*, plaintiffs stated that they "would seek leave to amend" in their response to defendants' motion for summary disposition if the trial court granted summary disposition to defendants. Plaintiffs failed to pursue the issue further and did not file proposed amended complaints or motions to amend the complaints with the trial court. Because plaintiffs failed to file motions to amend the complaints and proposed amended complaints with the trial court, they failed to comply with MCR 2.118(A)(4). See *Lown*, 235 Mich. App. at 725-726. Additionally, because plaintiffs failed to present proposed amended complaints to the trial court, the trial court had "no way" to determine whether plaintiffs' proposed amended complaints were justified. See *Anton*, 309 Mich. App. at 551.

***6** Plaintiffs additionally argue that it would be unreasonable to require them to move to amend their complaints before the trial court granted summary disposition to defendants because plaintiffs could not have known that such an action was necessary until after the trial court granted summary disposition to defendants and dismissed the case. Plaintiffs, however, failed to cite any legal authority to support this argument and this Court may consider the argument abandoned. *Mettler Walloon, LLC v. Melrose Twp.*, 281 Mich. App. 184, 220; 761 N.W.2d 293 (2008). Even if plaintiffs' argument that they had no reason to know they should have moved to amend their complaints before the trial court granted summary disposition to defendants was not abandoned, however, it would still fail.

Plaintiffs may file motions to amend their complaints when they respond to a defendant's motion for summary disposition. See, e.g., *Sharp v. City of Lansing*, 238 Mich. App. 515, 517-518, 523; 606 N.W.2d 424 (1999) (the defendant moved for summary disposition and, as that motion was pending, the plaintiff filed a motion to amend his complaint). Furthermore, plaintiffs may also file motions to amend their complaints after a trial court grants summary disposition to defendants. See, e.g., *Jackson v. White Castle Sys. Inc.*, 205 Mich. App. 137, 139, 142-143; 517 N.W.2d 286 (1994) (after the trial court granted summary disposition to the defendant, the plaintiff filed a motion to amend his complaint with a motion for reconsideration). Thus, plaintiffs could have filed motions to amend their complaints either before or after the trial

court granted summary disposition to defendants. Plaintiffs' choice to solely pursue an MCPA claim was strategic; their decision to not proactively amend their complaints proved to be a bad strategy, but that does not mean that this Court's established rule requiring plaintiffs to file motions to amend their complaints is unreasonable. Thus, the trial court did not abuse its discretion by denying plaintiffs' request to amend their complaints.

Because plaintiffs failed to move to amend their complaints we need not address whether the trial court should have granted plaintiffs' request to amend their complaints on the merits. We note, however, that if plaintiffs had moved to amend their complaints the trial court should have granted their motion to amend their complaints. Detroit's ordinances did not necessarily bar plaintiff's proposed claims that defendants breached Truth in Renting Act, MCL 554.631 *et seq.*, and the warranty of habitability. As such, the request to amend plaintiffs' complaints was not necessarily futile. We note, however, that without a proposed amended complaint we lack the information necessary to determine whether plaintiffs' amended complaints would have been futile. Furthermore, plaintiffs did not move to amend their complaints in bad faith and if the trial court granted plaintiffs leave to amend their complaints it would not have prejudiced defendants because the parties were not on the eve of trial, which was scheduled to begin almost three months after plaintiffs' request to amend. See *Weymers*, 454 Mich. at 659-660. Finally, because this was the first and only time that plaintiffs requested leave to amend their complaints, plaintiffs' request necessarily was not a "repeated failure to cure deficiencies by amendments previously allowed." See *Lane*, 231 Mich. App. at 697. As such, if plaintiffs had properly moved to amend their complaints the trial court should have granted them leave to do so.

Affirmed.

All Citations

Not Reported in N.W. Rptr., 2019 WL 2605789

Footnotes

1 We will refer to the plaintiffs from Docket Nos. 344824, 344729, and 344731 collectively as "plaintiffs" throughout this opinion except in instances in which it is necessary to differentiate plaintiffs by their appellate docket number or individually.

2 *Davis v. Boydell Development Co., Inc.*, unpublished order of the Court of Appeals, entered August 30, 2018 (Docket No. 344284); *Byrd v. Boydell Development Co., Inc.*, unpublished order of the Court of Appeals, entered August 30, 2018 (Docket No. 344729); *Alongi v. Boydell Development Co., Inc.*, unpublished order of the Court of Appeals, entered August 30, 2018 (Docket No. 344731).

3 We will refer to the defendants from Docket Nos. 344824, 344729, and 344731 collectively as "defendants" throughout this opinion except in instances in which it is necessary to differentiate defendants by their appellate docket number or individually.

4 We note that plaintiffs refer to these certificates as "certificates of occupancy," but that the Housing Law of Michigan, MCL 125.529, and Detroit Ordinances § 9-1-82 only reference certificates of compliance. Thus, we use the term "certificates of compliance" throughout this opinion.

EXHIBIT B

Frequently Asked Questions about CDER

1. What does the Center for Drug Evaluation and Research do?

The Center is a consumer watchdog in America's healthcare system. CDER's best-known job is to evaluate new drugs before they can be sold. The Center's review of new drug applications not only prevents quackery, but it provides doctors and patients with the information they need to use medicines wisely.

The Center makes sure that safe and effective drugs are available to improve the health of consumers. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks.

2. What drugs are regulated by CDER?

From aspirin to cancer treatments, CDER ensures that the benefits of drug products outweigh any known risks. The Center has oversight responsibilities for prescription, over-the-counter and generic drugs. This responsibility includes products that many consumers usually do not associate as drugs, such as fluoride toothpaste, dandruff shampoos and sunscreens. CDER carefully evaluates the benefits and risks of drugs and ensures that consumers have access, as quickly as possible, to promising new treatments. The Center oversees the research, development, manufacture and marketing of drugs. CDER ensures truth in advertising for prescription drugs and monitors the use of marketed drugs for unexpected health risks. If unexpected risks are detected after approval, CDER takes action to inform the public, change a drug's label, or--if necessary--remove a product from the market. Specifically, CDER regulates:

- *Prescription Drugs*. Prescription medicines include any drug product that requires a doctor's authorization to purchase.
- *Generic Drugs*. A generic drug is a drug product that is equivalent to brand name products in terms of quality and performance.
- *Over-the-Counter Drugs*. OTC drug products are available to consumers without a doctor's prescription.

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3. Are generic drugs the same as brand name drugs?

FDA works with pharmaceutical companies to assure that all drugs marketed in the United States meet specifications for identity, strength, quality, purity, and potency. Before approving a generic drug product, CDER requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug.

CDER bases evaluations of substitutability or "therapeutic equivalence" for generic drugs on scientific evaluations. By law, generic drug products must contain the identical amounts of the same active drug ingredient as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product. FDA considers drug products to be substitutable if they meet the criteria of therapeutic equivalence, even though the generic drug may differ in certain other characteristics (e.g., shape, flavor, or preservatives).

For more information on generic drugs, please visit Generic Drugs (/drugs/buying-using-medicine-safely/generic-drugs)

4. Why are some drugs changed from prescription to non-prescription or over-the-counter (OTC)?

Some drugs are initially approved as over-the-counter drugs. More often, however, medications are first approved as prescription drugs and then later switched.

Drugs are commonly switched one of two ways: under an OTC drug review, or by a manufacturer's submission of additional information to the original drug application.

When considering a prescription to OTC switch, the key question that must be answered is whether the drug can benefit consumers without endangering their safety.

Nonprescription or OTC drugs are considered safe for consumers to use if they can easily follow the directions and warnings on the label. To protect consumers, FDA regulations require that labeling of OTC drugs be written so that ordinary people, including those with low reading comprehension skills, are able to easily find and understand information like:

Toxicity (a drug's potential for poisonous effects) is the major issue in deciding whether to switch a drug from prescription to OTC. Since almost any drug, if misused, can have serious side effects, FDA considers the drug's overall safety.

Another consideration in deciding whether or not a drug should be available without a prescription is whether the condition being treated can be self-diagnosed and recognized without the help of a health-care practitioner. Not being able to self-diagnose a medical condition does not automatically prevent a product from switching to OTC status; FDA evaluates each drug on an individual basis.

- the intended uses and results of the product
- adequate directions for proper use
- warnings against unsafe use, side effects and adverse reactions.

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5. Does the FDA test drugs?

FDA does not develop, manufacture or test drugs. Drug manufacturers submit full reports of a drug's studies so that the Center can evaluate its data. The studies answer the question: "Does this drug work for the proposed use?" By analyzing the data, CDER reviewers assess the benefit-to-risk relationship and determine if the drug will be approved.

6. Once FDA approves a drug, does this mean that the product is perfectly safe?

No drug product is "perfectly" safe. Every single drug that affects the body will have some side effects. Since the FDA considers both the benefits and risks of all medications before approval,

side effects are generally not serious. For every drug FDA approves, the benefits are balanced against its risks. In addition, FDA makes sure the labeling (Prescribing Information) outlines the benefits and risks reported in the tested population. You and your health-care provider should decide together if the benefits outweigh the risks for YOU. Talking about your medicines with your health-care provider is just as important and good for your health as a complete check-up and taking your medicine as directed.

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7. What questions should I ask my health care provider before taking a new medication?

Before taking a new medication, always ask: If you don't understand the answers, always ask for an explanation.

- What is the name of the medication, and what is it for?
- How and when do I take it, and for how long?
- What are the side effects, and what should I do if they occur?
- Is this medication safe to take with other over-the-counter or prescription medication or dietary supplements that I am currently taking?

8. What should I do if I've had a serious side effect to an over-the-counter or prescription medicine?

Contact your health-care provider right away so that they can advise you on the necessary actions to take. Also, urge the provider to report the problem to FDA's MedWatch hotline, at 800-FDA-1088. Your health care provider, however, is not required to report to FDA. Therefore, consumers can report problems directly. For more information, visit MedWatch (/medwatch-fda-safety-information-and-adverse-event-reporting-program).

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9. What is required for a drug to be approved by CDER?

Under current law, all new drugs need proof that they are effective and safe before they can be approved for marketing. No drug is absolutely safe; there is always some risk of an adverse reaction. CDER decides--as quickly as a thorough evaluation allows--whether the studies submitted by the drug's sponsor (usually the manufacturer) show it to be safe and effective for its intended use. When a proposed drug's benefits outweigh known risks, CDER considers it safe enough to approve. Once a drug gets CDER approval, the drug is on the market as soon as the firm gets its production and distribution systems going.

10. What is a clinical trial?

A clinical trial is a study conducted to evaluate a drug. Each study is designed to answer scientific questions and find new and better ways to help people. With any new drug there are benefits as well as possible risks. There may also be some risks that are not yet known. Clinical trials help us find out if promising new treatments are safe and effective for patients. During a clinical trial, more and more information is gained about a new drug, its risks, and how well it may or may not work. You may be interested in or asked to enter a trial. Learn as much as you can about the clinical trial before deciding. Only patients that volunteer take part in a clinical trial.

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11. How are drugs found?

The search for new drugs begins with basic research in the laboratory and animal studies. If this research results in promising findings, then it is continued in patient studies. This patient research is used to determine how to use new drugs safely and effectively.

12. What is being done by FDA to gain more information about drugs approved for adults that doctors also use for children?

Every year more than half of newly approved drugs that are likely to be used in children lack information to permit safe and effective use. Without adequate information, doctors may be unwilling to prescribe certain drugs for their pediatric patients, or they may prescribe them improperly. However, if doctors decide against using adult drugs in their young patients because the proper dose is unknown, children may be deprived of useful treatments.

To resolve this, FDA finalized regulations, which require manufacturers of many drugs to provide information about how their drugs can safely and effectively be taken by children (from newborns to adolescents). This will give health-care practitioners specific dosing information--based on scientific evidence--which will make prescribing for children safer and better. Since doctors will have more complete information on how drugs affect children and what appropriate doses are needed, it enables children to receive better treatment.

For drugs already approved, FDA can require children's studies to be conducted in certain circumstances--for example, when pediatric information can help avoid serious risks to kids. Government regulations allow FDA to waive sending in pediatric data completely (under certain circumstances), or to submit data after a drug has already been on the market, if FDA has safety concerns about testing the drug on children prior to testing it on adults. FDA, however, will not delay approving a drug for adults if the pediatric studies are not yet completed.

13. How can I find out about drugs that are currently under review by FDA?

Due to confidentiality rules, FDA is prohibited from releasing information on any drug under development, review or pending approval unless the information has been made public. You may contact the manufacturer directly to ask about products under development.

Another possible source of information is the Pharmaceutical Research and Manufacturers of America (PhRMA).

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14. I've heard that in life-threatening situations, investigational drugs (those not yet FDA approved) can be obtained. What does this mean?

The use of drugs under investigational new drug status is important because it allows manufacturers to generate data to determine safety and effectiveness in marketing. However, FDA has established programs to allow patients with an immediately life-threatening disease "early access" to new treatments. The FDA defines "immediately life-threatening" as a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months, or in which premature death is likely without early treatment. For example, advanced cases of AIDS and cancer are considered to be immediately life-threatening diseases.

Since patients who have exhausted standard therapeutic options may be willing to accept additional risks and potentially dangerous side effects from drug products still under study, these programs allow patients access to investigational drugs.

A patient's health-care provider should contact the drug manufacturer for information about product availability for a specific patient if the health-care provider believes this treatment may be of benefit to their patient. However, FDA is not permitted to disclose any information regarding investigational drugs, or ask sponsors to provide investigational drugs to physicians.

15. Is it legal for me to bring foreign-made medications into the United States, or have such products mailed to me?

The United States Federal Food, Drug and Cosmetic Act prohibits the interstate shipment (which includes importation) of unapproved new drugs. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs that have not received FDA approval.

To find out more about FDA's Import Program visit the Import Information Page (/industry/import-program/importations-drugs).

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16. What can the FDA do about the cost of drugs?

We understand that high drug prices have a direct impact on patients—too many American patients are priced out of the medicines they need. However, the FDA has no legal authority to investigate or control the prices set by manufacturers, distributors and retailers. A number of factors can impact drug pricing, such as the costs of research and development and the amount of competition in the marketplace. Also, other factors, beyond FDA's purview can determine patient access to drugs. The agency is committed to facilitating increased competition in the market for prescription drugs through the approval of lower-cost, generic medicines.

If you are concerned about the price of your medications discuss your options with your health-care provider to determine if there is a lower-cost alternative or generic drug available. You can also contact the drug manufacturer. Some drug manufacturers have patient assistance programs to help patients pay for needed medications. Finally, consider contacting the Federal Trade Commission (https://www.ftc.gov/). The FTC enforces a variety of federal antitrust and consumer protection laws. The FTC seeks to ensure that the nation's markets function competitively, and are vigorous, efficient, and free of undue restrictions.

17. What should I know before buying medical products online?

Although some online pharmacies are legitimate businesses, patients must be cautious when purchasing drugs over the Internet. Patients should not buy drugs from web sites that: are not registered on a search engine; offer to prescribe a prescription drug without a physical exam; sell drugs not approved by FDA; do not offer the opportunity to ask questions of a registered pharmacist; require that you link to another web site to purchase the drug; and do not provide an U.S. phone number and address to contact for questions.

Before buying a prescription drug over the Internet, patients should check with the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met state practice standards. Patients who believe that a web site is unlawfully selling a drug should report it to the National Association of Boards of Pharmacy or to the FDA.

For more information on buying medical products online, see BeSafeRx: Know Your Online Pharmacy (/drugs/quick-tips-buying-medicines-over-internet/besaferx-your-source-online-pharmacy-information)

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18. What should I look for on the new over-the-counter medicine label?

The new format will have standardized headings and subheadings using terms that will be more familiar to consumers. For example, the new label will refer to "uses" instead of "indications,"

and it will no longer use the terms "precautions" or "contraindications." The new label will also require the information to appear in a standardized order. For more information, please see OTC Drug Facts Label (/drugs/information-consumers-and-patients-drugs/otc-drug-facts-label), and The Over-the-Counter Medicine Label: Take a Look. (/drugs/resources-you-drugs/over-counter-medicine-label-take-look)

For additional information about CDER, go to: http://www.fda.gov/Drugs/default.htm (/drugs). You can contact FDA by writing or calling:

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