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STATE OF NORTH DAKOTA

IN THE SUPREME COURT

STATE OF NORTH DAKOTA

STATE OF NORTH DAKOTA EX REL. WAYNE STENEHJEM, ATTORNEY GENERAL, Plaintiff/Appellant, -vs- PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY INC.; and DOES I THROUGH 100, INCLUSIVE, Defendant/Appellee.	Supreme Court No. 20190237 Burleigh Co. No. 08-2018-CV-01300 **ORAL ARGUMENT REQUESTED** CPAT 160247.004

APPEAL FROM THE DISTRICT COURT ORDER DATED MAY 10, 2019,
AND JUDGMENT DATED MAY 24, 2019.
HONORABLE JAMES S. HILL PRESIDING
BURLEIGH COUNTY DISTRICT COURT, CIVIL NO. 08-2018-CV-01300

BRIEF OF APPELLANT

STATE OF NORTH DAKOTA
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[¶1] STATEMENT OF THE ISSUES

1. Did the District Court err by converting Purdue's motion to dismiss into a motion for summary judgment, and granting the motion, without notice to the State and without allowing the State to present additional evidence or conduct discovery;
2. Did the District Court err by deciding that the State's claims are preempted by federal law;

3. Did the District Court err by concluding that the State is required to plead and prove causation in order to prevail in a cause of action under the Consumer Fraud Law;
4. Did the District Court err by concluding that the Nuisance Law is inapplicable to conduct involving the sale of goods; and
5. Did the District Court err by misapplying the standard for summary judgment?

STATEMENT OF THE CASE

[¶2]The State of North Dakota, ex rel. Wayne Stenehjem, Attorney General ("State") brought this action in Burleigh County District Court ("District Court") against Defendants Purdue Pharma L.P., Purdue Pharma Inc. and The Purdue Frederick Company Inc. ("Purdue") seeking relief under North Dakota Century Code (N.D.C.C.) § 51-15-01 *et seq*., Unlawful Sales or Advertising Practices ("Consumer Fraud Law"), N.D.C.C. § 42-01-01 *et seq*., Nuisances and § 42-02-01 *et seq*., Abatement of Common Nuisances ("Nuisance Law"), by serving a Summons and Complaint upon Purdue on May 15, 2018. Index # 1-3. The Complaint seeks statutory and equitable remedies, including injunctive relief, civil penalties, attorneys' fees and costs, restitution, disgorgement, and abatement of a public nuisance. Index # 2; Appellant's Appendix (App.) p. 6.

[¶3]On August 22, 2018, Purdue filed a Motion to Dismiss ("Motion") under N.D.R.Civ.P 12(b)(6). Index # 13-21. The State filed a Response in Opposition to Defendants' Motion to Dismiss on November 2, 2018. Index # 34. A hearing was held on February 26, 2019, before the Honorable James S. Hill, and, on May 10, 2019, the District Court issued an Order Granting Defendants' Motion to Dismiss ("Order").[1] Index # 56;

[1]The Attorney General is not aware that any judge in any other state's jurisdiction has dismissed an attorney general's lawsuit against Purdue relating to the same conduct as alleged in the State's Complaint. See, e.g., Index # 35.

App. p. 70. The District Court converted the Motion into a motion for summary judgment under N.D.R.Civ.P 12(d) and held that the State failed to adequately plead its causes of action against Purdue. Id. The Judgment was entered on May 24, 2019 ("Judgment"), with the Notice of Entry filed and served on June 11, 2019. App. p. 97; Index # 61; Index # 63. On June 13, 2019, the State, pursuant to N.D.R.Civ.P 60(b), moved for Relief from Judgment on the issue of preemption. Index # 66. The State's Rule 60(b) motion relied on Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 203 L.Ed.2d 822 (2019). Id. On July 22, 2019, the District Court issued an order denying the State's motion. Index # 74. The State appeals from the Order and the Judgment. App. p. 99; Index # 79.

REQUEST FOR ORAL ARGUMENT

[¶4]Pursuant to N.D.R.App.P. 28(h), the State requests the Court schedule oral argument. This case involves both procedural errors and several pure legal issues relating to federal preemption and interpretation of state statutes, and oral arguments would be helpful in the Court's review of the District Court's decision.

STATEMENT OF THE FACTS

[¶5]Purdue manufactures, promotes and sells powerful narcotic painkillers known as prescription opioids, which are highly addictive, and have serious health risks. App. pp. 7, 13, 23-29. Purdue has been a leading force in the prescription opioid market, and, after launching OxyContin in 1996, Purdue deliberately set out to reverse the stigma associated with opioid use, transform the medical and scientific thought that historically deemed opioids too dangerous, and change prescribers' and patients' attitudes about opioids, to broaden the opioid market and increase sales. App. pp. 7, 13, 14, 21, 22, 55.

[¶6]Purdue engaged in an aggressive, deceptive and successful marketing scheme

designed to deceive both prescribers and patients about the risks and benefits of long-term opioid use, and made claims unsupported by, or contrary to, scientific evidence, and contrary to pronouncements by and guidance from both the U.S. Food and Drug Administration ("FDA") and Centers for Disease Control and Prevention ("CDC") based on that evidence. App. pp. 7, 8, 15, 16, 19-41. Purdue's marketing campaign focused on the distribution of "core messages" that ensured consistent delivery of Purdue's messages across marketing channels in each sales territory. App. pp. 8, 15-16, 18.

[¶7]Purdue's "core messages" include nine groups of misrepresentations or deceptive messages, which: 1) trivialize and minimize the risks associated with addiction, dependence, and tolerance; 2) misrepresent that opioids improve function and quality of life; 3) invent "pseudoaddiction" to encourage prescribers to ignore signs of addiction; 4) trivialize the difficulties associated with withdrawal; 5) encourage escalating dosages while omitting risks; 6) misrepresent the effectiveness of mitigation tools; 7) exaggerate the risks of alternative treatment options compared to opioids; 8) deceptively market abuse-deterrent opioids; and 9) misrepresent that OxyContin effectively provides 12 hours of pain relief. App. pp. 21-38. The FDA and the CDC have confirmed the falsity of Purdue's representations. App. p. 8. Purdue marketed opioids inconsistent with the FDA-approved drug labels and made statements and claims that contradicted or undermined the warnings in the labels. App. pp. 19, 21-39, 53. Also, Purdue's unbranded marketing often contradicted Purdue's branded materials. Id.

[¶8]Purdue's marketing campaign utilized branded and unbranded advertisements, academic and scientific publications, treatment guidelines, studies and research, educational programs and materials, and physician detailing. App. pp. 15-21. Purdue used

unbranded advertising, key opinion leaders (KOLs), and Front Groups to give a false appearance that the information came from independent and objective sources. App. pp. 19-21. Over time, Purdue created a body of deceptive and misleading medical and popular literature concerning opioids and pain, and Purdue's marketing messages became ingrained in advertisements, branded and unbranded marketing materials, publications, pamphlets, videos, medical journals, literature, treatment guidelines, conferences, educational programs, Continuing Medical Education (CME), research, outreach, and programs and materials from patient and professional organizations. App. pp. 10, 18-21, 26. Purdue's deceptive marketing messages pervaded scientific, medical, and public opinion to such an extent that consumers, physicians and payors were deprived of the opportunity to exercise informed judgment when deciding whether to prescribe or use opioids. Id.

[¶9]Purdue spent an extraordinary amount of money promoting its opioids, and its marketing efforts were successful. App. pp. 8-9. Opioids became the most prescribed class of drugs, generating billions in revenue for drug companies. Id. Purdue continued its deceptive marketing scheme in the face of pronouncement and guidance issued by the FDA and the CDC confirming, based on scientific evidence, that Purdue's claims were false and deceptive. App. pp. 9, 16, 21, 41-42, 55. Further, Purdue failed to correct past misrepresentations. App. p. 27. Purdue continues to market, sell and profit from drugs that it knows are deadly. App. p. 55. The increase in opioid sales and use in the State of North Dakota is inextricably linked with Purdue's marketing campaign. Id.

[¶10]Through research, clinical experience, scientific studies, detailed prescription data, and reports of adverse events, Purdue has been well aware of the ineffectiveness and the adverse health and addictive effects of opioids. App. pp. 40, 52-53. Purdue carefully

watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. Id. Purdue closely monitored its sales and the habits of prescribers. Id. Purdue knew which prescribers were receiving their messages and how they were responding to those messages. Id. Purdue intended its misrepresentations to persuade physicians to prescribe, and patients to use, more opioids for chronic pain. Id.

STATEMENT OF THE STANDARD OF REVIEW

[¶11]A district court's grant of summary judgment is reviewed *de novo*. Twin City Technical LLC v. William County, 2019 ND 128, ¶5, 927 N.W.2d 467. The interpretation or application of a court rule or statute is a question of law that is reviewed *de novo*. State ex rel. Stenehjem v. FreeEats.com, Inc., 2006 ND 84, ¶5, 712 N.W.2d 828; State v. Ebertz, 2010 ND 79, ¶8, 782 N.W.2d 350. A district court's decision to convert a Rule 12(b)(6) motion to dismiss into a motion for summary judgment is reviewed for abuse of discretion. Hamm v. Rhone-Poulenc Rorer Pharm., Inc., 187 F.3d 941, 948 (8th Cir.1999).

LAW AND ARGUMENT

[¶12]When a court decides to convert a Rule 12(b)(6) motion to dismiss into a motion for summary judgment, "[a]ll parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." N.D.R.Civ.P. 12(d). The "term 'reasonable opportunity' requires that all parties be given 'some indication by the court ... that it is treating the 12(b)(6) motion as a motion for summary judgment,' with the consequent right in the opposing party to file counter affidavits or pursue reasonable discovery." Gay v. Wall, 761 F.2d 175, 177 (4th Cir. 1985) (citing Johnson v. RAC Corp., 491 F.2d 510, 513 (4th Cir.1974); Dale v. Han, 440 F.2d 633, 638 (2d Cir. 1971); Wright

& Miller, 5 Federal Practice and Procedure § 1366 (1969)).

[¶13]The party claiming preemption bears the burden of proving preemption. FreeEats.com, Inc., 2006 ND 84 at ¶¶21-22. There is a strong presumption against conflict preemption in cases that involve the historic police powers of the States. Id.; Wyeth v. Levine, 555 U.S. 555, 565, 129 S. Ct. 1187, 173 L.Ed.2d 51 (2009). Congress did not intend to preempt state consumer-protection laws in cases involving prescription-drug labeling when enacting the United States Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. 9. Id. at 574-575. Impossibility preemption arises when it is impossible to comply with both federal and state regulations, and it is a demanding defense. Id. at 573; Merck, 139 S. Ct. at 1678. The "'possibility of impossibility [is] not enough.'" Merck, 139 S.Ct at 1678 (quoting PLIVA, Inc. v. Mensing, 564 U. S. 604, 625, n. 8, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011)).

[¶14]An unlawful practice exists "whether or not any person has in fact been misled, deceived, or damaged thereby." N.D.C.C. §51-15-02. "The court may make an order or judgment as may be necessary to prevent the use or employment … of any unlawful practices, or which may be necessary to restore to any person in interest any money, or property that may have been acquired by means of any practice … declared to be unlawful…." N.D.C.C §51-15-07. "This language, construed in light of the 'concern that wrongdoers not retain the benefits of their misconduct' … has led courts repeatedly and consistently to hold that relief … is available without individualized proof of deception, reliance and injury". In re Tobacco II Cases, 46 Cal.4th 298, 320, 207 P.3d 20, 93 Cal.Rptr.3d 559 (2009).

[¶15]"A nuisance consists in unlawfully doing an act or omitting to perform a duty,

which act or omission: 1. Annoys, injures, or endangers the comfort, repose, health, or safety of others; ….” N.D.C.C. § 42-01-01. “‘[T]o say that a court of equity may not enjoin a public nuisance because property rights are not involved would be to say that the state is unable to enforce the law or protect its citizens from public wrongs.’” State ex rel. Burgum v. Hooker, 87 N.W.2d 337, 340 (1957) (quoting Stead v. Fortner, 255 Ill. 468, 478, 99 N.E. 680 (1912). A public nuisance does not necessarily involve interference with use and enjoyment of land. Restatement (Second) of Torts (1979) §821B, comment h.

I. The District Court erred because it converted and granted Purdue's Motion without providing the State notice and reasonable opportunity to present all pertinent material.

[¶16]The District Court abused its discretion when it converted Purdue's Motion into a motion for summary judgment without, first, providing notice to the State, and, second, providing the State a reasonable opportunity to conduct discovery and to present all material pertinent to the Motion. N.D.R.Civ.P. 12(d) provides:

> If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.

N.D.R.Civ.P. 12(d). The term “‘‘reasonable opportunity’ requires that all parties be given’ ‘some indication by the court … that it is treating the 12(b)(6) motion as a motion for summary judgment,’ with the consequent right in the opposing party to file counter affidavits or pursue reasonable discovery.’” Gay v. Wall, 761 F.2d at 177 (citing Johnson v. RAC Corp., 491 F.2d at 513; Dale v. Han, 440 F.2d at 638; C. Wright & Miller, 5 Federal Practice and Procedure, § 1366). [2]

[2] North Dakota courts “may look to persuasive federal authority when interpreting [North Dakota] rules.” City of Bismarck v. McCormick, 2012 ND 53, ¶12, 813 N.W.2d 599.

A. The District Court erred because it failed to provide notice to the State that the Motion would be treated as a motion for summary judgment.

[¶17]The District Court did not provide notice, or "some indication," to the State that it was converting Purdue's Motion into a motion for summary judgment. See generally, Index # 77. Notice of conversion, in most cases, is mandatory:

> Under our cases ..., a party against whom this [conversion] procedure is used (here, the plaintiffs) is normally entitled to notice that conversion is occurring. Only if he has such notice can he understand that the burden will be on him to produce affidavits, not merely allegations in pleadings, to rebut what has become a motion for summary judgment. The general rule in this Circuit is that "strict compliance" with this notice procedure is required.

Country Club Estates, L.L.C. v. Town of Loma Linda, 213 F.3d 1001, 1005 (8th Cir.2000). Purdue's Motion was argued by both parties, and heard by the Court, as a Rule 12(b)(6) motion to dismiss. See generally, Index # 77.

[¶18]The District Court did not provide any notice or communicate an intent to treat Purdue's Motion as one for summary judgment. Id. During the hearing on Purdue's Motion, the District Court indicated only that it had reviewed the briefings. Id. at pp. 4, 74. The District Court did not state that it would treat the Motion as a motion for summary judgment, and did not state that it had reviewed, or would review, matters outside the pleadings. See id. at pp. 4, 65, 74. The District Court did not discuss or rule on whether it would accept Purdue's exhibits. Id. In summary, where conversion of a Rule 12(b)(6) motion to dismiss requires "some indication" that the District Court would treat Purdue's Motion as a motion for summary judgment, the District Court provided none. See Gay, 761 F.2d at 177. Because the District Court did not provide the State with notice that the Motion would be converted, the District Court erred when it converted the Motion.

[¶19]The District Court's error was not harmless. Failure to give notice of conversion can be harmless error if, for example, "there was nothing that plaintiffs could

have presented by way of countervailing evidence," or the parties have "constructive notice" of the court's intent to consider matters outside of the complaint. E.E.O.C. v. American Home Prods. Corp., 199 F.R.D. 620, 628 (N.D. Iowa 2001); Country Club Estates, L.L.C., 213 F.3d at 1005. However, neither is true in this case. The State could have presented countervailing evidence regarding preemption and causation. Further, the State did not have constructive notice of the conversion.

[¶20]Purdue's submission of exhibits did not give the State constructive notice that the Motion would be converted into a motion for summary judgment. Purdue submitted six exhibits with its Motion, comprising its FDA-approved prescription drug labels (Index # 14-16), the FDA's responses to two citizen petitions (Index # 17-18), and a printout from the FDA's website about abuse deterrent opioid analgesics (Index # 19). Purdue expressly requested that the District Court take judicial notice of and consider its submissions without converting its Motion. Index # 13, ¶17. Relying on Riemers v. State ex rel. Univ. of N.D., 739 N.W.2d 248, 252 (N.D. App. 2007) and Miller v. Redwood Toxicology Lab., Inc., 688 F.3d 928, 931 (8th Cir. 2012), Purdue asked the District Court to consider its exhibits as materials embraced by the pleadings without converting its Motion into a motion for summary judgment, stating that its exhibits 1 to 6 are "all … cited by the State in the Complaint by name and reference." Id. at ¶17, n.9; See also App. pp. 27, 33-39, 53.

[¶21]Additionally, the State did not have constructive notice because Rule 12(d) is not absolute. A motion to dismiss is not automatically converted into a motion for summary judgment when a party submits additional material in support of its motion. Missouri ex rel. Nixon v. Coeur D'Alene Tribe, 164 F.3d 1102, 1107 (8th Cir.1999), cert. denied, 527 U.S. 1039 (1999). Materials that are embraced by the pleadings, that are part

of the public record, or that do not contradict the complaint, may be considered by a court when it decides a Rule 12(b)(6) motion to dismiss. Riemers, 2007 ND App. 4, ¶8; Coeur D'Alene Tribe, 164 F.3d at 1107. The documents submitted by Purdue in support of its Motion are public records, do not contradict the Complaint and, according to Purdue, are embraced by the pleadings; therefore, the District Court was able to consider those materials without conversion. Id.; see App. pp. 25, 27, 33-39, 53; Index #13, ¶17.

[¶22]Purdue's submission does not constitute matters outside the pleadings. "Most courts … view matters outside the pleading as including any written or oral evidence in support of or in opposition to the pleading that provides some substantiation for and does not merely reiterate what is said in the pleadings." BJC Health Sys. v. Columbia Cas. Co., 348 F.3d 685, 687 (8th Cir. 2003) (internal citations and quotations omitted). Legal arguments made in briefs or by counsel do not constitute "matters outside the pleadings." Pryor v. Nat'l Collegiate Athletic Ass'n, 288 F.3d 548, 560 (3d Cir. 2002). "The material made pertinent by Rule 56 includes such things as depositions, answers to interrogatories, admissions on file, affidavits, and the like." State of Ohio v. Peterson, Lowry, Barber & Ross, 585 F.2d 454, 457 (10th Cir. 1978). Purdue's Motion was supported by legal argument and public documents that do not contradict the Complaint. In opposition, the State presented legal argument without offering matters outside the pleadings. The parties did not offer "matters outside the pleadings," and the State did not have constructive notice.

B. The District Court erred because it failed to provide the State a reasonable opportunity to present all material pertinent to a motion for summary judgment.

[¶23]The District Court erred because it deprived the State of an opportunity to conduct reasonable discovery and present countervailing evidence regarding preemption and causation. Notification is only one of the requirements of Rule 12(d). N.D.R.Civ.P.

12(d) requires that, "[a]ll parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." N.D.R.Civ.P. 12(d); Livingood v. Meece, 477 N.W.2d 183, 187 (N.D. 1991) ("when [conversion] occurs, each party must be allowed a reasonable opportunity to present material pertinent to the motion under Rule 56"). The term "reasonable opportunity" requires that the opposing party be given the right "to file counter affidavits or pursue reasonable discovery." Gay, 761 F.2d at 177 (citing Johnson v. RAC Corp., 491 F.2d at 513). The failure to provide notice deprived the State of the opportunity to present relevant material in opposition to a motion for summary judgment.

[¶24]Furthermore, the District Court's failure to provide notice that it would treat Purdue's Motion as a motion for summary judgment prevented the State from seeking a continuance under N.D.R. Civ. P. 56(f) by showing "by affidavit that, for specified reasons, it cannot present facts essential to justify its opposition" to Purdue's Motion. N.D.R.Civ.P. 56(f); American Home Prods Corp., 199 F.R.D. at 632-33. In American Home Prods Corp., the court observed that because there had not been "strict compliance" with the notice requirement for conversion, (as is the case here), the plaintiff was unable to properly procure and submit an affidavit to support a motion for a continuance pursuant to Rule 56(f). Id. Similarly, because the State was without notice that the District Court was converting Purdue's Motion, the State was unable to procure an affidavit and request a continuance that would allow the State to properly resist a motion for summary judgment.

C. The District Court abused its discretion when it converted and granted Purdue's Motion at the current stage of the proceedings and without providing the State a reasonable opportunity to conduct discovery.

[¶25]The District Court abused its discretion by converting and granting Purdue's Motion. It is not appropriate to convert a motion to dismiss into a motion for summary judgment, and to grant the motion, where the parties have not had an opportunity for

reasonable discovery. E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc., 637 F.3d 435, 448 (4th Cir. 2011); see also, Aho v. Maragos, 1998 ND 107, ¶4, 579 N.W.2d 165 (summary judgment under Rule 56 is only appropriate if the nonmoving party has had a full opportunity to conduct discovery to develop information essential to its position). "Once notified, a party must be afforded a 'reasonable opportunity for discovery' before a Rule 12(b)(6) motion may be converted and summary judgment granted." Gay, 761 F.2d at 177. In Gay, where the plaintiff had barely begun discovery, the Court held that the lack of a reasonable opportunity for discovery made conversion of the Rule 12(b)(6) motion "wholly inappropriate." Id. at 177-78. Where a plaintiff is not afforded an opportunity for reasonable discovery, a court's treatment of a motion to dismiss as a motion for summary judgment constitutes abuse of discretion. Id. at 178. In this case, discovery has not started and Purdue has yet to file an answer to the Complaint. The State did not have the opportunity to conduct discovery to develop its case and defend against a motion for summary judgment. Therefore, the District Court's decision to convert and grant Purdue's Motion was "wholly inappropriate" and an abuse of discretion. Id. at 177-78.

II. The District Court erred when it concluded that the State's claims are preempted by federal law.

[¶26]The District Court erred when it adopted Purdue's argument that the State's claims are preempted by federal law based on impossibility preemption. Under the Supremacy Clause, U.S. Const. art. VI, the laws of the United States are the "supreme laws of the land" and state law that conflicts with federal law is without effect. FreeEats.com, Inc., 2006 ND 84, ¶19 (citing Home of Economy v. Burlington N. Santa Fe R.R., 2005 ND 74, ¶5, 694 N.W.2d 840). "[F]ederal preemption analysis includes three components: express preemption, field preemption and conflict preemption." Id. There are two types of

conflict preemption: impossibility and obstruction preemption. Id. Impossibility preemption arises when it is impossible to comply with both federal and state regulations, and it is a demanding defense. Wyeth, 555 U.S. at 573; Merck, 139 S. Ct. at 1678. The "'possibility of impossibility [is] not enough.'" Merck, 139 S.Ct at 1678 (quoting PLIVA, Inc. v. Mensing, 564 U. S. 604, 625, n. 8, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011)). Pre-emption "is ordinarily not to be implied absent 'actual conflict.'" English v. General Elec. Co., 496 U.S. 72, 90, 110 S.Ct. 2270 (1990).

[¶27]The analysis of a preemption claim begins with the "basic assumption that Congress did not intend to displace state law." FreeEats.com, 2006 ND 84, ¶20. The protection of consumers against deceptive business practices is an area traditionally regulated by the states, and there is a strong presumption against conflict preemption in cases involving the historic police powers of the States. See Wyeth, 555 U.S. at 565; FreeEats.com, 2006 ND 84, ¶21; California v. ARC Am. Corp., 490 U.S. 93, 101, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989). Congress did not intend to preempt state consumer-protection laws in cases involving prescription-drug labeling when it enacted the FDCA, 21 U.S.C. 9. Wyeth, 555 U.S. at 574-575. State law complements federal drug regulation and serves as an additional "layer of consumer protection." Id. at 579. In summarizing its holding in Wyeth, the court in Merck said:

> [W]e found nothing within that history to indicate that the FDA's power to approve or to disapprove labeling changes, by itself, pre-empts state law.
>
> Rather, we concluded that Congress enacted the FDCA "to bolster consumer protection against harmful products;" that Congress provided no "*federal* remedy for consumers harmed by unsafe or ineffective drugs"; that Congress was "awar[e] of the prevalence of state tort litigation;" and that, whether Congress' general purpose was to protect consumers, to provide safety-related incentives to manufacturers, or both, language, history, and purpose all indicate that "Congress did not intend FDA oversight to be the

> exclusive means of ensuring drug safety and effectiveness." *Id.,* at 574–575. 129 S.Ct. 1187 (emphasis added). See also *id.,* at 574 ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history").

139 S.Ct. at 1677. The FDCA does not preempt state consumer protection laws. Because this is a consumer protection action, the strong presumption against preemption applies in this case. Purdue bears the burden of proving preemption. FreeEats.com, 2006 ND 84, ¶22. Purdue failed to satisfy its burden.

A. There is no actual conflict between state law requirements and the FDCA or FDA-approved product labeling.

[¶28]There is no impossibility preemption because Purdue's unlawful conduct is not required by the FDCA or FDA-approved labeling. Impossibility preemption occurs when the relevant federal and state laws "irreconcilably conflic[t]." Merck, 139 S.Ct. at 1678. The State's claims are not premised on inadequate labeling, off-label marketing, or failure to warn. The State does not seek to compel Purdue to stop selling its opioids, does not seek to enforce FDA regulations, and does not assert claims that conflict with FDA regulatory activity. "The mere existence of a federal regulatory or enforcement scheme … does not by itself imply pre-emption of state remedies." General Elec. Co., 496 U.S. at 87. The FDA's approval of opioids for use in the management of pain does not conflict with the State's ability to protect its residents from Purdue's deceptive acts or practices concerning the marketing and sale of opioids.

[¶29]The State's claims are not based on the content of Purdue's labels. App. p. 53. Rather, the State alleges violations of the State's consumer fraud law as a result of the marketing conduct of Purdue and its pharmaceutical sales representatives. App. pp. 8-9. Purdue disseminated core marketing messages that trivialized, misrepresented and

undercut the warnings contained in its labels. App. pp. 56-63. Federal law does not require or authorize Purdue to deceptively market its opioids. On the contrary, the FDCA and its implementing regulations prohibit the use of false and misleading representations in the marketing of a drug. 21 U.S.C. §§ 331, 352, 355. Because neither the FDCA nor FDA-approved labeling require the unlawful conduct prohibited by the Consumer Fraud Law and the Nuisance Law, there is no conflict between state and federal law.

[¶30]The FDA's approval of a drug label does not conflict with state law regulating marketing of the drug. "[L]abeling and advertising are separate actions." Norabuena v. Medtronic, Inc., 2017 Ill.App (1st) 162928, 86 N.E.3d 1198, 1208 (2017). As Judge Polster stated in the National Prescription Opiate MDL in the Northern District of Ohio (in which Purdue is one of the defendant manufacturers): "Despite Manufacturers' contention to the contrary, the Court has *never* held that the term 'labeling' is so broad it encompasses the massive marketing campaign alleged here." In Re National Prescription Opiate Litigation, 117-md-02804-DAP, page 8 (emphasis in original). "Initial approval of a label amounts to a finding by the FDA that the label is safe for purposes of gaining federal approval to market the drug." Wyeth, 555 U.S. at 592 (Thomas, J., concurring). "It does not represent a finding that the drug, as labeled, can never be deemed unsafe by later federal action, or as in this case, the application of state law." Id. "[T]he FDA has not approved … advertisements either explicitly or implicitly by approving the statements on its label." Prohias v. Pfizer, Inc., 490 F. Supp.2d 1228, 1233 (S.D.Fla.2007). Labels do not preclude fraud claims based on misrepresentations of the label information. City of Chicago v. Purdue Pharma L.P., N.D.Ill. No. 14 C 4361, 2015 WL 2208423, at *10 (May 8, 2015).

[¶31]Purdue's labels do not justify or excuse its deceptive marketing. Purdue's

disclosure of the risks associated with its opioids on the labels does not authorize it to misrepresent those risks in its marketing. See State ex rel. Wilson v. Ortho-McNeil-Janssen Pharmaceuticals, Inc. 414 S.C. 33, 777 S.E.2d 176, 187-88 (2015) (holding defendants liable for misrepresenting a drug's risks to prescribers while updating the label to include a warning of the risks). The FDA does not require labeling "so that manufacturers can mislead consumers and then rely on the [label] to correct those misrepresentations and provide a shield for liability for the deception." Reid v. Johnson & Johnson, 780 F.3d 952, 958-59 (9th Cir. 2015). Deceptive marketing exists separate from labeling. Therefore, the FDA's approval of Purdue's labels does not prevent or conflict with state law claims of deceptive marketing and the resulting public nuisance.

[¶32]The FDA-approved labels simply authorize Purdue to market and sell its opioids for the management of pain. Index # 14, 15. "[T]here is no evidence the FDA approved or endorsed Manufacturers' campaign message that the risk of addiction is manageable for patients with a history of addiction problems, or that signs of opioid addiction are actually pseudoaddiction ameliorated with *more* opioids." In Re National Prescription Opiate Litigation, 117-md-02804-DAP, p. 8-9 (emphasis in original). A majority of Purdue's marketing, including unbranded advertising and detailing, was neither approved nor reviewed by the FDA. App. pp. 16-21. The FDA's approval of Purdue's opioids for the management of pain does not conflict with state law prohibiting Purdue from falsely and deceptively: (1) representing that its opioids improve function and quality of life; (2) minimizing the risks associated with addiction, dependence, and tolerance; (3) inventing "pseudoaddiction" to encourage prescribers to ignore signs of addiction; (4) trivializing the difficulties associated with withdrawal; (5) encouraging escalating dosages

while omitting risks; (6) misrepresenting the effectiveness of mitigation tools; (7) exaggerating the risks of alternative treatment options; (8) marketing abuse-deterrent opioids as safer; and (9) promoting OxyContin as effectively providing 12 hours of pain relief. App. pp. 21-38. Purdue's false and deceptive representations about its opioids are not contained in or supported by its labels. Id.

[¶33]Impossibility preemption can only exist when federal law requires conduct that state law prohibits, and *vice versa*. See Merck, 139 S.Ct. at 1679. The U.S. Supreme Court has refused to find impossibility preemption where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit. Merck, 139 S.Ct. at 1679. For example, Purdue's FDA-approved labels include strong black box warnings regarding addiction. Index # 14. However, in its marketing, Purdue: (1) trivialized, misrepresented and omitted the true risk of addiction; (2) falsely claimed that addiction is unlikely to develop when opioids are prescribed, (as opposed to obtained illicitly); and (3) mischaracterized the risk of addiction as low, rare, and limited to extreme cases, including misrepresenting that "bad apple" patients, and not opioids, are the source of addiction. App. pp. 22-26. The FDA's approval of Opioid Analgesic REMS does not require Purdue to misrepresent the effectiveness of screening and risk mitigation tools, particularly since the 2016 CDC Guideline confirms that there are no studies assessing the effectiveness of risk mitigation strategies. App. pp. 28-29. Purdue's unsubstantiated claim that long-term use of opioids for pain relief improves patient functions and gives pain patients a better quality of life, is not required by federal law when such representations are not found in or supported by the labels and the FDA has made it clear that there is no support in the scientific literature for such claims. App. pp. 34-35.

[¶34]The District Court concluded that "the marketing practices of Purdue that the State claims are improper were consistent with the FDA-approved product labeling." App. p. 78. This completely ignores the allegations in the Complaint. The State alleges that Purdue's deceptive marketing: (1) contradicted the FDA-approved labels, (2) concerned information and concepts that the FDA had neither reviewed nor approved, and (3) improperly misrepresented, omitted or minimized the FDA-recognized risks and dangers of Purdue's opioids. App. pp. 19, 21-38. Purdue failed to show an actual conflict between federal and state law that establishes preemption. Merck, 139 S.Ct. at 1678. Without actual conflict, it is not impossible for Purdue to comply with both state and federal law. At a minimum, a genuine dispute of facts exist regarding whether the representations and claims made by Purdue were approved and required by the FDA.

B. The District Court erred when it concluded that it was impossible for Purdue to comply with state law because the FDA would not have approved changes to Purdue's labels.

[¶35]The District Court erred when it concluded that Purdue cannot comply with State law because the FDA would not approve changes to Purdue's labels. A state law claim that a drug manufacturer failed to warn consumers of a risk associated with using a drug, in its label, is preempted where there is "clear evidence" that the FDA would not have approved a change to the drug's label to include a warning of such risk. Wyeth, 555 U.S. at 571. The State, however, is not alleging that Purdue failed to include a particular or adequate warning in its labels, and the State is not asking Purdue to change or add to its labels. App. pp. 67-69; see In Re National Prescription Opiate Litigation, 117-md-02804-DAP at p. 8 ("Plaintiffs simply have not proposed any label changes"). Rather, the State alleges Purdue, in its marketing, systematically and continuously made false and deceptive

representations regarding the risks and benefits associated with long-term opioid use, contrary to the label. App. p. 8.

[¶36]To establish impossibility preemption based on label changes, Purdue must show that complying with state law requires Purdue to change or add to its labels, and demonstrate that it would be impossible for Purdue to do so because of federal law. Merck, 139 S.Ct. at 1678. Purdue must provide "clear evidence that the FDA would not have approved a change to [the drug's] label" that is required by state law. Wyeth, 555 U.S. at 571. Purdue did not provide such "clear evidence."

[¶37]Purdue's preemption argument fails because the State has not requested a label change, and Purdue has not shown that compliance with state law requires Purdue to change its labels. Purdue is not required to change the label to refrain from making false or deceptive statements that conflict with or undermine current statements in the labels or that are absent from the labels. For example, no label change is required for Purdue to accurately represent the risk of opioid addiction in its marketing consistent with the labels' "black box" warning. App. pp. 22-26. No labeling change is required for Purdue to present a true comparison between the risks and benefits of opioids and competing products like NSAIDs (Nonsteroidal Anti-inflammatory Drugs), when OxyContin's label expressly limits its indication for pain "for which alternative treatment options are inadequate." App. p. 36; Index # 14, page 1. No labeling change is required for Purdue to truthfully represent, in its marketing, that OxyContin has a ceiling dose that is imposed by adverse reactions, and that an increase in dosage requires close monitoring for respiratory depression. App. pp. 30-32; Index # 14 at §2.1. The State is not demanding that Purdue include a maximum dose in its labels. App. pp. 30-32. At a minimum, a genuine dispute of fact exists regarding

whether Purdue is required to change its labels to comply with state law.

[¶38]Assuming, *arguendo*, that state law requires Purdue to change its labels, then Purdue, to establish preemption, is required to show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed Purdue that the FDA would not approve changing the drug's label to include that warning." Merck, 139 S.Ct. at 1668. "[T]he mere fact that the FDA approved [a drug's] label does not establish that it would have prohibited a change to the [label]." Wyeth, 555 U.S. at 751. [A]bsent clear evidence that the FDA would not have approved a change to [the] label, [the Court] will not conclude that it was impossible for [the drug manufacturer] to comply with both federal and state requirements." Merck, 139 S.Ct. at 1677. The Merck court stated:

> 'Clear evidence' is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning.

Id. at 1672.

[¶39]Purdue did not present such "clear evidence" to the District Court. Instead of meeting their burden of production, Purdue disingenuously misconstrued the nature of the State's Complaint and advanced their argument premised upon hypothetical or potential conflicts. Index # 13, ¶18, Index # 37, ¶12. Hypothetical or potential conflicts are insufficient to satisfy their high burden for impossibility preemption. Merck, 139 S.Ct. at 1678. The FDA did not reject a request from Purdue to change the labels. Assuming that a label change was necessary to comply with state law, Purdue did not request such a change and did not provide the FDA with any knowledge, data and information that would support such a change. Therefore, Purdue did not present "clear evidence" that the FDA would have rejected a labeling change.

[¶40]A denial made to a third party who possessed and presented limited evidence that is different than, and inferior to, information Purdue has in its possession, is not "clear evidence" that the FDA would have rejected a request from Purdue. It has "remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." Merck, 139 S.Ct. at 1677. Also, as Merck stated: "[T]he meaning and scope of … [a] decision [to reject an application to change a drug label] might depend on what information the FDA had before it." Id. at 1680. Purdue has not demonstrated that the changes it alleges would be required by state law are the same as the changes requested by third parties in the FDA documents that Purdue submitted with its memorandum of law in support of its Motion. Index #13 at ¶21; Index # 17, 18. Purdue possesses knowledge and data about the benefits, effectiveness, and the adverse health and addictive effects of opioids, including scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths. App. pp. 36-37, 40, 52-53. Purdue did not show that it presented all this information to the FDA. Index # 13. Purdue did not show that it requested a change to its label, and that it presented all, if any, relevant information and data to the FDA, as required by Merck. Index # 13; Merck, 139 S.Ct. at 1668-1678. Therefore, its preemption argument fails.

[¶41]Purdue bears the burden of establishing preemption. FreeEats.com, Inc., 2006 ND 84 at ¶22. Once the Court converted the motion to a summary judgment, Purdue's burden changed, and Purdue was obligated to demonstrate, in accordance with the requirements of Rule 56, that there exist no genuine issue as to any material facts and that Purdue is entitled to judgment as a matter of law. Golden v. SM Energy Co., 2013 ND 17 at ¶7; N.D.RCiv. P 56. Merck sets a high standard for impossibility preemption that Purdue

failed to meet. 139 S.Ct. at 1678-1679. The documents and arguments offered by Purdue are not sufficient to establish a preemption defense. Id. at 1668. The existence of a hypothetical or potential conflict, created by Purdue's mischaracterization of the State's Complaint, is insufficient to warrant the preemption of state statutes. Id. at 1679. Therefore, the District Court erred when it held that the State's claims are preempted. [3]

III. The District Court erred when it concluded that the State is required to plead and prove causation under the Consumer Fraud Law.

[¶42]The District Court erred when it concluded that the State must plead and prove causation to prevail in an action under the Consumer Fraud Law. The plain language of N.D.C.C. § 51-15-02 provides that neither reliance nor loss are required. This statutory language, together with the public policy underlying the Consumer Fraud Law, demands a conclusion that the State is not required to plead and prove causation to obtain the remedies available under the Consumer Fraud Law, including restitution or disgorgement. The District Court's ruling, which is contrary to long-standing North Dakota and other states' consumer protection laws and enforcement, eviscerates the Consumer Fraud Law that is intended to protect the citizens of North Dakota.

A. The State is not required to plead and prove causation to prevail in a consumer protection action.

[¶43]The State is not required to plead or prove reliance or loss to prevail in a cause of action under the Consumer Fraud Law. N.D.C.C. §51-15-02 provides that a practice is unlawful "whether or not any person has in fact been misled, deceived, or damaged" by the unlawful conduct. N.D.C.C. §51-15-02 (emphasis added). N.D.C.C. § 51-15-02 does

[3] "*North Dakota* is, by leaps and bounds, an outlier on the question of preemption." In Re National Prescription Opiate Litigation, 117-md-02804-DAP, page 9 (N.D.Ohio, Sept. 3, 2019)(emphasis in original)

not contain a requirement to prove causation. Id.; compare N.D.C.C. § 51-15-09. Liability is established without proof of reliance or injury. See also State ex rel. Brady v. Publishers Clearing House, 787 A.2d 111, 116 (Del. Ch. 2001) (allegations of causation are not necessary to state a claim under the DCFA); Oliveira v. Amoco Oil Co., 201 Ill.2d 134, 776 N.E.2d 151, 160 (2002) ("[A]n action brought by the Attorney General under … [the Illinois Consumer Fraud Act] … does not require that 'any person has in fact been misled, deceived or damaged'").

[¶44]It is common that consumer protection statutes do not require a state to plead and prove causation, reliance, or injury. See, e.g., State v. Mandatory Poster Agency, Inc., 398 P.3d 1271, 1276, 199 Wash.App. 506, review denied, 404 P.3d 496 (2017) ("Unlike a private plaintiff under the CPA, the State is not required to prove causation or injury"); City of Chicago v. Purdue Pharma L.P., 211 F. Supp. 3d 1058, 1071 (N.D. Ill. 2016) ("The City need not allege injury or causation to state a claim under the [Illinois Consumer Fraud Act]"); State ex rel. Nixon v. Beer Nuts, Ltd., 29 S.W.3d 828, 837 (Mo. Ct. App. 2000) ("By providing a statutory cause of action, the Act eliminates the need for the Attorney General to prove intent to defraud or reliance"); Nygaard v. Sioux Valley Hosp. & Health Syst, 731 N.W.2d 184, 196-97 (S.D. 2007) ("SDCL 37–24–6(1) makes these violations actionable 'regardless of whether any person has in fact been misled, deceived, or damaged thereby'").

[¶45]Relief is available under the Consumer Fraud Law upon a finding of a violation. Where a violation of N.D.C.C. § 51-15-02 has been proven, equitable relief is available, including: injunctive relief under N.D.C.C. § 51-15-07 (to prohibit a person from continuing in or engaging in the unlawful conduct); recovery of costs and attorney fees

under N.D.C.C. § 51-15-10 (shall be awarded to the attorney general in any action brought); and civil penalties under N.D.C.C. § 51-15-11 (may be assessed for each violation). The District Court did not consider or address these remedies sought by the State, which are all awarded based on the existence of a violation. The District Court erred in dismissing the State's claim for Consumer Fraud based on failure to plead causation.

B. Individualized allegations or proof of reliance or loss are not required for an order of restitution or disgorgement.

[¶46]The District Court, by ignoring and conflating the marked legal differences between damages and restitution or disgorgement, erred when it concluded that the State is seeking damages and must plead and prove causation to obtain an order for restitution or disgorgement. App. pp. 85-92. In addition to statutory and equitable remedies in the form of injunctive relief, civil penalties, and attorney fees and costs, the Consumer Fraud Law allows the court to order such equitable relief as "may be necessary" to prevent the unlawful practice or restore the status quo. N.D.C.C. §§ 51-15-07; 51-15-10; 51-15-11. In pertinent part, N.D.C.C. § 51-15-07 provides:

> The court may make an order or judgment as may be necessary to prevent the use or employment by a person of any unlawful practices, or which may be necessary to restore to any person in interest any money, or property that may have been acquired by means of any practice … declared to be unlawful….

N.D.C.C. §51-15-07.

[¶47]Equitable remedies include restitution or disgorgement of any sales proceeds and profits Purdue obtained from unlawful conduct. See, e.g., United States v. Universal Mgmt. Servs., Inc., 191 F.3d 750, 760-61 (6th Cir.1999) (Restitution and disgorgement are part of a court's traditional equitable authority); FTC v. Gem Merch. Corp., 87 F.3d 466, 469 (11th Cir.1996) ("Among the equitable powers of a court is the power to grant

restitution and disgorgement"). Such equitable remedies are not considered damages. See, e.g., Jaffe v. Cranford Ins. Co., 168 Cal.App.3d 930, 935, 214 Cal.Rptr. 567 (1985) (restitution is not damages, because it is restitutionary rather than compensatory in nature); O'Neill Investigations v. Ill. Emp. Ins., Etc., 636 P.2d 1170 (Alaska 1981) (a claim for the restoration of money acquired from consumers is not considered damages); Haines v. St. Paul Fire & Marine Ins. Co., 428 F.Supp. 435, 439-442 (D.Md.1977) (a judgment requiring disgorgement of attorneys' fees is not considered "damages"). The State's claim for restitution and disgorgement are restitutionary, not compensatory, and are based on Purdue's conduct and gain, not proof of individual damages. The State is not seeking indirect damages under the Consumer Fraud Law that would turn on a conjectural analysis of cause and effect, such as increased costs of social services, expenses for law enforcement, fire and ambulance, and other speculative financial burdens on the state and local governments arising out of increased opioid addiction. See App. pp. 56-63.

[¶48]The Consumer Fraud Law is like many consumer protection laws that contain a clear distinction between law enforcement actions and private civil actions. An individual, who brings a claim under a consumer protection law's private right of action, may be required to plead and prove causation. See, e.g., Nygaard v. Sioux Valley Hosp. & Health Syst., 731 N.W.2d at 196-97 ("Patients' civil actions are governed by SDCL 37–24–31, which specifically requires a causal connection between the alleged violation and the damages suffered."). Unlike a private litigant, the State can bring a law enforcement action in the public interest, and need not demonstrate that a defendant's actions proximately harmed the State in order to bring the action and seek injunctive and other relief as authorized, including restitution and disgorgement. People ex rel. Madigan v.

United Constr. of Am. Inc., 367 Ill.Dec. 79, 981 N.E.2d 404, 411 (Ill. App. Ct. 2012); see also, City of New Haven v. Purdue Pharma, L.P., et al.,, Docket No. X07 HHD CV 17 6086134 (Conn. Super. Ct., Hartford, January 8, 2019) (Index # 41) ("Enforcement claims are superior … because individual damages aren't at issue …[and] they don't require the same causation analysis as ordinary individual lawsuits for compensatory damages"); State ex rel. Wilson v. Ortho-McNeil-Janssen Pharm., Inc. 777 S.E.2d at 193 ("while a private party … action requires the traditional showing of an injury, an action brought by the Attorney General on behalf of the State contains no actual injury element).

[¶49]The District Court relied on Ackre v. Chapman & Chapman, P.C., 2010 ND 167, 788 N.W.2d 344 when it concluded that proof of causation is required for the State to obtain restitution and disgorgement under the Consumer Fraud Law. However, Ackre was a case brought under the private right of action provided by N.D.C.C. §51-15-09. Ackre, 2010 ND 167 at ¶23. The court in Ackre held that a private plaintiff is required to show that the putatively illegal action caused some threatened or actual injury to his or her legal rights and interests to establish standing to bring an action. Id. Ackre is distinguishable and does not apply to this case. The State has express standing, by statute, to enforce the Consumer Fraud Law in the public interest. N.D.C.C. §51-15-07; see also, People ex rel. Madigan v. United Constr. of Am. Inc., 367 Ill.Dec. 79, 981 N.E.2d 404, 411 (Ill. App. Ct. 2012)(Private individuals have standing to litigate a violation only if they have actual damages … but the Attorney General may litigate a violation and seek injunctive and other relief without that same requirement"). The State seeks remedies that vindicate the public interest as a whole, not individual damages. App. pp. 67-69. Private parties, like the plaintiff in Ackre, are not authorized to bring enforcement actions to vindicate the public

interest, and must prove some threatened or actual injury to his or her legal rights and interests. 2010 ND 167 at ¶23. Ackre does not hold that the State is required to plead and prove threatened or actual injury to prevail under the Consumer Fraud Law. Id.

[¶50]The statutory language in N.D.C.C. 51-15-07 does not require individualized proof of reliance or loss for the State to obtain restitution or disgorgement. N.D.C.C. §51-15-07 permits a trial court to enter an order or judgment "which may be necessary to restore to any person in interest any money, or property that may have been acquired by means of any practice … declared to be unlawful." N.D.C.C. ¶51-15-07 (emphasis added). A statute's language must be interpreted in context, and this Court attempts to give "meaning and effect to every word, phrase, and sentence." Wheeler v. Gardner, 2006 ND 24, ¶11, 708 N.W.2d 908 (citing N.D.C.C. §§ 1–02–03, 1–02–38(2)). Also, consumer protection statutes are remedial in nature, and therefore must be liberally construed in favor of protecting consumers. State ex rel. Spaeth v. Eddy Furniture Co., 386 N.W.2d 901, 903 (N.D. 1986). The legislature's use of "may have been" indicates that it did not intend to require the State demonstrate an actual causal link. Compare N.D.C.C. §51-15-09 ("any person who has acquired any moneys or property by means of").

[¶51]Other state courts construe the phrase "may have been acquired by means of any [unlawful] practice" in consumer protection statutes to mean that proof of causation is not required. California courts hold that the language is "unquestionably broad enough to authorize a trial court to order restitution without requiring the often impossible showing of the individual's lack of knowledge of the fraudulent practice in each transaction." Fletcher v. Sec. Pac. Nat'l Bank, 23 Cal.3d 442, 450, 591 P.2d 51, 153 Cal.Rptr. 28 (1979). The Fletcher court stated:

> By this language the Legislature obviously intended to vest the trial court with broad authority to fashion a remedy that would effectively "prevent the use . . . of any practices which violate (the) chapter (proscribing unfair trade practices)" and deter the defendant, and similar entities, from engaging in such practices in the future. The requirement that a wrongdoing entity disgorge improperly obtained moneys surely serves as the prescribed strong deterrent.

Id. The "'which may have been acquired standard' is 'substantially less stringent than a reliance or 'but for' causation test.'" Thieme v. Cobb, 2016 WL 3648531 *7 (N.D. Cal. July 8, 2016) (citing Sevidal v. Target Corp., 189 Cal. App. 4th 905, 924 (2010)). "This language, construed in light of the 'concern that wrongdoers not retain the benefits of their misconduct' … has led courts repeatedly and consistently to hold that relief … is available without individualized proof of deception, reliance and injury." In re Tobacco II Cases, 46 Cal.4th at 320. Idaho and Washington courts, when interpreting similar statutory language, hold that equitable relief and restitution orders apply to all aggrieved consumers and are not limited to consumers who testify at trial. State ex rel. Kidwell v. Master Distributors, Inc., 101 Idaho 447, 456, 615 P.2d 116, 125 (1980); State v. Ralph Williams' North West Chrysler Plymouth, Inc., 87 Wash.2d 298, 553 P.2d 423, 439 (1976). The statutory language of N.D.C.C. § 51-15-07 should be construed not to require the State to plead and prove causation to obtain restitution or disgorgement.

[¶52]Public policy and the policy considerations underpinning the Consumer Fraud Law support a conclusion that causation is not a required element of a consumer fraud action. Actions seeking injunctive relief and consumer restitution are brought in the public interest to restore the status quo. State v. Ralph Williams' NW Chrysler Plymouth, Inc., 82 Wash.2d 265, 510 P.2d 233, 241 (1973). The public purpose to be served by the Consumer Fraud Law can be accomplished effectively only by recognizing the authority of the State

to intervene on behalf of all consumers similarly affected by the fraudulent sales tactics of sellers and to obtain relief on behalf of such consumers. Kugler v. Romain, 58 N.J. 522, 279 A.2d 640, 654 (1971); see, also, Ralph Williams' NW Chrysler Plymouth, Inc., 553 P.2d at 439 (to limit restitution to the consumers who testified at trial would unduly complicate consumer protection trials). To require the State to prove causation to recover restitution on behalf of consumers affected by or subjected to consumer fraud would eviscerate the Consumer Fraud Law.

[¶53]Equitable remedies of restitution and disgorgement are not only sought to compensate for loss, but to also make violations of the law unprofitable so as to deter and prevent the future use or employment of unlawful practices. Restitution orders are appropriate and necessary as a part of equitable relief. Ralph Williams' NW Chrysler Plymouth, Inc., 510 P.2d at 241. "The recovery of that which has been illegally acquired and which has given rise to the necessity for the injunctive relief not only restores the property to the party but insures future compliance where it is assured a wrongdoer is compelled to restore illegal gains." Id. Restitution can be ordered, in the absence of individualized proof of lack of knowledge, to preclude an entity which has engaged in an unlawful trade practice from improperly profiting from its wrongdoing. Fletcher, 23 Cal.3d at 446. Injunctive relief is only a partial remedy since it does not correct the consequences of past conduct. Id. at 451 (quoting S.E.C. v. Golconda Mining Co., 327 F.Supp. 257, 259-260 (S.D.N.Y. 1971). To permit the retention of illicit profits, because reliance or injury is not proven, impairs the full impact of the deterrent force that is essential if adequate enforcement of the law is to be achieved. Id. "'One requirement of such enforcement is a basic policy that those who have engaged in proscribed conduct surrender all profits

flowing therefrom.'" Id. Restitution and disgorgement are necessary, in addition to injunctive relief, to restore the status quo, correct the consequences of Purdue's past conduct, and deter future unlawful conduct, and is justified through proof of the conduct.

[¶54]Proof of Purdue's conduct justifies an order for restitution and disgorgement without proof of causation. The State seeks these remedies because of Purdue's unlawful conduct and the resulting financial gain, rather than threatened or actual injury to the State or its consumers. See, e.g., In re Avandia Mktg, Sales Practices and Prod. Liab. Action, 2011 WL 5105503 *5 (E.D.Pa, October 26, 2011) (Because restitution focuses on the defendants' wrongful gains, rather than the purchasers' losses, restitution can be awarded without individualized proof of deception or loss). Evidence of Purdue's marketing scheme and the effect it has had on the prescribing and use of opioids can justify an award of restitution and disgorgement without the necessity of hearing additional evidence. See Ralph Williams' NW Chrysler Plymouth, Inc., 553 P.2d at 439 ("proof that the defendants have acquired possession of and are holding property of a customer unlawfully can be reasonably expected as part of the proof of the allegations of unfair and deceptive acts and practices … [and] [w]here these facts are shown, the court can order restitution without the necessity of hearing additional evidence.").

[¶55]All consumers, prescribers and payors were exposed to Purdue's deceptive marketing scheme, and should be presumed to have relied on Purdue's deceptive marketing message, to varying degrees. See, e.g., Tourgeman v. Collins Fin. Servs., Inc., 2011 WL 5025152 (U.S. Dist. S.D. Cal., October 21, 2011) ("Because they were exposed to the misrepresentation, any money … 'may have been acquired by means of' Defendants' misidentification" and the "Court need not inquire into whether [class members] would

have paid money to Defendants but for Defendants' misidentification."). "Once the court finds that a violation of the Act has occurred or is about to occur, irreparable harm and harm to the public are presumed." State ex rel. Nixon v. Beer Nuts, Ltd., 29 S.W.3d at 837-38. All sales Purdue made while engaged in its deceptive marketing scheme are unlawful and tainted. App. pp. 9-10, 15, 40-41. Even if every individual opioid sale did not contribute to the opioid crisis, every sale was made in violation of the Consumer Fraud Law. Index # 34, ¶80. Purdue exposed every consumer, prescriber, and payor to Purdue's core marketing messages through advertisements, branded and unbranded marketing materials, publications, pamphlets, videos, medical journals, literature, guidelines, conferences, educational programs, CMEs, research, outreach, programs and materials from patient and professional organizations. App. pp. 10, 16-21. Consumers, prescribers and payors were affected by Purdue's conduct because consumers and prescribers were deprived of the chance to exercise informed judgment. App. pp. 15-21.

[¶56]The Consumer Fraud Law was enacted to allow the State, in the public interest, to enjoin consumer fraud and seek recovery for all consumers affected, independent of proof of reliance, to restore the status quo and prevent a defendant from benefiting from consumer fraud. A causation requirement will obstruct the State's ability to effectively prevent and prosecute consumer fraud.

IV. The District Court erred when it determined that the public nuisance statute does not apply to conduct involving the sale of goods.

[¶57]The District Court erred when it determined that North Dakota's nuisance law does not apply to cases involving the sale of goods. The plain statutory language of the Nuisance Law, N.D.C.C. §42-01-01 *et seq.*, does not exclude conduct involving the sale of goods. N.D.C.C. § 42-01-01 defines nuisance as:

> A nuisance consists in unlawfully doing an act or omitting to perform a duty, which act or omission:
>
> 1. Annoys, injures, or endangers the comfort, repose, health, or safety of others;
> 2. Offends decency;
> 3. Unlawfully interferes with, obstructs or tends to obstruct, or renders dangerous for passage, any lake, navigable river, bay, stream, canal, basin, public park, square, street, or highway; or
> 4. In any way renders other persons insecure in life or in the use of property.

N.D.C.C. § 42-01-01.

[¶58]Nuisance is broadly defined as "unlawfully doing an act or omitting to perform a duty," and does not exclude conduct involving the sale of goods. N.D.C.C. § 42-01-01. The District Court erred when it created an exception to the statute that the legislature easily could have enacted but did not. Miller v. Turner, 64 N.D. 463, 253 N.W. 437, 441 (1934); Walsvik v. Brandel, 298 N.W.2d 375, 377 (N.D. 1980). If the legislature wants to exclude conduct involving the sale of goods, it can do so anytime. The District Court should not displace the legislature's prerogative by substituting its opinion. The State's Complaint asks the District Court to apply the nuisance law, as it is, to Purdue's conduct; the State does not ask the District Court to expand the nuisance law. Although this Court has not expressly stated that the nuisance statute applies to conduct involving the sale of goods, it also has not determined that it does not. In fact, this Court has applied the nuisance law to cases involving the sale of goods or products.

[¶59]In its Order, the District Court relies on Tioga Pub. Sch. Dist. No. 15 of Williams Cty. State of N. Dakota v. United States Gypsum Co., 984 F.2d 915 (8th Cir. 1993), where the Eighth Circuit concluded that the North Dakota Supreme Court would not extend the nuisance doctrine to cases involving the sale of goods. App. pp. 94-96.

Tioga concerned a private nuisance claim to recover cost of removing asbestos-containing plaster used to coat school ceilings. 984 F.2d at 917. A federal district court decision interpreting North Dakota law is not binding upon North Dakota courts, but courts will "respect a federal district court opinion if it is persuasive and based upon sound reasoning." N.D. Fair Hous. Council, Inc. v. Peterson, 2001 ND 81, ¶19, ¶45, 625 N.W.2d 551.

[¶60]The decision in Tioga lacks sound reasoning in light of the statutory language of the Nuisance Law and this Court's precedent on nuisance. Therefore, the Tioga holding should be deemed unpersuasive. Tioga's narrow reading of the Nuisance Law contradicts the broad definition of "nuisance." N.D.C.C. § 42-01-01. Further, the Tioga court incorrectly concluded that "North Dakota cases applying the state's nuisance statute all appear to arise in the classic context of a landowner or other person in control of property conducting an activity on his land in such a manner as to interfere with the property rights of a neighbor." 984 F.2d at 920. Historically, North Dakota's law on nuisance has been applied to a wide variety of conduct, including conduct involving the sale of goods or services. See, e.g., State v. Kelly, 22 N.D. 5, 132 N.W. 223 (1911) (the defendant was convicted of maintaining a common nuisance for the sale of intoxicating liquors); City of Minot v. Central Ave. News, Inc., 308 N.W.2d 851 (N.D. 1981) (nuisance law may be used to enjoin the distribution of obscene material by a retail business).

[¶61]This Court has held that the Nuisance Law may be applied to protect consumers against unlawful business practices. In State ex rel. Burgum v. Hooker, 87 N.W.2d 337 (1957), this Court held that issuing loans in an unlawful manner was a public nuisance, and while quoting Stead v. Fortner, 255 Ill. at 478, said:

> The maintenance of the public health, morals, safety, and welfare is on a plane above mere pecuniary damage, although not susceptible of

> measurement in money, and to say that a court of equity may not enjoin a public nuisance because property rights are not involved would be to say that the state is unable to enforce the law or protect its citizens from public wrongs (citations omitted).

Id. at 340. Quoting State ex rel. Goff v. O'Neil, 205 Minn. 366, 286 N.W. 316, 319 (1939), this Court further stated:

> 'It would seem reasonable to conclude that the carrying on, advertising, and openly conducting a business so that every transaction thereof is an intentional violation of the usury law enacted for the protection of the large class of necessitous persons in every community is a public nuisance. Courts of high standing have so declared. * * * Commonwealth ex rel. Grauman v. Continental Company, Inc., 275 Ky. 238, 121 S.W.2d 49.'

Id. at 341-2. The Court in Hooker concluded that the defendant "indulged in unlawful practices constituting a public nuisance and a menace to public welfare," and that the "business of the defendants comes within the definition of a public nuisance." Id. The Court did not consider whether the defendant's conduct fell outside of the definition of nuisance simply because it involved the sale of a product. Id. Tioga should not be deemed persuasive where it conflicts with this Court's precedent. Additionally, Tioga also is distinguishable. Instead of involving a deceptive marketing scheme causing injury to the health and safety of the public, it involved a product liability claim. Tioga, 984 F.2d at 917.

[¶62]Other jurisdictions have denied Purdue's motions to dismiss the attorneys general's nuisance claim for the same conduct alleged in the State's complaint.[4] Courts in other jurisdictions have allowed public-nuisance action for injuries caused by a product if the facts establish that the design, manufacturing, marketing, or sale of the product

[4] See, e.g., Index # 35; State of Minnesota v. Purdue Pharma L.P., Ct. File No. 27-CV-18-10788 (Hennepin Cty. Ct., Minn. Jan. 4, 2019) (denying Purdue's motion to dismiss nuisance claim); Staubus v. Purdue Pharma, L.P., 2018 WL 3349093, Case No. 1-173-18 (Tenn. Cir. Ct. June 12, 2018) (same); But see State of Delaware v. Purdue Pharma L.P, 2019 WL 446382 *12, Case No. N18C-01-223 MMJ CCLD (Del. Super. Ct. February 4, 2019) ("In Delaware, public nuisance claims have not been recognized for products").

unreasonably interfered with a right common to the general public. See, e.g., Cincinnati v. Beretta U.S.A. Corp., 95 Ohio St.3d 416, 419, 768 N.E.2d 1136 (2002) (public nuisance law is not strictly limited to actions connected to real property or to statutory or regulatory violations involving public health or safety). Further, the Restatement (Second) of Torts provides a "broad definition" of public nuisance developed from common law nuisance. Restatement (Second) of Torts §821B(1). A public nuisance does not necessarily involve interference with the use and enjoyment of land. Id. at § 821B, comment h. An action for public nuisance is not limited to cases involving real property and property rights, and the District Court erred when it concluded that the Nuisance Law does not apply in this case because Purdue's conduct involves the sale of goods.

V. The District Court erred because it misapplied the standard for summary judgment.

[¶63]Once the District Court converted Purdue's Motion into a motion for summary judgment pursuant to N.D.R.Civ.P 12(d) the District Court erred when it did not properly apply the standard for summary judgment. The District Court, first, should have determined whether Purdue met its burden of production to demonstrate that there exists no genuine issue as to any material facts and, then, whether Purdue was entitled to judgment as a matter of law. Golden v. SM Energy Co., 2013 ND 17, ¶7; N.D.R.Civ.P 56. However, after referring to the standard for summary judgment, the District Court issued its Order, determining that "the State has failed to adequately plead causation" and that "the State has not adequately plead its cause of action against Purdue." App. pp. 73, 92, 96. Therefore, the District Court did not properly apply the standard for summary judgment. App. pp. 70-96; Golden v. SM Energy Co., 2013 ND 17, ¶7. Further, the District Court did not properly apply the rule N.D.R.Civ.P. 12(b)(6) standard. The District Court

did not construe the Complaint in a light most favorable to the State, and did not take the allegations of the complaint as true. See Rose v. United Equitable Ins. Co., 2001 ND 154, ¶10, 632 N.W.2d 429. Therefore, the District Court did not properly apply either standard to Purdue's Motion, and erred when it granted Purdue's motion to dismiss.

CONCLUSION

[¶64]For the reasons stated herein, the State respectfully requests that the Court reverse the District Court's decision and hold that: (1) the District Court erred and abused its discretion in converting and granting Purdue's Motion; (2) the State's claims are not preempted by federal law; (3) the State is not required to plead and prove causation to prevail on its claims under the Consumer Fraud Law; (4) the Nuisance Law applies to conduct involving the sale of goods; and (5) the District Court misapplied the standard for summary judgment. Further, the State respectfully requests that the Court direct the District Court to deny Purdue's Motion and allow the case to proceed on the merits.

[¶65]Respectfully submitted this 10th day of September, 2019.

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IN THE SUPREME COURT

STATE OF NORTH DAKTOA

State of North Dakota, ex rel. Wayne Stenehjem, Attorney General Plaintiff-Appellant -vs- Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company Inc.; and does 1 through 100, Inclusive, Defendants – Appellees	Supreme Court No. 20190237 Case No. 08-2018-CV-01300 **Certificate of Compliance** CPAT160247.004

[¶1]The undersigned certifies pursuant to the Supreme Court's order of August 27, 2019, granting the Appellant's motion for enlargement of the page limit in N.D.R. App. P. 32(a)(8)(A), the text of the Brief of Appellant contains no more than 43 pages.

[¶2]The Brief of Appellant has been prepared in a proportionally spaced typeface using Microsoft Office Word 2016 word processing software in Times New Roman 12 point font.

[¶3]Respectfully submitted this 10th day of September, 2019.

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IN THE SUPREME COURT

STATE OF NORTH DAKOTA

State of North Dakota, ex rel. Wayne Stenehjem, Attorney General Plaintiff-Appellant -vs- Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company Inc.; and does 1 through 100, Inclusive, Defendants - Appellees	Supreme Court No. 20190237 Case No. 08-2018-CV-01300 **Certificate of Service** CPAT160247.004

[¶1] I hereby certify that on this 10th day of September, 2019 the following documents:

(1) Brief of Appellant;
(2) Certificate of Compliance;
(3) Appellant's Appendix; and
(4) Certificate of Service

were filed electronically with the North Dakota Supreme Court and that copies of the foregoing were sent via electronic mail via the Supreme Court's E-filing Portal to the following:

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[¶2]Dated this 10th day of September, 2019.

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