IN THE SUPREME COURT OF THE STATE OF NEVADA

TEVA PHARMACEUTICALS USA, INC., MCKESSON CORPORATION, AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., CARDINAL HEALTH 6 INC., CARDINAL HEALTH TECHNOLOGIES LLC, CARDINAL HEALTH 108 LLC d/b/a METRO MEDICAL SUPPLY, CEPHALON, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., ALLERGAN USA, INC., ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., ACTAVIS LLC, and MALLINCKRODT, LLC,

Petitioners,

v.

SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA, in and for the County of Washoe, and the HONORABLE BARRY L. BRESLOW, DISTRICT JUDGE,

Respondents,

and

CITY OF RENO,

Real Party in Interest.

Supreme Court Case No.

District Court Case No. CV18-01895

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PETITIONERS' APPENDIX
VOLUME VIII

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CHRONOLOGICAL INDEX TO PETITIONERS' APPENDIX

DATE	DOCUMENT	VOLUME	PAGE RANGE	
12/7/2017	Complaint and Demand for Jury Trial (Case No. A-17-765828-C)	I	PA00001	PA00050
5/15/2018	First Amended Complaint and Demand for Jury Trial (Case No. A-17-765828-C)	I	PA00051	PA00109
9/18/2018	Complaint (Case No. CV18-01895)	II	PA00110	PA00167
12/03/2018	First Amended Complaint (Case No. CV18-01895)	II	PA00168	PA00226
3/4/2019	Manufacturer Defendants' Joint Motion to Dismiss First Amended Complaint	III	PA00227	PA00264
3/5/2019	Distributors' Joint Motion to Dismiss First Amended Complaint	III	PA00265	PA00386
4/26/2019	City of Reno's Opposition to Manufacturer Defendants' Joint Motion to Dismiss and All Joinders Thereto	IV-V	PA00387	PA00709
4/26/2019	City of Reno's Opposition to Distributor Defendants' Joint Motion to Dismiss and All Joinders	VI-VII	PA00710	PA00958
5/28/2019	Reply in Support of Manufacturer Defendants' Joint Motion to Dismiss First Amended Complaint	VIII-IX	PA00959	PA01214
5/28/2019	Distributors' Joint Reply in Support of Motion to Dismiss First Amended Complaint	X	PA01215	PA01285

DATE	DOCUMENT	VOLUME	PAGE RANGE	
6/17/2019	Complaint (Case No. A-19-796755-B)	XI-XII	PA01286	PA01535
6/27/2019	First Amended Complaint (Case No. A-19-796755-B)	XIII-XV	PA01536	PA02049
7/3/2019	Order Directing Answer (Case No. 79002)	XVI	PA02050	PA02052
8/22/2019	Complaint (Case No. A-19-800695-B)	XVI	PA02053	PA02144
8/22/2019	Complaint (Case No. A-19-800697-B)	XVI	PA02145	PA02235
8/22/2019	Complaint (Case No. A-19-800699-B)	XVII	PA02236	PA02326
9/12/2019	Third Amended Complaint and Demand for Jury Trial (Case No. A-17-76828-C)	XVII	PA02327	PA02423
9/13/2019	City of Reno's Supplemental Briefing in Support of Oppositions to Defendants' Motions to Dismiss	XVIII	PA02424	PA02560
10/4/2019	Distributors' Response to Plaintiff's Supplemental Briefing re Motions to Dismiss	XVIII	PA02561	PA02566
10/4/2019	Manufacturer Defendants' Response to Plaintiff's Supplemental Briefing re Motions to Dismiss	XVIII	PA02567	PA02587
10/21/2019	Order Dismissing Petition (Case No. 79002)	XVIII	PA02588	PA02591

DATE	DOCUMENT	VOLUME	PAGE RANGE	
1/4/2020	City of Reno's Supplemental Briefing in Support of Oppositions to Distributors' Joint Motion to Dismiss	XVIII	PA02592	PA02602
1/7/2020	Transcript of Proceedings	XIX-XX	PA02603	PA02871
1/8/2020	Transcript of Proceedings	XXI	PA02872	PA03034
2/14/2020	Omnibus Order Granting In Part and Denying in Part Defendants' Motions to Dismiss; and Granting Leave to Amend	XXI	PA03035	PA03052

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1/7/2020	Transcript of Proceedings	XIX-XX	PA02603	PA02871
1/8/2020	Transcript of Proceedings	XXI	PA02872	PA03034

AFFIRMATION

Pursuant to NRS 239B.030, the undersigned does hereby affirm that Petitioners' Appendix Volume VIII does not contain the social security number of any person.

Dated this 1st day of May, 2020.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I am an employee of McDonald Carano LLP, and that on this 1st day of May, 2020, a copy of the foregoing Petitioners' Appendix Volume VIII was electronically filed with the Clerk of the Court for the Nevada Supreme Court by using the Nevada Supreme Court's E-Filing system (Eflex) and served via U.S. Mail, postage prepaid, on the following individuals:

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In addition, in compliance with NRAP 21(a)(1) and Administrative Order 2020-05, a copy of this Petitioners' Appendix Volume VIII was served upon the Honorable Barry Breslow, District Judge via electronic service and email to Christine.Kuhl@washoecourts.us.

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An Employee of McDonald Carano LLP

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IN THE SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF WASHOE

CITY OF RENO,

Plaintiff,

vs.

PURDUE PHARMA, L.P. et al.,

Defendants.

Case No.: CV18-01895
Dept. No.: 8

REPLY IN SUPPORT OF MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS FIRST AMENDED COMPLAINT

Oral Argument Requested

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INTRODUCTION

The City's Opposition ("Opp.") to Manufacturer Defendants'[1] Joint Motion To Dismiss ("Joint MTD") invites the Court to expand the settled boundaries of Nevada law by advancing legal theories that have no support in traditional doctrine. The City asserts these novel theories to remedy a complex, multifaceted societal crisis and seeks to impose unprecedented liability on pharmaceutical companies for developing and marketing FDA-approved prescription medications. It urges the Court to follow the examples of courts in some other jurisdictions that have permitted claims of municipal government plaintiffs seeking money damages for opioid-related social ills to survive a motion to dismiss.

Recently, however, a North Dakota court, following the lead of *City of New Haven v. Purdue Pharma, L.P.*, 2019 WL 423990 (Conn. Super. Ct. Jan. 8, 2019), dismissed a similar opioid-related action brought by North Dakota's Attorney General at the pleading stage. *See* Order, *North Dakota v. Purdue Pharma L.P. et al.*, No. 08-2018-CV-01300 (Burleigh Cty. Dist. Ct. May 10, 2019), **Exhibit A**. These decisions underscore that governmental lawsuits to recover claimed losses flowing from the opioid abuse crisis "are ordinary civil damages cases and face the ordinary civil rules about who can sue for what." *City of New Haven*, 2019 WL 423990, at *1. As in *City of New Haven* and *North Dakota*, the dispassionate application of "ordinary civil rules" to the City's First Amended Complaint ("FAC") compels its dismissal as against Manufacturer Defendants.

MEMORANDUM OF POINTS AND AUTHORITIES

I. THE CITY LACKS AUTHORITY TO MAINTAIN THIS ACTION

In the FAC, the City alleged it had "standing to bring this litigation" "to address matters of local concern[.]" FAC ¶ 45. Now that Manufacturer Defendants have shown this case does not address a "matter of local concern" as defined by Nevada law (Joint MTD at 4:5-5:23), the City has pivoted sharply and all but abandoned reliance on the "local concern" statute. Now the City says it may bring this action—whether or not it addresses a matter of local concern—simply because it

[1] The moving "Manufacturer Defendants" are identified in footnote 1 of the Joint MTD.

claims it can prove cognizable injury flowing from opioid abuse sufficient to establish traditional standing. Opp. at 2:11-4:6, 7:25-26 ("Reno has standing to bring this lawsuit, regardless of whether the opioid crisis is a matter of local concern."). It further argues that Dillon's Rule, the bedrock legal principle that limits municipalities to taking only those actions the Nevada Legislature has expressly authorized, is outdated, and asks this Court to ignore it. *Id.* at 4:8-7:26. The City's arguments are without merit.

A. The City Lacks Authority To Maintain This Lawsuit Under Dillon's Rule, Which Strictly Limits Cities To Exercising Only Powers Expressly Granted By The Legislature

As the Nevada Supreme Court has explained, "a municipal corporation . . . is but a creature of the legislature, and derives *all* its powers, rights and franchises from legislative enactment or statutory implication." *Ronnow v. City of Las Vegas*, 57 Nev. 332, 65 P.2d 133, 136 (1937) (emphasis added). This principle is commonly known as Dillon's Rule, which the Nevada Supreme Court adopted in *Ronnow*:

> It is a general and undisputed proposition of law that a municipal corporation possesses and can exercise the following powers, *and no others*: First, those granted in express words; second, those necessarily or fairly implied in or incident to the powers expressly granted; third, those essential to the accomplishment of the declared objects and purposes of the corporation,—not simply convenient, but indispensable.

Id. (some emphasis omitted). In short, "[n]either the [municipal] corporation nor its officers can do *any* act . . . not authorized," and "*[a]ll* acts beyond the scope of the powers granted are void." *Id.* (emphasis added). Moreover, "[a]ny fair, reasonable, substantial doubt concerning the existence of power is resolved . . . against the [municipal] corporation, and the power is denied." *Id.*

In 2015, the Nevada Legislature codified Dillon's Rule. It declared that "Dillon's Rule serves an important function in defining the powers of city government and remains a vital component of Nevada law." NRS 268.001(5). The Nevada Legislature elaborated on Dillon's Rule as follows:

> 1. Historically under Nevada law, the exercise of powers by the governing body of an incorporated city has been governed by a common-law rule on local governmental power known as Dillon's Rule, which is named after former Chief Justice John F. Dillon of the Iowa Supreme Court who in a case from 1868 and in later treatises on the law governing local governments set forth the common-law rule defining and limiting the powers of local governments.

> 2. In Nevada's jurisprudence, the Nevada Supreme Court has adopted and applied Dillon's Rule to county, city and other local governments.
>
> 3. As applied to city government, Dillon's Rule provides that the governing body of an incorporated city possesses and may exercise only the following powers and no others:
>
> (a) Those powers granted in express terms by the Nevada Constitution, statute, or city charter;
>
> (b) Those powers necessarily or fairly implied in or incident to the powers expressly granted; and
>
> (c) Those powers essential to the accomplishment of the declared objects and purposes of the city and not merely convenient but indispensable.

NRS 268.001(1)-(3). The Nevada Legislature also reaffirmed that, under Dillon's Rule, "if there is any fair or reasonable doubt concerning the existence of a power, that doubt is resolved against the governing body of an incorporated city and the power is denied." NRS 268.001(4).

The City asks the Court to ignore Dillon's Rule. It claims that there "have been debates in various jurisdictions regarding the viability of Dillon's Rule," criticizes the "policy" underlying the Rule, and cites a Utah case to claim "Dillon's Rule is outdated." Opp. at 5:3-4, 6:14-17, 7:12-13. But "debates in various [*other*] jurisdictions" cannot override the *Nevada* Legislature's controlling determination that Dillon's Rule remains "a vital component of Nevada law." NRS 268.001(5).

The City further asserts that "Dillon's Rule does not" preclude this action "[s]o long as this litigation is not contrary to the laws of the state or federal government and so long as it does not infringe on any state regulations[.]" Opp. at 7:19-22. This assertion turns Nevada law on its head, and there is no support for it. Under Dillon's Rule, the City lacks authority to take any action unless the Nevada Legislature positively grants it authority to act, and all doubts about that authority are resolved against the City. *See* NRS 268.001(3)-(4). Indeed, the City concedes that "Dillon's rule limits localities to exercis[ing] . . . those powers expressly delegated to them by the state legislature or necessary to implement or necessarily implied from express legislative grants." Opp. at 4:12-13 (internal quotation marks and citation omitted).

The City has plainly failed to show that it is empowered to maintain this action under Dillon's Rule (and that explains its request that the Court ignore the Rule). It has not identified any "express

term[]" of "the Nevada Constitution, statute, or city charter" that authorizes this lawsuit. NRS 268.001(3)(a). Nor does it contend that such authority is "necessarily or fairly implied" from any "expressly granted" power. NRS 268.001(3)(b). And finally, the City nowhere contends that this action is "indispensable" to "the accomplishment of the declared objects and purposes of the city"; indeed, the City has not even identified its "declared objects and purposes." NRS 268.001(3)(c).

Instead, the City offers the unremarkable assertion that "the Reno City Charter was created to 'provide for the orderly government of the City of Reno and the general welfare of its citizens.'" Opp. at 10:6-7 (citing Reno City Charter Art. I, § 1.010(1)). But that provision merely explains why the City created its charter; it does not affirmatively grant the City authority to do anything, much less do *everything* that might possibly "provide for . . . the general welfare of" its citizens. The City also claims its charter "empowers Reno to adopt and enforce local health and safety measures." *Id.* at 10:8-9. But the FAC does not allege the City is seeking to enforce any municipal health and safety measures here; rather, it asserts claims for statutory and common-law public nuisance, negligence, negligent misrepresentation, unjust enrichment, and punitive damages. FAC ¶¶ 178-308.

The City accepts that Dillon's Rule can "prevent local governments from passing ordinances," (Opp. at 3:15-17) but contends it has no application when a city "bring[s] a lawsuit" (*id.* at 5:11-14). That assertion likewise ignores Nevada law. As the Nevada Supreme Court has explained, "*[a]ll* acts beyond the scope of the powers granted" to a municipality "are void." *Ronnow*, 57 Nev. 332, 65 P.2d at 136 (emphasis added). Moreover, this action seeks to halt conduct just as an ordinance or regulation would. Among other things, the City seeks "injunctive relief" to alter "Defendants' promotion and marketing of opioids." FAC Prayer for Relief ¶ 8. When it comes to whether a city has authority to regulate business conduct, there is no meaningful distinction between legislative, executive, or judicial actions to achieve that result. *See City of Philadelphia v. Beretta U.S.A., Corp.*, 126 F. Supp. 2d 882, 889 (E.D. Pa. 2000) (refusing to distinguish between ordinances and lawsuits in an action seeking to regulate the gun industry, explaining that "[w]hat the City cannot do by an act of the City Council it now seeks to accomplish with a lawsuit. The United States Supreme Court has recognized that the judicial process can be viewed as the extension of a

government's regulatory power.") (citing *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 572 n.17 (1996)).

The City has failed to establish its authority to maintain this action under Dillon's Rule.

B. The City Also Lacks Authority To Maintain This Lawsuit Under The Narrow Exception To Dillon's Rule For "Matters Of Local Concern"

Because the City cannot satisfy Dillon's Rule, its FAC relies on the narrow exception to Dillon's Rule for "matters of local concern." *See* FAC ¶ 45; Opp. at 9:5-12.

The Nevada Legislature supplemented the limited powers that Dillon's Rule affords to cities by expressly granting them "all powers necessary or proper to address matters of local concern." NRS 268.001(6)(a). As the Nevada Legislature declared, "*with regard to matters of local concern*, a strict interpretation and application of Dillon's Rule unnecessarily restricts [cities] from taking appropriate actions[.]" NRS 268.001(5) (emphasis added). Accordingly, the Legislature "[m]odif[ied] Dillon's Rule as applied to [cities] so that if there is any fair or reasonable doubt concerning the existence of a power of [a city] *to address a matter of local concern*, it must be presumed that the [city] has the power unless the presumption is rebutted by evidence of a contrary intent by the Legislature." NRS 268.001(6)(b) (emphasis added). In other words, the Legislature reversed Dillon's Rule's presumption that a power does *not* exist, but only for actions that address matters of local concern. The Legislature made clear that the strict requirements of Dillon's Rule continue to apply as to "*[a]ny* powers other than those powers necessary or proper *to address matters of local concern*." NRS 268.001(7)(b) (emphasis added).

The Legislature clearly defined what constitutes a "matter of local concern":

> 1. "Matter of local concern" means any matter that:
>
> (a) Primarily affects or impacts areas located in the incorporated city, or persons who reside, work, visit or are otherwise present in areas located in the city, *and* does not have a significant effect or impact on areas located in other cities or counties;
>
> (b) Is not within the exclusive jurisdiction of another governmental entity; *and*
>
> (c) Does not concern:
>
> (1) A state interest that requires statewide uniformity of regulation;

> (2) The regulation of business activities that are subject to substantial regulation by a federal or state agency; *or*
>
> (3) Any other federal or state interest that is committed by the Constitution, statutes or regulations of the United States or this State to federal or state regulation that preempts local regulation.

NRS 268.003(1) (emphasis added). The Legislature's use of the conjunctive "and" connecting subdivisions (a), (b), and (c) requires the City to plead and prove that the subject matter of its lawsuit satisfies *all* three subdivisions. *See State Dept. of Employment, Training and Rehabilitation, Employment Sec. Div. v. Reliable Health Care Services of Southern Nevada, Inc.*, 15 Nev. 253, 257-58, 983 P.2d 414, 417 (1999) (holding that a party must satisfy all three criteria of NRS 612.085, which has three statutory requisites conjoined by "and"). And under subdivision (1)(c), which contains three discrete subparts connected by the disjunctive "or," if the "matter" concerns any of the three subparts, then the "matter" is *not* one of local concern. *See Anderson v. State*, 109 Nev. 1129, 1134, 865 P.2d 318, 321 (1993) (use of the disjunctive "or" requires "one or the other, but not necessarily both").

In an effort to satisfy the statutory definition, the City leapfrogs subsection 1 (cited above) and seizes on the statement in subsection 2 that "matters of local concern" can include "[p]ublic health, safety and welfare in the city," and "[n]uisances and graffiti in the city." NRS 268.003(2)(a), (c); *see* Opp. at 10:9-12. But the Legislature could not have made more clear that the examples listed in subsection 2 do *not* relieve the City from satisfying the strict threshold requirements of subsection 1: "[t]he provisions of subsection 2 . . . [m]ust not be interpreted as . . . expanding the meaning of the term 'matter of local concern' as provided in subsection 1." NRS 268.003(3)(c). In other words, a matter affecting "[p]ublic health, safety and welfare in the city" or "[n]uisances and graffiti in the city" can be a "matter of local concern" *only* if all three prongs of subsection 1 are independently satisfied. This conclusion is further confirmed by the Legislature's statement, in introducing subsection 2, that "[t]he term includes, without limitation, any of the following *matters of local concern*"—*i.e.*, the "illustrative" examples in subsection 2 must, as a threshold, qualify as a "matter of local concern" under subsection 1. NRS 268.003(2) (emphasis added).

The City does not and cannot satisfy subsection 1.

1. The Action Does Not Satisfy The Local "Impact" Requirement Of NRS 268.003, Subdivision (1)(a)

Subdivision 1(a) requires the City to show *both* that the opioid abuse crisis "[p]rimarily affects or impacts" persons or areas within the City *and* "does not have a significant effect or impact on areas located in other cities or counties." NRS 268.003(1)(a). The City's allegations, accepted as true on a motion to dismiss, foreclose it from making this showing. Joint MTD at 4:12-5:23. Indeed, in its opposition, the City concedes "it is not alone in its struggle to address the *nationwide* opioid epidemic." Opp. at 8:4-5 (emphasis added). The widespread impact of the opioid abuse crisis is underscored by the fact that the same private lawyers representing the City have filed a virtually identical complaint on behalf of Clark County (*see Clark Cty. v. Purdue Pharma L.P. et al.*, No. A-17-765828-C (Clark Cty. Dist. Ct.)), and the State of Nevada, through its Attorney General, has likewise filed a lawsuit seeking "relief for Nevada, *and its municipalities and counties*," from the same statewide opioid abuse crisis. Compl., *State v. Purdue Pharma L.P.*, Case No. A-18-1774437-B, ¶ 3 (emphasis added). What's more, the City's private lawyer has traversed the state to recruit Nevada cities and counties to become plaintiffs in opioid cases and, in presenting to these localities, has repeatedly emphasized the statewide impact of the opioid abuse crisis.[2]

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[2] *See* **Exhibit B** (Mar. 21, 2018 Opioid Epidemic in Nevada Counties Presentation) at 037 ("The opioid epidemic has placed a financial burden on every Nevada City and County."); **Exhibit C** (Mar. 21, 2018 Churchill County Board of County Commissioners Meeting Transcript) at 12:13-18 ("Counties' criminal justice budgets from top to bottom in Nevada . . . have had to expend anywhere from 25 to in excess of 35 percent of their annual budget on the opiate crisis."); *id.* at 15:25-16:3 (asserting the opioid abuse crisis "has affected everybody . . . . [I]t is an epidemic that is plaguing our state unbelievably, and it is a huge crisis."); *see also* **Exhibit D** (Feb. 15, 2018 Board of Lyon County Commissioners Meeting Minutes); **Exhibit E** (Mar. 19, 2018 Humboldt County Board of Commissioners Agenda); **Exhibit F** (Apr. 4, 2018 Letter from Robert C. Eglet to Mayor Carolyn Goodman); **Exhibit G** (Opioid Epidemic in Nevada's Counties Presentation to Nevada Association of Counties during January 2018 Board of Directors Meeting). These materials are publicly available and subject to judicial notice pursuant to NRS 47.130 and 47.150. While matters outside the complaint ordinarily cannot be considered in determining a motion to dismiss, exceptions to this rule include "matters of public record." *Breliant v. Preferred Equities Corp.*, 109 Nev. 842, 847, 858 P.2d 1258, 1261 (1993). These exhibits are supported by the Declaration of Pat Lundvall, **Exhibit I**.

The City asks the Court to ignore its repeated dispositive concessions of statewide and nationwide impact and focus instead on the alleged impact to the City alone. *See* Opp. at 8:5-15 ("Reno is only seeking redress for the financial burdens it has been forced to bear . . . . As such, this case is limited to matters of local concern . . . and the City is not seeking to recover any costs incurred by . . . other municipalit[ies] for injuries they have suffered."). This strained argument, if accepted, would rob NRS 268.003(1)(a) of any meaning. *See Arguello v. Sunset Station, Inc.*, 127 Nev. 365, 371, 252 P.3d 206, 210 (2011) ("[W]e must not render any of the phrases of [a statute] superfluous.") (citation omitted). Accordingly, under the plain language of NRS 268.003(1)(a), this action does not address a "matter of local concern." *See City Council of City of Reno v. Reno Newspapers, Inc.*, 105 Nev. 886, 891, 784 P.2d 974, 977 (1989) ("When the language of a statute is plain and unambiguous, a court should give that language its ordinary meaning and not go beyond it.").

2. The Action Does Not Satisfy The "No Substantial Regulation" And "Statewide Uniformity" Requirements Of NRS 268.003, Subdivision (1)(c)

Nor can the City satisfy subdivision (1)(c)(2), which requires it to show that the "matter . . . [d]oes not concern . . . [t]he regulation of business activities that are subject to substantial regulation by a federal or state agency[.]" NRS 268.003(1)(c)(2); *see* Joint MTD at 4:16-19. The "business activit[y]" the City seeks to change is Manufacturer Defendants' marketing of FDA-approved prescription opioid medications. *See*, *e.g.*, FAC ¶¶ 8, 240, 242-43. The City expressly seeks to enjoin Manufacturer Defendants' "promotion and marketing of opioids for inappropriate uses in Nevada, currently and in the future." *Id.* Prayer for Relief ¶ 8. Yet the marketing and promotion of these medications is comprehensively regulated by federal laws and agencies. *See generally* 21 C.F.R. Parts 201-203, 310, 312, 314 *et seq.* (FDA regulations regarding the manufacture, marketing, and sale of prescription opioid medications).[3]

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[3] *See also United States v. Harkonen*, No. C 08-00164 MHP, 2009 WL 1578712, at *11 (N.D. Cal. June 4, 2009) ("FDA regulations and the case law make clear that labeling under the [federal Food, Drug, and Cosmetic Act] is construed expansively, such that it may encompass nearly every form of promotional activity, including package inserts, pamphlets, mailing pieces, fax bulletins, reprints of press releases, and all other literature that supplements, explains, or is otherwise textually related to the product."); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013)

As one commentator has explained:

> The FDA has extensive authority over the advertising and marketing claims that drug manufacturers may make for all approved pharmaceuticals, whether to patients or physicians. . . . [T]he FDA's regulatory reach over the private sector is panoptic—the FDA controls nearly every aspect of communication that the drug industry has with every prescriber and consumer of pharmaceutical products in the United States.

Katherine A. Helm, *Protecting Public Health From Outside the Physician's Office: A Century of FDA Regulation From Drug Safety Labeling to Off-Label Drug Promotion*, 18 Fordham Intell. Prop. Media & Ent. L.J. 117, 120-21 (2007). Further underscoring the comprehensive nature of federal regulation, a North Dakota district court recently dismissed (at the pleading stage) substantially identical claims brought by North Dakota's Attorney General on the ground that the claims, "which are based on the marketing of [opioid] medications for their FDA-approved uses," were preempted by federal law. Order, *North Dakota v. Purdue Pharma L.P. et al.*, No. 08-2018-CV-01300 (Burleigh Cty. Dist. Ct. May 10, 2019), at 15, **Exhibit A**. Accordingly, the City's claims squarely seek to regulate "business activities that are subject to substantial regulation by a federal or state agency[.]" NRS 268.003(1)(c)(2).

The City likewise cannot satisfy subdivision (1)(c)(1), which requires a showing that this action does not concern "[a] state interest that requires statewide uniformity of regulation." NRS 268.003(1)(c)(1). The Nevada Legislature has declared that "the practice of pharmacy"—broadly defined to include "activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug"—is "subject to protection and regulation by the State." NRS 639.213 and 639.0124(1). The State's ability to "protect[] and regulat[e]" these activities would be undermined if cities could impose their own views of how to regulate the "practice of pharmacy," through litigation or otherwise, as the City attempts here.

The Nevada Attorney General agrees. As he has made clear, the State has a strong interest in uniform rules controlling the manufacture, marketing, and distribution of prescription opioid

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(similar); *Del Valle v. PLIVA, Inc.*, 2011 WL 7168620, at *4 (S.D. Tex. Dec. 21, 2011) ("In essence, virtually all communication with medical professionals concerning a drug constitutes labeling.").

medications. Contrary to the City's assertion that "the Nevada Attorney General has never objected to this lawsuit" (Opp. at 8:21-22), the Attorney General explicitly discouraged the City from pursuing this action, emphasizing the importance of "battl[ing] Nevada's opioid crisis" with "a unified front, not separately," explaining that "patchwork litigation" by municipalities could "thwart" the Attorney General's ability to "uniformly address the opioid crisis in Nevada." Nov. 8, 2017 Letter from A. Laxalt to H. Schieve at 1, 3, see **Exhibit H**.[4] Patchwork litigation by Nevada municipalities would untenably undermine the State's interest in a uniform response to opioid abuse. *See*, *e.g.*, *Craig v. Cty. of Chatham*, 356 N.C. 40, 48, 565 S.E.2d 172, 177-78 (2002) ("If each of North Carolina's one hundred counties is free to create its own particularized regulations . . . , the overall balance which the General Assembly has reached within a uniform plan for the entire state will be lost. . . . [Businesses] could be forced to adapt to differing, even conflicting, regulations. Any such dual regulation would present an excessive burden on [businesses]."). Thus, the City's lawsuit also concerns "[a] state interest that requires statewide uniformity of regulation." NRS 268.003(1)(c)(1).

3. The City Is Not Presumed To Have Authority To Bring This Action

Despite its clear failure to satisfy the "matter of local concern" definition, the City baldly asserts that "[p]ursuant to NRS 268.001, it is presumed that the City has authority to bring this action." Opp. at 12:9-10 (emphasis omitted); *see also id.* at 9:23-27. The City blatantly misreads the statute. The Legislature "[m]odif[ied] Dillon's Rule as applied to [cities] so that if there is any fair or reasonable doubt concerning the existence of a power . . . to address *a matter of local concern*, it must be presumed that the [city] has the power unless the presumption is rebutted by evidence of a contrary intent by the Legislature." NRS 268.001(6)(b) (emphasis added). By the plain terms of this provision, a "presum[ption] that the [city] has the power" arises if, *and only if*, "there is a[] fair or reasonable doubt" about whether the City is empowered to take action "to address a matter of local concern." *Id.* Here, as discussed, the City does not and cannot show that its lawsuit involves a "matter of local concern" as defined in subsection 1 of NRS 268.003, and accordingly, the question

[4] This letter is a publicly available document subject to judicial notice. *Supra* note 2.

never arises whether a power exists to address such a matter. Thus, the conditions for triggering the "presum[ption] that the [city] has the power" do not exist, and the presumption does not arise.

Simply put, under the plain language of NRS 268.003, the City's action does not address a "matter of local concern."

C. The City's "Standing" Argument Is A Red Herring

The City's assertion that it can maintain this action because it has allegedly sustained cognizable injury is a red herring. Opp. at 2:11-7:26. To be sure, any plaintiff, the City included, must plead and prove cognizable injury. Separately, however, the City must *also* establish that it has authority from the Legislature to maintain this action. *See Ronnow*, 57 Nev. 332, 65 P.2d at 136 ("*All* acts beyond the scope of the powers granted [to municipalities] are void.") (emphasis added). As courts have explained, this latter requirement is distinct from the traditional concept of "standing." *See*, *e.g.*, *Cmty. Bd. 7 of Borough of Manhattan v. Schaffer*, 84 N.Y. 2d 148, 154-56 (1994) (distinguishing "capacity" to bring an action from "the concept of standing," explaining that "[g]overnmental entities created by legislative enactment . . . have neither an inherent nor a common-law right to sue. Rather, their right to sue, if it exists at all, must be derived from the relevant enabling legislation or some other concrete statutory predicate."). The City plainly recognizes this independent requirement of legislative authorization to bring this action, having alleged "standing to bring this litigation . . . to address matters of local concern including the public health, safety . . . and general welfare" of City citizens (FAC ¶ 45)—language closely tracking various provisions of NRS 268.003.

The City also asserts that "[t]here is no other entity better situated to bring these claims[.]" Opp. at 3:25. Yet the City ignores that Nevada's Attorney General has already filed a lawsuit seeking redress for the statewide opioid abuse crisis. *See* Compl., *State of Nevada v. Purdue Pharma L.P.*, Case No. A-18-1774437-B (Clark Cty. Dist. Ct.). In that action, the Attorney General seeks "relief for Nevada, *and its municipalities and counties*[.]" *Id.* ¶ 3 (emphasis added); *see also id.* ¶ 4 (alleging the Attorney General's Consumer Advocate "is vested . . . with parens patriae authority to represent the public interest on behalf of the State, which includes its municipalities and counties."); *id.* ¶ 13 (alleging the opioid abuse crisis has "caus[ed] extensive public harm to . . . the State[] and its

municipalities and counties"); *id.* ¶ 192 (alleging that "[t]he opioid epidemic exists in all counties in Nevada").

II. THE CITY'S CLAIMS FOR RECOUPMENT OF GOVERNMENT EXPENDITURES ARE BARRED BY THE MUNICIPAL COST RECOVERY RULE

The City attempts to distinguish the municipal cost recovery rule from the Nevada Firefighter's Rule on the ground that the principles underlying each are "entirely different." Opp. at 14:9-11. The opposite is true. The Firefighter's Rule "developed from the notion that taxpayers employ firemen and policemen, at least in part, to deal with future damages that may result from the taxpayers' own negligence." *Steelman v. Lind*, 97 Nev. 425, 427, 634 P.2d 666 (1981). The principle underlying the municipal cost recovery rule is analogous. In *City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co.*, 719 F.2d 322 (9th Cir. 1983), then-Judge Kennedy explained that the rule is rooted in the legislative policy of taxing citizens to pay for governmental services. *Id.* at 323-24. As such, the City's attempt to distinguish the two rules is unavailing—both are concerned with spreading the cost burden of government services among all taxpayers. Any decision to redistribute the cost of government services is the province of the Legislature rather than the courts. *Id.* at 324 ("[T]he legislature and its public deliberative processes, rather than the court, is the appropriate forum to address such fiscal concerns.").

The City asserts that the municipal cost recovery rule is limited to "isolated emergency incident[s]." Opp. at 15:17-20. That assertion is wrong. *See*, *e.g.*, *Matter of James AA*, 594 N.Y.S.2d 430, 432 (N.Y. App. Div. 1993) (barring recovery of public expenditures made in the performance of a governmental function in a non-emergency situation, where Attorney General's costs of bringing conservatorship action were not recoverable from conservatee); *Torres v. Putnam County*, 541 S.E.2d 133, 136 (Ga. App. 2000) (county's costs of "enforcing its laws and protecting its citizens" by conducting zoning inspections for ongoing violations were not recoverable from violators of zoning laws). Rather, "[w]hether a municipality is dealing with an isolated emergency or a continuing problem has little to do with the municipal cost recovery [rule's] rationale." *Baker v. Smith & Wesson Corp.*, 2002 WL 31741522, at *6 (Del. Super. Ct. Nov. 27, 2002). If anything, applying the municipal cost recovery rule to ongoing conduct is *more* appropriate than applying it to

isolated emergencies. Unlike isolated emergencies, which are often unpredictable, a local government can anticipate its response to "ongoing" conduct. Opp. at 15:7-9; *see Baker*, 2002 WL 31741522, at *6 ("[R]epetitive or on-going wrongs lend themselves to the [municipal cost recovery] rule better than isolated acts. Almost by their nature, repeated or on-going acts are predictable.").

There is no legitimate reason to reject the municipal cost recovery rule in Nevada. That Nevada's Legislature has enumerated circumstances allowing for recovery of certain municipal costs suggests that in *other* circumstances not so enumerated the Legislature expects State and local governments to finance their expenses through taxes and fees. *See*, *e.g.*, NRS 475.230 (allowing fire department to recover expenses incurred as a result of fighting fire on State-owned property); NRS 405.230 (allowing county agency to recover expenses incurred for removing obstacles placed on public roads by private persons). This result is consistent with the well-established maxim of construction "'expressio Unius Est Exclusio Alterius,' the expression of one thing is to the exclusion of another," which "has been repeatedly confirmed in" Nevada. *Galloway v. Truesdell*, 83 Nev. 13, 26, 422 P.2d 237, 246 (1967).

Citing dicta from *Flagstaff*, the City asserts that an exception to the municipal cost recovery rule arises where "the acts of a private party create a public nuisance which the government seeks to abate." Opp. at 15:28-16:3 (emphasis omitted). But Nevada has never recognized such an exception to its Firefighter's Rule or any analogous principle. Moreover, in *Flagstaff*, the Ninth Circuit cited three cases in recognizing that "recovery has been allowed" in certain public nuisance cases. 719 F.2d at 324. All three cases are distinguishable because they involved federal common-law nuisance claims regarding interstate waterways and/or a state statute authorizing recovery of the damages at issue. *See Town of East Troy v. Soo Line R. Co.*, 653 F.2d 1123, 1127 (7th Cir. 1980) (statutory authorization); *City of Evansville v. Kentucky Liquid Recycling*, 604 F.2d 1008, 1017–19 (7th Cir. 1979) (federal common law); *United States v. Illinois Terminal R. Co.*, 501 F. Supp. 18, 21 (E.D. Mo. 1980) (same). Indeed, courts presented with state-law public nuisance claims have repeatedly rejected a general public nuisance abatement exception to the rule where, as here, the municipality lacks express statutory authorization to recover the municipal costs sought. *See*, *e.g.*, *County of Erie, New York v. Colgan Air, Inc.*, 711 F.3d 147, 152 (2d Cir. 2013); *Walker Cty. v. Tri-State Crematory*,

643 S.E.2d 324, 328 (Ga. App. 2007); *Baker*, 2002 WL 31741522, at *6; *Board of Sup'rs of Fairfax Cty., VA v. U.S. Home Corp.*, 1989 WL 646518, at *2 (Va. Cir. Ct. Aug. 14, 1989); *City of Philadelphia*, 126 F. Supp. 2d at 894-95.

Moreover, even if this Court were inclined to create a so-called public nuisance abatement exception (no Nevada court has done so), the exception would not apply here. The City's claims cannot properly be characterized as claims merely to *abate* a public nuisance. Rather, the City's action seeks *damages*, namely, the cost of public services. FAC ¶¶ 21, 35, 40, 181, 194-95, 221-22. For instance, the City cannot recast "reimbursement for all prescription costs incurred by consumers related to opioids" (*id.* Prayer for Relief ¶ 7) as mere costs to eliminate the alleged nuisance. *See Abatement*, Black's Law Dictionary (10th ed. 2014) ("The act of eliminating or nullifying."). Nor can the City legitimately categorize recovery of costs for "prosecution, corrections and other services" (FAC ¶¶ 194, 221) as "abating a public nuisance." *Baker*, 2002 WL 31741522, at *5 ("[T]here remains an area where the people as a whole absorb the cost of such services—for example, the prevention and detection of crime. No one expects the rendering of a bill (other than a tax bill) if a policeman apprehends a thief.") (internal quotation marks omitted). Plainly, the costs the City seeks here represent *recoupment* and *reimbursement*—not abatement—for expenses purportedly caused by the Manufacturer Defendants' alleged acts. FAC Prayer for Relief ¶¶ 5-7. Thus, even if a public nuisance abatement exception existed, the City's claims would not fall within it.

III. THE FAC SUFFERS FROM MULTIPLE PLEADING FAILURES

A. The FAC Is Replete With Improper Group Pleading

The City baldly claims that its allegations lumping the Manufacturer Defendants together are sufficient because "there is no bar on group pleading in Nevada." Opp. at 17:6. That is incorrect. The City's allegations fail to give each Defendant "fair notice of the nature and basis or grounds of the claim and a general indication of the type of litigation involved." *Taylor v. State*, 73 Nev. 151, 152, 311 P.2d 733, 734 (1957) (affirming dismissal because plaintiff pleaded insufficient facts, leaving defendants "wholly unable to admit or deny [plaintiff's claim] intelligently or conscientiously"); *see also Breliant*, 109 Nev. at 846, 858 P.2d at 1260 ("The test for determining

whether the allegations of a complaint are sufficient to assert a claim for relief is whether the allegations give fair notice of the nature and basis of a legally sufficient claim and the relief requested."). By lumping all individual Manufacturer Defendants into an indistinguishable monolith, the City has made it impossible for any Manufacturer Defendant to know which allegations are being levied against it. *See Taylor*, 73 Nev. at 153, 311 P.2d at 734 (complaint properly dismissed because "[w]ithout knowledge of the basis for the plaintiff's conclusion defendants are wholly unable to admit or deny it intelligently or conscientiously").

Courts routinely dismiss complaints that, like the FAC, rely on group pleading that requires defendants to "guess which facts apply to which parties." *See Volcano Developers LLC v. Bonneville Mort.*, 2012 WL 28838, at *5 (D. Nev. Jan. 4, 2012); Joint MTD at 8:10-9:2 (collecting cases). The Court should do the same here.

B. The City Fails To Plead Its Fraud Allegations With Sufficient Particularity

The City asserts that its claims do not sound in fraud because "fraud is not an essential element to any of the City's claims[.]" Opp. at 18:9-12. This assertion is contrary to settled law (Joint MTD at 9:11-20) and ignores the very standard the City itself sets forth: even "where fraud is not an essential element of a claim," "allegations of fraudulent conduct must satisfy the heightened pleading requirements of Rule 9(b)." Opp. at 18:5-7 (internal quotation marks and citations omitted).

The City unmistakably alleges a unified course of fraudulent conduct. *E.g.*, FAC ¶ 8. It alleges, for example, that Manufacturer Defendants sought to "convinc[e] doctors that it was safe and efficacious to prescribe opioids" even as they "knew" otherwise. *Id.* ¶¶ 11-13. The City further avers that Manufacturer Defendants "manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not." *Id.* ¶ 131. The City concedes that its claims sound in fraud. *See* Opp. at 19:25-27 (describing "Manufacturers' massive scheme . . . to cause physicians to be misled"); *id.* at 24:19-22 ("This case involves claims . . . all based upon Defendants' deceptive . . . conduct"); *id.* at 33:16-19 (describing "Manufacturers' fraudulent and deceptive marketing campaign"). The City's claims thus sound in fraud. *See In re Daou Sys., Inc.*, 411 F.3d 1006, 1028 (9th Cir. 2005) (regardless of whether claims required proof of fraud as an element, claims sounded

in fraud where plaintiffs sought "damages resulting from a fraudulent scheme and course of business by defendants").

The City alternatively asserts it has pleaded its claims with particularity because the FAC includes generic descriptions of how Manufacturer Defendants purportedly promoted their products and examples of marketing materials. *See* Opp. at 18:12-19:6. These allegations are insufficient because under Nevada law, "[t]o plead with particularity, plaintiffs must include in their complaint 'averments to the time, the place, the identity of the parties involved, and the nature of the fraud.'" *Rocker v. KPMG LLP*, 122 Nev. 1185, 1192, 148 P.3d 703, 708 (2006) (citation omitted), *abrogated on other grounds by Buzz Stew, LLC v. City of N. Las Vegas*, 124 Nev. 224, 181 P.3d 670 (2008). These required details are absent from the FAC. *See* Joint MTD at 10:8-25.

The City attacks a straw man by asserting that "Manufacturers argue that Reno must identify each and every prescribing doctor who heard a false statement and prescribed an opioid because of that false statement[.]" Opp. at 19:19-22. Manufacturer Defendants make no such argument. Rather, the FAC is fatally flawed because it does not allege sufficient particulars—indeed, *any* particulars—about the alleged "massive scheme . . . to cause physicians to be misled into changing their prescribing habits." *Id.* at 19:25-27. It does not even attempt to identify a single false statement by each Manufacturer Defendant in the City, much less connect such a statement to a single doctor or prescription in the City. Rather, the FAC offers only the conclusory assertion that "[u]pon information and belief . . . Defendants employed . . . the same marketing plans and strategies and deployed the same messages in Nevada as they did nationwide." FAC ¶ 102.[5]

Citing *Rocker*, the City asserts that "in certain cases, a plaintiff is unable to plead a fraud or mistake claim with the required particularity because the facts of the fraudulent activity are in the defendant's possession." Opp. at 19:7-9. This observation falls far short of triggering *Rocker*'s

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[5] The City's argument that it need not identify a single misled prescriber because NRCP 9(b) allows "[m]alice, intent, knowledge, and other conditions of . . . mind" to "be alleged generally" (*see* Opp. at 20:6-8) misses the mark. This standard concerns the state of mind of the purported defrauder (*i.e.*, scienter), not whether the recipient was actually misled (*i.e.*, identity of defrauded person, reliance, injury). In any event, the City does not even allege generally that any specific City prescriber was misled.

exception, which requires a plaintiff to "state *facts* supporting a strong inference of fraud" and "*show* in [the] complaint that [plaintiff] cannot plead with more particularity because the required information is in the defendant's possession." *Rocker*, 122 Nev. at 1195, 148 P.3d at 709 (emphasis added); *accord Snyder v. US Bank, N.A.*, 2015 WL 3400512, at *3 (D. Nev. May 27, 2015) (same). As shown, the City has failed to allege *any* particularized details about the allegedly misleading marketing scheme. Joint MTD at 10:8-25. Nor has the City "show[n]" in the FAC that it "cannot plead with more particularity." *Rocker*, 122 Nev. at 1195, 148 P.3d at 709. Indeed, the FAC's allegations show why this is *not* such a circumstance. The City alleges that the purportedly misleading statements forming the basis of its claims were widely and publicly disseminated (*see* FAC ¶¶ 96, 101-02, 105) going so far as to call it "one of the biggest pharmaceutical marketing campaigns in history" (*id.* ¶ 8). These allegations contradict the City's assertion that it cannot identify with further particularity the factual basis of its claims.

IV. THE STATUTORY PUBLIC NUISANCE CLAIM FAILS (COUNT I)

A. The City Cannot Bring A Criminal Statutory Public Nuisance Claim

The City does not deny that NRS 202 *et seq*. is a criminal statute that does not expressly permit a civil cause of action. Opp. at 20:22-23:10. The City instead asserts that "a civil cause of action . . . is implied[.]" *Id*. at 20:24-25. However, neither of the two cases cited by the City establishes that a criminal statute providing for a misdemeanor criminal conviction and limited penalties somehow also gives rise to an implied civil cause of action for "compensatory damages, and punitive damages . . . attorney fees and costs, and pre- and post-judgment interest."[6] FAC ¶ 198.

[6] The City cites *Baldonado v. Wynn Las Vegas, LLC*, 124 Nev. 951, 194 P.3d 96 (2008), and *Neville v. Eighth Judicial District Court*, 406 P.3d 499 (2017). Opp. at 21. Both cases examined *civil* statutes on unpaid wages under NRS Chapter 608, and both narrowly held that a provision allowing an employee-plaintiff to recover attorneys' fees when suing for unpaid wages could imply that the Legislature intended to create a private cause of action for unpaid wages. As the *Neville* court explained, "[i]t would be absurd to think that the Legislature intended a private cause of action to obtain attorney fees for an unpaid wages suit but no private cause of action to bring the suit itself." 406 P.3d at 504. Furthermore, the *Baldonado* court examined several other subsections within NRS Chapter 608 and found *no* implied private cause of action existed under the relevant statutes. *Baldonado*, 124 Nev. at 960, 194 P.3d at 102.

The City argues the "related legislative history[] demonstrates there is an implied private cause of action for public nuisance in Nevada" (Opp. at 21:8-9), but cites no legislative history to support that argument. Instead, it relies on self-serving divination of the Legislature's "intent." Yet the best evidence of what the Legislature intended—the statute itself—squarely contradicts the City's argument: by enacting NRS 202 *et seq*. within the criminal statute—and by limiting the penalties to a misdemeanor conviction and a fine "of not less than $500 but no more than $5,000"—the Legislature made clear that there are no parallel civil remedies implied in the statute. NRS 202.450 and 202.470. Indeed, as the City's own authorities recognize, "the absence of an express provision providing for a private cause of action to enforce a statutory right strongly suggests that the Legislature did not intend to create a privately enforceable judicial remedy." *Baldonado*, 124 Nev. at 959, 194 P.3d at 101.

Notably, the Legislature *did* enact a civil cause of action for *private* nuisance: "other than the criminal public nuisance statutes . . . , the only other nuisance cause of action recognized under Nevada law . . . is a civil cause of action for private nuisance [under] N.R.S. § 40.140." *Coughlin v. Tailhook Ass'n, Inc.*, 818 F. Supp. 1366, 1372 (D. Nev. 1993) (holding that NRS 202.450 is a criminal statute and does not create a civil cause of action for statutory public nuisance), *aff'd sub nom.*, 112 F.3d 1052 (9th Cir. 1997).[7] Thus, the Legislature decided it was necessary to create a civil cause of action for a private nuisance available to "any person whose property is injuriously affected." NRS 40.140. Had the Legislature also intended to create a civil cause of action for *public* nuisance, it could have done so. It did not. The City has not alleged a nuisance under NRS 40.140. Because the criminal statute the City relies on to bring its statutory public nuisance claim only authorizes abatement and civil penalties in a criminal proceeding, not in a civil action, the claim fails as a matter of law.

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[7] The City's attempt to distinguish *Coughlin* by arguing that it does not analyze whether there is an "implied civil right of action" fails. Opp. at 23:1-3 (emphasis omitted). As discussed above, the Legislature clearly conveyed its intention by enacting a criminal statute to prosecute public nuisances and a civil statute for private nuisances affecting persons' property. Moreover, the City's argument that because NRS 202 *et seq*. "outline[s] the criminal misdemeanor offenses, the language of the statutes . . . indicate[s] a legislative intent to permit a private, civil cause of action arising out of [a] public nuisance," has no legal basis. *Id*. at 21:21-25.

Finally, even if NRS 202 *et seq*. were a civil statute (it is not), it still would not apply because NRS 202.450 does not apply to the sale of lawful products. Under the statute, a "public nuisance" is limited to specific "place[s]" or "building[s]" not applicable here, and certain "[a]gricultural activit[ies]" and "shooting range" noise levels that are likewise inapplicable. NRS 202.450(2), (4)-(6). While the statute also applies to certain "act[s] unlawfully done" which "endanger[] the safety, health, comfort or repose of any considerable number of persons," or "render[] a considerable number of persons insecure in life or in the use of property" (NRS 202.450(3)), no Nevada appellate court has ever applied that provision to the sale of lawful goods. Notably, a North Dakota district court very recently dismissed a substantially similar statutory public nuisance claim in an opioid-related action. In that case, the State of North Dakota asserted a public nuisance claim under a statute that proscribes acts and conditions that are substantially identical to NRS 202.450(3). *See* Order, *North Dakota v. Purdue Pharma L.P. et al.*, No. 08-2018-CV-01300 (Burleigh Cty. Dist. Ct. May 10, 2019), at 24, **Exhibit A**.[8] The district court explained that "North Dakota courts have not extended the nuisance statute to cases involving the sale of goods" (*id.* at 25) yet the State was "clearly seeking to extend the . . . nuisance statute to a situation where one party has sold to another a product that later is alleged to constitute a nuisance" (*id.* at 26 (emphasis in original)). Because the statute did not apply "to cases involving the sale of goods," the court dismissed North Dakota's statutory public nuisance claim. *Id.* at 27. The same result is warranted here.

B. The City Cannot Recover The Damages It Seeks

The City does not deny that the plain language of NRS 202 *et seq*. allows only for a misdemeanor conviction and an order to abate the nuisance and/or "pay a civil penalty of not less than $500 but not more than $5,000." NRS 202.450, 202.470. The statute does not permit recovery of damages.

Citing no authority, the City asserts that it may recover monetary damages because such damages "are appropriate under a public nuisance claim." Opp. at 23:22-25. That assertion ignores settled Nevada law. Where "the statute's express provision of . . . remedies reflects the Legislature's

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[8] *Compare* N.D.C.C. § 42-01-01, *with* NRS 202.450(3).

intent to provide only those specified remedies, [courts] decline to engraft any additional remedies therein." *Stockmeier v. Nevada Dep't of Corr. Psychological Review Panel*, 124 Nev. 313, 317, 183 P.3d 133, 136 (2008); *see also Builders Ass'n of N. Nevada v. City of Reno*, 105 Nev. 368, 370, 776 P.2d 1234, 1235 (1989) ("If a statute expressly provides a remedy, courts should be cautious in reading other remedies into the statute."); *Richardson Const., Inc. v. Clark Cty. Sch. Dist.*, 123 Nev. 61, 65, 156 P.3d 21, 24 (2007) ("Because NRS 338.1381 provides this express remedy, we will not read any additional remedies into the statute."). Lacking *any* statutory basis to recover the damages the City seeks, the statutory public nuisance claim is limited only to the criminal penalties available under NRS 202 *et seq.* The City's statutory public nuisance claim thus fails.

V. THE COMMON-LAW PUBLIC NUISANCE CLAIM FAILS (COUNT II)

An essential element of common-law public nuisance is interference with a public right—a right "common to all members of the general public" that is "collective in nature and *not like* the individual right that everyone has not to be assaulted or defamed *or defrauded or negligently injured*." Joint MTD at 14:19-21. The City invites the Court to ignore the well-defined contours of a "public right" in favor of a virtually limitless construction of the concept, one that would threaten to "devour in one gulp the entire law of tort.'" *Camden Cnty. Bd. of Chosen Freeholders*, 273 F.3d 536, 540 (3rd Cir. 2001) (quoting *Tioga Pub. Sch. Dist. v. U.S. Gypsum Co.*, 984 F.2d 915, 921 (8th Cir 1993)). The common-law public nuisance claim should be dismissed.

A. The City Fails To Plead Interference With A Public Right

The City's assertion that it has "adequately alleged an interference with" a public right merely because it alleges the Manufacturer Defendants' conduct "impact[ed] . . . the public health" and "resulted in widespread harm" is contrary to settled law. Opp. at 26:25-27:1, 28:11-16.

"[A] public right is more than an aggregate of private rights by a large number of injured people." *State v. Lead Industries Ass'n, Inc.*, 951 A.2d 428, 448 (R.I. 2008). Thus, "allegation[s] that defendants have interfered with the health, safety, peace, comfort or convenience of the residents of the state standing alone do[] not constitute an allegation of interference with a public right." *Id.* at 453 (internal quotation marks and brackets omitted). Rather, "[t]he term public right is reserved more appropriately for those *indivisible resources shared by the public at large*, such as air, water,

or public rights of way." *Id.* (emphasis added); *see also City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill. 2d 351, 374 (2004) ("We are . . . reluctant to recognize a public right so broad and undefined that the presence of any potentially dangerous instrumentality in the community could be deemed to threaten it.").

Consistent with these principles, "[t]he manufacture and distribution of products rarely, if ever, causes a violation of a public right as that term has been understood in the law of public nuisance. Products generally are purchased and used by individual consumers, and any harm they cause—even if the use of the product is widespread and the manufacturer's . . . conduct is unreasonable—is not an actionable violation of a public right." *Lead Industries*, 951 A.2d at 448 (citations omitted).

No Nevada appellate court has adopted the City's expansive construction of "public right," which lies far outside the established meaning of that term and does not remotely resemble the types of public nuisance claims permitted by Nevada courts. *See* Joint MTD at 16:9-17:2. The City notes the absence of any Nevada decision "*reject[ing]* public nuisance claims in the face of a vast interference on [sic] the public health," but its reasoning has it backwards. Opp. at 30:22-24 (emphasis added). The City is the one seeking to invoke a novel theory of what constitutes a "public right," and the City must establish that its theory is permitted by Nevada law. It has not done so.

Nor does the Restatement support the City's argument. Seizing on isolated, out-of-context phrases from the Restatement, the City asserts that "[a] public nuisance can be something that 'affect[s] the health of so many persons as to involve the interests of the public at large.'" *Id.* at 29:1-2 (quoting Restatement (Second) of Torts § 821B cmt. g). This assertion improperly conflates distinct concepts: a "public right" and "the interests of the public at large." *Id.* "That which might benefit (or harm) 'the public interest' is a far broader category than that which actually violates 'a public right.'" Donald G. Gifford, *Public Nuisance as a Mass Products Liability Tort*, 71 U. Civ. L. Rev. 741, 815 (2003). "[W]hile it is in the public interest to promote the health and well-being of citizens generally, there is no common law public right to a certain standard of medical care" and "a government recoupment action . . . initiated to . . . protect the public interest[] is not necessarily a

legitimate vindication of the violation of a public right." *Id.* at 815-16; *see also Lead Industries*, 951 A.2d at 448 (same).

Moreover, the City self-servingly omitted key limiting language from the Restatement phrases it quoted: "*the spread of smoke, dust or fumes over a considerable area*"—a classic example of a nuisance—"may interfere also with the use of the public streets or affect the health of so many persons as to involve the interests of the public at large." Restatement (Second) of Torts § 821B cmt. g (emphasis added). No similar allegations are (or could be) made here.

The City's citation to non-binding dismissal orders from opioid-related suits in other states is likewise unavailing. *See* Opp. at 30:15-26. To the extent those courts concluded that the plaintiffs adequately alleged interference with a public right under the laws of their respective jurisdictions, Manufacturer Defendants respectfully submit that those courts erred. For example, in *In re Opioid Litig.*, Index No. 400000/2017 (N.Y. Sup. Ct. June 18, 2018), which is currently pending appeal, the court concluded that merely alleging that conduct impacted "public health" was sufficient to plead interference with a public right. *See id.* at 28. As shown above, this reasoning departs from well-established limits defining a public right and improperly conflates the public *interest* with a public *right*. The court also conflated the elements of "public right" and "unreasonable interference." *See id.* Under the Restatement, conduct does not qualify as a public nuisance absent interference with a public right, even if that conduct constitutes "significant interference" to the "public health." Restatement (Second) of Torts § 821B(1)-(2)(a).[9]

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[9] The remaining orders cited by the City are likewise unpersuasive. *See* Opp. at 30:15-26. The Ohio court reasoned that it was bound by state supreme court precedent not applicable here. *See State of Ohio v. Purdue Pharma L.P. et al.*, No. 17 CI 261 (Ohio Ct. Com. Pleas Aug. 22, 2018), slip op. at 7. The MDL order the City cites narrowly held that the Ohio Product Liability Act did not abrogate a common-law absolute public nuisance claim. *See County of Summit v. Purdue Pharma L.P. et al.*, No. 1:17-md-02804-DAP (N.D. Ohio Dec. 19, 2018), Dkt. 1203 at 22-28. The New Hampshire decision placed undue weight on "behavior" that interferes with public health, without recognizing that that behavior must independently interfere with a public right. *See State of New Hampshire v. Purdue Pharma Inc. et al.*, No. 217-2017-cv-00402 (N.H. Super. Ct. Sept. 18, 2018), slip op. at 27. The West Virginia decision does not include any analysis of the public right issue. It simply cites to a prior order and notes that there is "nothing new" requiring the court to depart from that prior order. *See State of West Virginia et al. v. Cardinal Health, Inc.*, No. 12-C-140 (W. Va. Cir. Ct. Feb. 19, 2016), slip op. at 27. In any event, the prior order cited by the West Virginia court erred by concluding that conduct interfered with a public right simply if it imposed "unwarranted injuries." *State of West Virginia et al. v. Cardinal Health, Inc.*, No. 12-C-140 (W. Va. Cir. Ct. Apr.

The City also ignores that Manufacturer Defendants' activities are extensively regulated by federal and state laws and agencies (Joint MTD at 15:21-27) and that "[i]f a defendant's conduct in interfering with a public right does not come within one of the traditional categories of the common law crime of public nuisance or is not prohibited by a legislative act, the court is acting without an established recognized standard." Restatement (Second) of Torts § 821B cmt. e.

Because the City has failed to plead interference with a public right, its common-law public nuisance claim should be dismissed.

B. The City's Novel Theory Impermissibly Collapses Product Liability and Public Nuisance Law

In addition to having no basis in Nevada law, the City's public nuisance theory collapses the critical distinction between nuisance and product liability law.

The City argues that its claims do not sound in product liability because it "does not seek to recover damages for personal injuries suffered by individual Reno residents." Opp. at 28:21-22. Yet the City plainly seeks indirect expenses (*e.g.*, healthcare and criminal justice costs) purportedly flowing from injuries to individual consumers allegedly caused by Manufacturer Defendants' products. *See* FAC ¶¶ 214, 220-22. Indeed, in arguing its claims are not barred by the economic loss rule, the City asserts that "*[t]he underlying physical harm and injuries Defendants caused to the public* show that there is more at stake here than purely economic damages[.]" Opp. at 25:18-20 (emphasis added). The City cannot disavow product liability claims and then rely on underlying injuries to consumers as a basis to pursue its claims for indirect expenses arising therefrom. The Court should reject the City's transparent effort to end-run the particular requirements applicable to product liability claims by dressing up such claims in the garb of a novel public nuisance action. *See* Victor E. Schwartz & Phil Goldberg, *The Law of Public Nuisance: Maintaining Rational Boundaries on a Rational Tort*, 45 Washburn L.J. 541, 543 (2006) ("The current effort to expand public nuisance theory to provide sanctions against manufacturers of lawful products is disconcerting because it

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17, 2015), slip op. at 17. And finally, the Clark County order contains no analysis whatsoever of common-law public nuisance. *See* Order Re Defs.' Mot. to Dismiss, *Clark County v. Purdue Pharma L.P. et al.*, No. A-17-765828-C (Clark Cty. Dist. Ct. Mar. 15, 2019).

would fundamentally change the entire character of public nuisance doctrine, as well as undermine products liability law.").

VI. THE NEGLIGENCE CLAIM FAILS (COUNT III)

The City does not and cannot dispute that Manufacturer Defendants do not owe the City a duty to protect it from third-party misconduct. *See* Opp. at 31:1-32:28. Instead, the City asserts that "Reno's claims are based on the Manufacturers' own . . . conduct," and that it "is not alleging that Manufacturers failed to protect the City from harm caused by others." Opp. at 32:14-18. But that is precisely what the City has alleged.

The City seeks to hold Manufacturer Defendants liable for "all costs incurred . . . to combat the abuse and diversion of opioids[.]" FAC ¶ 40(e); *see also id.* ¶ 32 (alleging damages from "opioid misuse," "criminal justice costs," and "the secondary drug market"). For the City to incur such costs, a downstream third-party actor must intervene: a doctor must write an improper prescription; a patient must misuse a medication; or a pharmacy, distributor, or individual must divert the medication from the legitimate distribution chain. *See*, *e.g.*, *id.* ¶¶ 67-68, 73-74, 76-80, 152-64, 261-86 (alleging third parties who "play[] an integral role in the chain of opioid[]" distribution). And the City has alleged that third parties—not Manufacturer Defendants—have "exclusive control of the distribution management of opioids that [they] distributed and/or sold in Reno." *Id.* ¶ 280.

Because the City has failed to plead any facts establishing that Manufacturer Defendants owed a duty to protect the City from third-party misconduct, the negligence claim fails. *See* Joint MTD at 18:1-23. The claim also fails under the economic loss rule. *Id.* at 18:24-27.[10]

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[10] The City misstates the law by suggesting that the economic loss rule cannot apply because the City "does not allege any breaches of contract[.]" Opp. at 24:18-19. Under well-established law, the absence of a contract between the parties does *not* foreclose application of the economic loss rule. Dan B. Dobbs et al., The Law of Torts § 608 (2nd ed. 2018) ("The plaintiff's economic harm may also be barred when the parties are strangers, which is to say when they are *not* in a contractual relationship."). As Utah's Supreme Court recently explained, "[t]he economic loss rule has two complementary yet distinct applications," one of which "bars recovery of economic losses in negligence actions unless the plaintiff can show physical damage to other property or bodily injury," and "[t]his branch of the economic loss rule applies when there is no contract between the relevant parties." *HealthBanc Int'l, LLC v. Synergy Worldwide, Inc.*, 881 Utah Adv. Rep. 46, 435 P.3d 193, 196 (2018) (internal quotation marks and citation omitted).

VII. THE NEGLIGENT MISREPRESENTATION CLAIM FAILS (COUNT IV)

Putting aside that the City does not identify a single false statement or omission made by any Manufacturer Defendant to the City or any City provider, its assertion that it has stated a negligent misrepresentation claim because Manufacturer Defendants "were transacting business in" the City is a red herring. Opp. at 33:20-21. The City must allege it received false information from a defendant *while engaged in a business transaction with that defendant*. *See* Joint MTD at 19:2-20. Merely alleging that a defendant "transact[ed] business" is not sufficient. Similarly, the City's assertion that its claim is based on both affirmative misrepresentations and "wrongful concealment" is immaterial because it has nothing to do with whether the City received false information while engaged in a business transaction with Manufacturer Defendants. Opp. at 34:18-20.

The City further asserts that "courts have interpreted [Restatement] § 552 to extend liability for a misrepresentation made to a third party." *Id.* at 33:28-34:1. While that proposition is true, it has no bearing here because the question is whether the City has alleged facts sufficient to support an inference that Manufacturer Defendants "supplie[d] false information for the guidance of [*the City*] in [*the City's*] business transactions." *Bill Stremmel Motors, Inc. v. First Nat'l Bank of Nevada*, 94 Nev. 131, 134, 575 P.2d 938, 940 (1978) (quoting Restatement (Second) of Torts § 552(1) (1977)). The City's assertion that Manufacturer Defendants misled "the public at large" is likewise inapt. Opp. at 34:8-10. Liability for negligent misrepresentation "is limited to loss suffered (a) by the person or *one of a limited group of persons for whose benefit and guidance* [the defendant] intends to supply the information . . . and (b) through reliance upon it *in a transaction that [the defendant] intends the information to influence*." Restatement (Second) of Torts § 552(2) (emphasis added). The City's "public-at-large" argument cannot be squared with the limited group of indirect recipients who could potentially pursue a negligent misrepresentation claim under Nevada law (set forth in the Restatement). Under the City's argument, every single person (*i.e.*, the "public at large") would have

a negligent misrepresentation claim, which would render the specific limitations under Nevada law meaningless.[11]

Separately, the claim fails under the economic loss rule. Joint MTD at 20:3-5; *supra* note 10.

VIII. THE UNJUST ENRICHMENT CLAIM FAILS (COUNT VI)

The City advances a theory never before adopted by any Nevada appellate court: that by paying for alleged downstream "costs" of Manufacturer Defendants' purported misconduct, *i.e.*, "externalities,"[12] the City somehow conferred a benefit on those Defendants. *See* Opp. at 35:3-6 (citing FAC ¶ 290), 36:2-3. No Nevada case law recognizes that paying for "externalities" can be sufficient to establish that the plaintiff conferred a benefit on the defendant for purposes of an unjust enrichment claim, and other appellate courts that have considered the theory have rejected it. *See*, *e.g.*, *City of Miami v. Bank of Am. Corp.*, 800 F.3d 1262, 1270-71 (11th Cir. 2015) (affirming district court's conclusion that "paying for externalities cannot sustain an unjust enrichment claim"), *vacated on other grounds*, 137 S. Ct. 1296 (2017). This Court should decline to adopt a theory of unjust enrichment that has no basis in Nevada law. *See id.*; *see also Badillo v. Am. Brands, Inc.*, 117 Nev. 34, 42, 16 P.3d 435, 440 (2001) (though the Supreme Court of Nevada "possesses the power to create a common law cause of action" it "construe[s] such power narrowly and exercise[s] it cautiously").

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[11] The City incorrectly cites *Epperson v. Roloff*, 102 Nev. 206, 212, 719 P.2d 799, 803 (1986), for the proposition that a defendant can be "liable for misrepresentation where it communicates misinformation to the recipient with the intent of, or having reason to believe that, the recipient would communicate the misinformation to a third party." Opp. at 34:4-8. The standard the *Epperson* court noted is far narrower than the City suggests: "a party may be held liable for misrepresentation where he communicates misinformation *to his agent*, intending or having reason to believe that *the agent* would communicate the misinformation to a third party." *Epperson*, 102 Nev. at 212, 719 P.2d at 803 (emphases added). Moreover, *Epperson* concerned a fraudulent misrepresentation claim, which is governed by a different standard than the City's negligent misrepresentation claim. *See id.*, 102 Nev. at 210-211, 719 P.2d at 802. And in any event, the City does not allege that Manufacturer Defendants communicated any false information with intent or knowledge that some unidentified recipient would or did communicate such information to the City (much less that Manufacturer Defendants' intent was to guide the City in a business transaction or that the City did rely on it in a business transaction).

[12] The City refers to "externalities" and "negative externalities," terms that are interchangeable insofar as, according to the City, they both denote "the [alleged] costs of the harm caused by Defendants' [alleged] negligent distribution and sales practices." *See* Opp. at 35:3-36:3.

Moreover, the City does not address the FAC's complete lack of factual allegations supporting the other elements of an unjust enrichment claim. *See* Joint MTD at 20:16-21:3.

Lastly, the City's contention that Manufacturer Defendants "raise[] issues of fact not appropriate for resolution at the pleading stage" (*see* Opp. at 36:9-11) does nothing to rectify the City's failure to adequately plead an unjust enrichment claim. Nor has the City explained what "issues of fact" are supposedly "raise[d]." *Id.* The issue is ripe for decision now, and the Court should dismiss this claim.

IX. THE CITY'S PUNITIVE DAMAGES CLAIM AND ITS REQUEST FOR PUNITIVE, SPECIAL, AND EXEMPLARY DAMAGES AGAINST THE MANUFACTURER DEFENDANTS FAIL (COUNT VII)

The City argues that it is not "prohibited" from asserting a claim for punitive damages. Opp. at 37:6-9. The City is wrong. The Nevada Supreme Court has held that no stand-alone claim for punitive damages exists. *See*, *e.g.*, *Massi v. Nobis*, 2016 Nev. Unpub. LEXIS 249, at *2-3 (Apr. 15, 2016) ("punitive damages is not a cause of action, but a remedy…."); *see also* Dan B. Dobbs et al., The Law of Torts § 483 (2d ed. 2018) ("No cause of action exists for punitive damages as such.").[13]

Moreover, the City may not recover punitive damages in connection with its negligence or unjust enrichment claims because neither claim involves intentional wrongdoing. NRS 42.005(1) requires clear and convincing proof of "oppression, fraud or malice," and the Nevada Supreme Court has expressly held that negligence—even gross negligence or recklessness—is insufficient as a matter of law to support a punitive damages award. *Countrywide Home Loans, Inc. v. Thitchener*, 124 Nev. 725, 742-43, 192 P.3d 243, 254-55 (2008) ("Since its language plainly requires evidence that a defendant acted with a culpable state of mind, we conclude that N.R.S. 42.001(1) denotes conduct that, at a minimum, must exceed mere recklessness or gross negligence."); *see also Ford v. Marshall*, Dist. Ct. Nev., Case No. 12A670205, 2013 WL 1092060, ¶¶ 30-33 ("Negligence claims

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[13] Contrary to the City's assertion, *Davenport v. GMAC Mortg.*, No. 56697, 2013 Nev. Unpub. LEXIS 1457, at *14 n.5 (Sept. 25, 2013), did not "reinstate" a punitive damages claim. Rather, *Davenport* confirmed that there is no such stand-alone punitive damages claim by ruling that plaintiff's "demand" for punitive damages could be considered only "if [plaintiff] prove[d] his claim for civil conspiracy." *Id.*

exist for breaches of duty due to carelessness; if a mental state to cause injury existed, then the claim would be an intentional tort.").

The City further fails to plead *facts* showing oppression, fraud, or malice as to any Manufacturer Defendant. All but conceding this, the City argues that state of mind may be "averred generally" and cites to conclusory assertions in the FAC that do no more than parrot the requisite scienter language. Opp. at 37:17-38:13. Nevada law, however, requires factual allegations—not mere conclusions—to support the alleged state of mind. *See*, *e.g.*, *Elliott v. Prescott Co., LLC*, 2016 WL 2930701, at *2-3 (D. Nev. May 17, 2016) (allegations that defendants "acted with conscious disregard of his safety or rights" were conclusory and did not include sufficient facts to establish the requisite state of mind); *Taylor v. State & University*, 73 Nev. at 153, 311 P.2d at 734 (alleging a legal conclusion without pleading "the facts from which the conclusion flows" renders a complaint deficient).

X. THE CITY SHOULD NOT BE GRANTED LEAVE TO AMEND

The City requests leave to amend "[s]hould this Court find any . . . deficiencies with the City's pleading." Opp. at 38:25-27. But the City is not automatically entitled to an opportunity to amend (NRCP 15(a)) and it has not identified *any* new allegations it would plead to cure the FAC's numerous deficiencies (*see* Opp. at 38:19-39:2). The decision to permit amendment "is addressed to the sound discretion of the trial court" (*MEI-GSR Holdings, LLC v. Peppermill Casinos, Inc.*, 134 Nev. Adv. Op. 31, 416 P.3d 249, 254 (2018)) and the Court should decline to exercise that discretion here because the City has offered no concrete reason to believe it can cure its deficient pleading.

CONCLUSION

For the reasons stated herein and in the Joint MTD, Manufacturer Defendants respectfully request that the Court dismiss the FAC with prejudice as against them.

AFFIRMATION

The undersigned affirms that the preceding document does not contain personal information as described in WDCR 10(7).

DATED this 28th day of May, 2019.

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CERTIFICATE OF SERVICE

I hereby certify, under penalty of perjury, that I am an employee of McDonald Carano and that on this date, a true and correct copy of the **REPLY IN SUPPORT OF MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS FIRST AMENDED COMPLAINT** was electronically served via the Court's electronic filing system to the following parties associated with this case. For the following parties not registered with the court's electronic filing system, then a true and correct copy of the above-named document was served via U.S. mail:

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I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 28, 2019.

/s/ Beau Nelson
An employee of McDonald Carano LLP

EXHIBIT A

STATE OF NORTH DAKOTA **IN DISTRICT COURT**

COUNTY OF BURLEIGH **SOUTH CENTRAL JUDICIAL DISTRICT**

State of North Dakota Ex Rel. Wayne Stenehjem, Attorney General,

Plaintiff,

v.

Purdue Pharma L.P.; Purdue Pharma, Inc., The Purdue Frederick Company, Inc., and Does 1 through 100, inclusive,

Defendants.

Case No. 08-2018-CV-01300

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

INTRODUCTION

[¶1] This matter is before the Court on the Defendants', Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc. (collectively "Purdue"), Motion to Dismiss for failure to state a claim. The State has sued Purdue in this matter seeking to essentially hold it liable for the impact of opioid overuse and addiction in North Dakota. The State asserts claims for alleged violations of the North Dakota Unlawful Sales or Advertising Practices statute, N.D.C.C. § 51-15-01 *et seq.* (Consumer Fraud law) (Counts 1 & 2) and the nuisance statute, N.D.C.C. § 42-01-01 *et seq.* (Count 3).

[¶2] In its Motion, Purdue argues the present case should be dismissed on the pleadings for various reasons, including the following:

1. The State's claims fail as a matter of law because it seeks to impose liability for Purdue's lawful promotion of FDA-approved medications for an FDA-approved use, i.e. the claims are preempted by federal law.

2. The State does not plead the essential elements of causation.

3. The State's statutory public nuisance claim fails because North Dakota

> courts have not extended that statute to cases involving the sale of goods, and, even it did apply, the State does not allege that Purdue unlawfully interfered with a public right in North Dakota.

[¶3] The Plaintiff, the State of North Dakota ex rel. Wayne Stenehjem, Attorney General ("the State"), resists the Motion arguing they have sufficiently pled their claims and Purdue's arguments mischaracterize the claims.

[¶4] A hearing was held on the Motion on February 26, 2019. Parrell Grossman and Elin Alm appeared on behalf of the State. Will Sachse appeared and argued on behalf of Purdue. Robert Stock also appeared on behalf of Purdue.

[¶5] The Court has extensively reviewed the parties' briefing on the present Motion, on more than one occasion, and has reviewed the oral arguments presented by both parties. The Court has also extensively reviewed the State's Complaint in this matter, paying careful attention to the allegations detailed therein, following oral argument.

FACTS

[¶6] The facts underlying this Action are detailed at length in the Complaint [DE 2], and in the parties' respective briefing on the present Motion to Dismiss [DE 13 & DE 34]. The Court will not restate the facts as outlined by the parties, but incorporates those facts by reference into this Order.

[¶7] The State of North Dakota filed this action against drug manufacturer, Purdue Pharma, alleging the opioid epidemic and a public health crisis in North Dakota were caused, in large part, by a fraudulent and deceptive marketing campaign intended by Purdue to increase sales of its opioid products. The State alleges it has paid and will continue to pay expenses for the medical care and law enforcement response of North Dakota's population due to overuse, addiction, injury, overdose, and death. The State

seeks damages, injunctive relief, and civil penalties.

[¶8] The State's Complaint asserts three causes of action: (1) violations of North Dakota's Consumer Fraud Law – Deceptive Practices (N.D.C.C. 51-15-01 et seq.); (2) violation of North Dakota's Consumer Fraud Law – Unconscionable Practices (N.D.C.C. 51-15-01 et seq.); and (3) statutory public nuisance.

[¶9] Purdue now seeks to dismiss the State's claims as a matter of law.

LEGAL STANDARD

[¶10] A motion to dismiss a complaint under N.D.R.Civ.P. 12(b)(6) test the legal sufficiency of the statement of the claim presented in the complaint. *Ziegelmann v. Daimler Chrysler Corp.*, 2002 ND 134, ¶ 5, 649 N.W.2d 556. "Because determinations on the merits are generally preferred to dismissal on the pleadings, Rule 12(b)(vi) motions are viewed with disfavor." *Id.* A complaint "should not be dismissed unless it is disclosed with certainty the impossibility of proving a claim upon which relief can be granted." *Id.* A court's scrutiny of the pleadings should be deferential to the plaintiff. *Id.*

[¶11] The Court notes at the outset that Purdue filed the present Motion as a Motion to Dismiss under Rule 12(b)(6). However, both parties have cited to multiple documents and sources outside of the pleadings and each relies heavily on these sources in their briefing. "When a motion to dismiss for failure to state a claim upon which relief can be granted is presented before the court and 'matters outside the pleadings are presented to and not excluded by the court, the motion should be treated as one for summary judgment and disposed of as provided in Rule 56.'" *Podrygula v. Bray*, 2014 ND 226, ¶7, 856 N.W.2d 791 (quoting *Livingood v. Meece*, 477 N.W.2d 183, 187 (N.D. 1991)).

[¶12] The Court does not intend to ignore or exclude the materials cited by the parties and incorporated in their briefing, which are technically outside the pleadings. Based on the parties framing of the issues, both in their briefing and at the hearing on the present Motion, and based upon Purdue's reliance on matters technically outside the pleadings, the Court will treat Purdue's Motion as a motion for summary judgment.

[¶13] Rule 56(c) of the North Dakota Rules of Civil Procedure directs a trial court to enter summary judgment "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law."

[¶14] The standard for summary judgment is well established:

> Summary judgment is a procedural device for the prompt resolution of a controversy on the merits without a trial if there are no genuine issues of material fact or inferences that can reasonably be drawn from undisputed facts, or if the only issues to be resolved are questions of law. A party moving for summary judgment has the burden of showing there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. . . . [W]e must view the evidence in the light most favorable to the party opposing the motion, and that party will be given the benefit of all favorable inferences which can reasonably be drawn from the record.

Golden v. SM Energy Co., 2013 ND 17, ¶ 7, 826 N.W.2d 610, 615 (quoting *Hamilton v. Woll*, 2012 ND 238, ¶ 9, 823 N.W.2d 754.

[¶15] "Although the party seeking summary judgment bears the initial burden of showing there is no genuine issue of material fact, the party opposing the motion may not simply rely upon the pleadings, but must present competent admissible evidence which raises an issue of material fact." *Black v. Abex Corp.*, 1999 ND 236, ¶ 23, 603 N.W.2d 182. "Summary judgment is appropriate against a party who fails to establish

the existence of a factual dispute on an essential element of her claim and on which she will bear the burden of proof at trial." *Id.*

ANALYSIS

A. Federal Preemption

[¶16] Purdue first argues the State's claims are improper because they seek to impose liability for lawful promotion of FDA-approved medications for an FDA-approved use. Specifically, Purdue argues that the FDA has approved opioid medications for long-term treatment of chronic non-cancer pain, and Purdue's promotion is consistent with the FDA-approved indications and labeling decisions. Because their promotion/marketing is consistent with FDA-approved labeling decisions and because the FDA has previously declined to alter the labeling and/or warnings, Purdue argues the State's claims are preempted.

[¶17] The Supremacy Clause of the United States Constitution makes federal law the supreme law of the land, and state law that conflicts with federal law is without effect. *Home of Economy v. Burlington N. Santa Fe R.R.*, 2005 ND 74, ¶ 5, 694 N.W.2d 840. Whether claims are preempted is a question of law that may be resolved at the pleading stage. *See NoDak Bancorporation v. Clarkson*, 471 N.W.2d 140, 142 (N.D. 1991). The North Dakota Supreme Court has described when federal law preempts state law under the Supremacy Clause:

> First, Congress can define explicitly the extent to which its enactments pre-empt state law. Pre-emption fundamentally is a question of congressional intent, and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one.
>
> Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. Such an intent may be

> inferred from a "scheme of federal regulation ... so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," or where an Act of Congress "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." Although this Court has not hesitated to draw an inference of field pre-emption where it is supported by the federal statutory and regulatory schemes, it has emphasized: "Where ... the field which Congress is said to have pre-empted" includes areas that have "been traditionally occupied by the States," congressional intent to supersede state laws must be "'clear and manifest.'"
>
> Finally, state law is pre-empted to the extent that it actually conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements, or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Home of Economy v. Burlington N. Santa Fe R.R., 2005 ND 74, at ¶ 5.

[¶18] "The United States Supreme Court's framework for analyzing preemption claims starts with the assumption that Congress does not intend to displace state law." *Id.* at ¶ 6. "The assumption that Congress did not intend to displace state law is not triggered when a state regulated in an area where there has been history of significant federal presence." *Id.* (citing *United States v. Locke*, 529 U.S. 89 (2000)).

[¶19] Although there are three established types of federal preemption as detailed above, the parties in this case agree that "conflict preemption" is the only potential basis for preemption in this case. Conflict preemption exists where state law has not been completely displaced but is superseded to the extent that it conflicts with federal law. *Lefaivre v. KV Pharmaceutical Co.*, 636 F.3d 935, 939 (8th Cir. 2011). There are two types of conflict preemption, impossibility preemption and obstruction preemption. *Id.* "Impossibility preemption arises when compliance with both federal and state regulations is a physical impossibility. *Id.* (internal quotations omitted). "Obstruction

preemption exists when a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.*

[¶20] "[T]he FDCA's treatment of prescription drugs includes neither an express preemption clause (as in the vaccine context, 42 U.S.C. § 300aa-22(b)(1)), nor an express non-preemption clause (as in the over-the-counter drug context, 21 U.S.C. §§ 379r(e), 379s(d))." *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 493 (2013). "In the absence of that sort of 'explicit' expression of congressional intent, we are left to divine Congress' will from the duties the statute imposes." *Id.*

[¶21] In determining whether the State's claims against Purdue in this case are preempted in this case, the Court must review Congress' purpose and intent in enacting the Federal Food, Drug, and Cosmetic Act (FDCA). This was succinctly summarized by the 10th Circuit in *Cereveny v. Aventis, Inc.*, 855 F.3d 1091, 1096 (10th Cir. 2017):

> The Federal Food, Drug, and Cosmetic Act has long required a manufacturer to obtain approval from the FDA before the manufacturer can introduce a new drug in the market. 21 U.S.C. § 355(a). For brand-name drugs, a manufacturer must submit an application. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 133 S.Ct. 2466, 2470–71, 186 L.Ed.2d 607 (2013). The application must include the proposed label, "full reports of investigations which have been made to show whether such drug is [safe and effective]," comprehensive information of the drug's composition and the "manufacture, processing, and packing of such drug," relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source." 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50(c)(2)(i), (d)(1), (2), (5)(iv).
>
> If the FDA approves the application, the manufacturer generally is restricted from changing the label without advance permission from the FDA. 21 U.S.C. §§ 331(a), (c), 352; 21 C.F.R. § 314.70(a), (b). But an exception exists, allowing a manufacturer under certain circumstances to change the label before obtaining FDA approval. 21 C.F.R. § 314.70(c).4 But even when this exception applies, the FDA will ultimately approve the label change only if it is based on reasonable evidence of an

> association between the drug and a serious hazard. 21 C.F.R. §§ 201.80(e), 314.70(c)(6)(iii).

Cereveny v. Aventis, Inc., 855 F.3d 1091, 1096 (10th Cir. 2017).

[¶22] Purdue argues the FDCA "preempts state-law claims that seek to impose a duty to alter FDA-approved labeling or to market FDA-approved prescription medications in a way that conflicts with federal law." [DE 13 (Purdue's Brief in Support of Motion to Dismiss) at ¶ 20. Specifically, Purdue argues the State's claims are preempted because they require Purdue to include, either in the label for opioids or in its marketing of the opioids, a more extensive warning of the risks and benefits of Opioids than what has been approved by the FDA. Purdue contends federal law preempts such state law claims where they would require a pharmaceutical manufacturer to make statements about safety or efficacy that are inconsistent with what the FDA has required after it evaluated the available data.

[¶23] Similar issues were addressed by the United States Supreme Court in *Wyeth v. Levine*, 555 U.S. 555 (2009). At issue in *Levine* was the label warning and accompanying use instructions for Phenargen, an antihistamine approved by the FDA for the intravenous treatment of nausea. *Id.* at 559. The plaintiff argued the manufacturer violated its common law duty to warn of the risks associated with the injection of Phenargen, including the manner in which it is injected. *Id.* at 559-60. The manufacturer argued the claim was preempted because the FDA had previously approved the warning and use instructions for the drug's label. *Id.* at 560.

[¶24] The United States Supreme Court held that the state failure to warn claim was not preempted by FDA regulations. *Id.* at 581. The Court rejected the manufacturer's argument that, once a label is approved by the FDA, the manufacturer is not obligated

to seek revision of its contents. *Id.* at 570-71. The Court outlined that FDA regulations permit a drug manufacturer, without first obtaining FDA approval, to strengthen a warning contained in a label already approved by the FDA, if the manufacturer has evidence to support an altered warning. *Id.*

[¶25] The *Levine* Court established a "clear evidence" standard of proof required to support a claim of conflict preemption based on FDA labeling regulations. *Id.* at 571-72. *Levine* did not hold that impossibility preemption based on FDA labeling regulations is precluded in all cases. Rather, *Levine* established that the FDA labeling regulations do not preempt state law claims unless the manufacturer presents "clear evidence that the FDA would not have approved a change" to the drug's label or warning, thereby making it "impossible" for the manufacturer to comply with "both federal and state requirements." *Levine*, 555 U.S. at 571.

[¶26] The *Levine* Court did not define "clear evidence," and it did not establish the level of proof required to constitute such evidence. The Court simply held that in the circumstances of that case, there was no evidence that the manufacturer tried to alter the label to include additional warnings, and, therefore, the state law claims were not preempted by FDA regulations.

[¶27] In this case, the Court concludes the marketing practices of Purdue that the State claims are improper – including claims relating to OxyContin's appropriateness for long-term treatment of chronic pain [DE 2 (Complaint) at ¶¶107-08], maximum dosing [Complaint at ¶¶ 95, 115-16], and the use of screening tools [Complaint at ¶¶ 85-89], were consistent with the FDA-approved product labeling. *See generally* [DE 14-16 (Exhibits 1-3 to Purdue's Brief)].

[¶28] The State claims it is not pursuing an inadequate labeling theory, but simultaneously argues Purdue could have, and should have, strengthened its labeling and warnings to include additional risk information without prior FDA approval. [DE 34 (State's Opposition Brief) at 26-27]. The Complaint, however, contains no allegations of newly acquired information that could provide a basis for Purdue to change its labeling without prior FDA approval. Instead, consistent with the Supreme Court's decision in *Levine*, there is "clear evidence" that the FDA would not have approved changes to Purdue's labels to comport with the State's claims.

[¶29] In 2013, the FDA addressed the same issues raised by the State, and concluded that no modification to the product labeling was necessary. [DE 14-16 (Exhibits 1-3)]. In response to a 2012 citizen's petition from PROP, the FDA studied the available scientific evidence and concluded that it supports the use of ER/LA opioids to treat chronic non-cancer pain. [DE 17 (Exhibit 4)]. Therefore, the FDA has communicated its disagreement with the State's specific contention that Purdue "falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence," and therefore that it was improper to promote OxyContin for chronic pain. PROP and other commentators raised these same concerns as a reason to limit the indication for opioid medications, but the FDA rejected the request. [DE 17 (Exhibit 4) at 5]. Nor did the FDA direct Purdue to stop marketing the medications for long-term use. *Id.* at 14 ("FDA has determined that limiting the duration of use for opioid therapy to 90 days is not supportable.").

[¶30] As to certain risks that were already included in the labeling for Purdue's opioid medications, the FDA required Purdue to conduct additional studies and further assess those risks along with the benefits of use before any changes or additional warnings would be included. *Id.* at 11. The FDA is awaiting any new evidence to determine whether the medications' labeling should be revised to provide any different or additional information about those risks and benefits to physicians.

[¶31] The following allegations made by the State in its Complaint similarly conflict with statements the FDA has specifically approved:

[¶32] **Oxy Contin and 12-hour relief**: The State alleges "Purdue misleadingly promoted OxyContin as . . . providing 12 continuous hours of pain relief with one dose." [DE 2 (Complaint) at ¶ 115]. The FDA specifically addressed and rejected this claim. In a January 2004 citizen's petition, the Connecticut Attorney General requested labeling changes for OxyContin, asserting that OxyContin is not a true 12-hour drug and that using it on a more frequent dosing schedule increases its risk for diversion and abuse. In September 2008, the FDA denied the petition, and concluded the evidence failed to support that using OxyContin more frequently than every 12 hours created greater risk. *See* [DE 18 (FDA's September 2008 letter to Richard Blumenthal, Attorney General, State of Connecticut) at 14-17; cited by Complaint at ¶ 117). Since then, the FDA continues to approve OxyContin as a 12-hour medication. [DE 14 (Exhibit 1)].

[¶33] **Higher Doses**: The State alleges Purdue misrepresented the safety of increasing opioid doses. [DE 2 (Complaint) at ¶¶ 94-100]. This allegation is contrary to the FDA's labeling decision in response to the PROP Petition, which denied a request to limit the

dose of opioids. The FDA concluded "the available information does not demonstrate that the relationship [between opioid dose and risk of certain adverse events] is necessary a causal one." [DE 17 (Exhibit 4)].

[¶34] **Pseudoaddiction**: The State claims Purdue falsely promoted the concept of "psuedoaddiction" – drug seeking behavior that mimics addiction, occurring in patients who receive adequate pain relief – to diminish addiction concerns by implying this concept is substantiated by scientific evidence. [DE 2 (Complaint) at ¶¶ 77-84]. However, the FDA has approved labeling for Purdue's medications that embody this concept, both before and after the FDA's evidentiary review in response to the PROP petition. The FDA-approved labeling for extended-release opioid medications discusses "[d]rug-seeking behavior" in "persons with substance use disorders[,]" but also recognizes that "preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control." *See* FDA REMS, FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics at 3.

[¶35] **Manageability of Addiction Risk**: The State alleges Purdue misrepresented that addiction risk screening tools allow prescribers to identify and safely prescribe opioids to patients predisposed to addiction. [DE 2 (Complaint) at ¶¶ 85-89]. However, again, the State ignores that the FDA-approved REMS for Purdue's medications directs doctors to use screening tools and questionnaires to help mitigate opioid abuse. [DE 14 (Exhibit 1 - Oxy Contin Labeling)]. The FDA's response to the PROP Petition also clarified this distinction between physical dependence and addiction. [DE 17 (Exhibit 4) at 16 n.64 (the DSM-V "combines the substance abuse and substance dependence categories into a single disorder measured on a continuum, to try to avoid an

inappropriate linking of 'addiction' with 'physical dependence,' which are distinct issues.")].

[¶36] **Withdrawal**: The State alleges Purdue falsely claimed that "opioid withdrawal is not a problem." [DE 2 (Complaint) at ¶ 90]. The State contends symptoms associated with withdrawal can "decrease the likelihood that . . . patients will be able to taper or stop taking opioids." *Id.* However, the FDA approved Purdue's labeling, which informs doctors that physically dependent patients can be withdrawn safely by gradually tapering the dosage, and that addiction is "separate and distinct from physical dependence." [DE 14 (Exhibit 1 - Oxy Contin Labeling)].

[¶37] **Abuse-Deterrent Formulations**: The State alleges Purdue deceptively claimed that abuse-deterrent formulations of its opioid medications could "deter abuse," and "create false impressions that" abuse-deterrent formulations could "curb addiction and abuse." [DE 2 (Complaint) at ¶ 101]. The FDA-approved Oxy Contin labeling states that "OXYCONTIN is formulated with inactive ingredients intended to make the tablet more difficult to manipulate for misuse and abuse." [DE 14 (Exhibit 1 – OxyContin Labeling)]. Therefore, statements that abuse-deterrent formulations are designed to reduce the incidence of misuse, abuse, and diversion, [Compl. At ¶¶101-106], are consistent with the FDA-approved labeling and FDA policies. The State's allegations are also inconsistent with the FDA's 2013 "extensive review of the data regarding reformulated OxyConin" and the FDA's conclusion that reformulated Oxy Contin is "expected" to "make abuse via injection difficult," "reduce abuse via the intranasal route," and "deter certain types of misuse in therapeutic contexts." 78 Fed. Reg. 23273-01, 2013 WL 1650735 (Apr. 18, 2013).

[¶38] In other words, when presented with many of the same concerns the State alleges against Purdue in its Complaint regarding the enhanced risks of using opioids in high doses and for long durations, and with inadequate or misleading warnings, the FDA chose neither to impose those limits on opioid use nor to add warnings about those risks. The Court concludes this is "clear evidence" under *Levine* that the FDA would not have approved the changes to Purdue's labeling that the State contends were required to satisfy North Dakota law.

[¶39] "[T]he Court in *Levine* did not say that for evidence to be clear it must result from a formal procedure of approval or disapproval." *Rheinfrank v. Abbott Laboratories, Inc.*, 680 Fed. Appx. 369, 386 (6th Cir. 2017). The *Levine* Court concluded the claims were not preempted in that case because there was "**no** evidence in [the] record." *Wyeth*, 555 U.S. at 572. However, the Court noted that the claims in *Levine* "would have been preempted upon clear evidence that the FDA would have rejected the desired label change." *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1098 10th Cir. 2017). "*Levine* did not characterize the proof standard as requiring a manufacturer in every case to prove that it would have been impossible to alter the drug's label." *Dobbs v. Wyeth Pharmaceuticals*, 797 F. Supp.2d 1264, 1279 (W.D. Okla. 2011). "[T]his court does not interpret *Levine* as imposing upon the drug manufacturer a duty to continually 'press' an enhanced warning which has been rejected by the FDA." *Id.*

[¶40] In this case, the Court concludes Purdue has met its burden under *Levine's* clear evidence standard. "[A] court cannot order a drug company to place on a label a warning if there is clear evidence that the FDA would not approve it." *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010). Given that the FDA

does not yet believe the state of the data supports additional warnings or altered labeling when presented with the issues asserted by the State in this case, it would have been impossible for Purdue to comply with what the State alleges was required under North Dakota law while still respecting the FDA's unwillingness to change the labeling and warnings, both on its labels for opioids and in its advertising.

[¶41] Accordingly, federal law preempts the State's state-law claims, which are based on the marketing of Purdue's medications for their FDA-approved uses, including for treatment of chronic, non-cancer pain. Those claims necessarily "conflict[] with the FDA's jurisdiction over drug labeling, and specifically its approval of" those indications. *Prohias v. Pfizer, Inc.*, 490 F.Supp.2d 1228, 1234 (S.D. Fla. 2007). Because Purdue has met its burden under *Wyeth v. Levine*, the court concludes the state law claims asserted by the State are preempted in this matter by federal law.

B. Consumer Fraud Law Claims

[¶42] In addition to the preemption arguments detailed above, Purdue also argues the State's Consumer Fraud Law claims (First and Second Causes of Action) should be dismissed because the State has failed to plead the essential element of causation. The State argues it is not required to allege causation to prevail under the Consumer Fraud Law.

[¶43] The Unlawful Sales or Advertising Practices Act prohibits deceptive or fraudulent conduct in the sale or advertising of merchandise:

> The act, use, or employment by any person of any deceptive act or practice, fraud, false pretense, false promise, or misrepresentation, with the intent that others rely thereon in connection with the sale or advertisement of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is declared to be an unlawful practice. The act, use, or employment by any person of any act or

> practice, in connection with the sale or advertisement of any merchandise, which is unconscionable or which causes or is likely to cause substantial injury to a person which is not reasonably avoidable by the injured person and not outweighed by countervailing benefits to consumers or to competition, is declared to be an unlawful practice.

N.D.C.C. § 51-15-02.

[¶44] Purdue relies on *Ackre v. Chapman & Chapman, P.C.*, 2010 ND 167, 788 N.W.2d 344, for the argument that causation is an element the State must plead and prove to support its cause of action under the Consumer Fraud Law. *Ackre* involved a lawsuit brought under the private right of action in N.D.C.C. § 51-15-09. Because of this, the State argues "[w]hen the Court stated that the Plaintiff was required 'to show the putatively illegal action caused some threatened or actual injury to his or her legal rights and interests,' the Court was referring to what is required for a private plaintiff to have standing to bring a private right of action under N.D.C.C. § 51-15-09." [DE 34 (State's Response Brief) at ¶ 66]. Specifically, the State asserts "Consumer Fraud Actions brought by the Attorney General are civil law enforcement actions, not civil tort actions, and causation, and requirements applied to tort actions are, therefore, inapplicable to consumer fraud claims." [DE 34 (State's Response Brief) at ¶ 65].

[¶45] These arguments blatantly ignore the State's own Complaint and the types of damages it is seeking in this lawsuit.

[¶46] The State specifically alleges that "Purdue's conduct has resulted in a financial burden on the State of North Dakota." [DE 2 (Complaint) at ¶ 15]. It goes on to allege that the State and its Departments have "spent millions of dollars on opioid prescriptions for chronic pain and addiction treatment – costs directly attributable to the opioids Purdue unleashed on the State." *Id.* "Purdue's deceptive marketing of opioids

and the resulting opioid epidemic also has caused the State to incur additional cost for law enforcement, North Dakota Workforce Safety and Insurance, Department of Corrections, North Dakota Department of Human Services, and North Dakota Behavioral Health and other agencies." *Id.* at ¶ 16. "The State seeks injunctive relief, disgorgement and restitution for amounts the State's Medicaid program and other State agencies have paid for excessive opioid prescriptions." *Id.* at ¶ 17. The State also clearly asserts it is seeking "restitution for North Dakota consumers who, like the State, paid for excessive prescriptions of opioids for chronic pain." *Id.*

[¶47] The State's Complaint clearly includes requests for money damages for purported violations of the Consumer Fraud Law. For additional examples, the Complaint requests the Court to "restore any loss suffered by persons as a result of the deceptive acts or practices of Defendants as provided in N.D.C.C. § 51-15-07." [DE 2 (Complaint) at ¶ 186(d) (emphasis added)]. The State also alleges "Purdue is responsible for the claims submitted and the amount the State's Medicaid program and other State agencies spent on its opioids." *Id.* at ¶ 182. The Prayer for Relief also requests "[t]hat Purdue be ordered to pay restitution to the State, [and] State agencies, including the Department of Human Services." [DE 2 (Complaint – Prayer for Relief (E)].

[¶48] The plain language of § 51-15-07 requires proof that the money to be restored was acquired "by means of" the allegedly deceptive act. Whether styled as a claim for money damages or for restitution pursuant to § 51-15-07, the requirement is the same: The State must plead and prove causation, i.e. the loss of money occurred "by means of" the alleged deception. *Compare* N.D.C.C. § 51-15-09 (allowing claim "against any

person who has acquired any moneys or property by means of any practice declared to be unlawful un this chapter") (emphasis added) *with* N.D.C.C. § 51-15-07 (allowing restitution of money "that may have been acquired by means of any practice in this chapter . . . declared to be unlawful") (emphasis added).

[¶49] When the State makes a claim under the Consumer Fraud Law for out-of-pocket losses, it is no different than a private plaintiff's claim to recover actual damages suffered "by means of" the deception. *See* N.D.C.C. § 51-15-09. There is simply no basis in North Dakota law to conclude the "by means of" language in the private consumer section of the Consumer Fraud Act (51-15-09) has a different meaning than the "by means of" language in § 51-15-07.

[¶50] The State's Complaint fails to identify which losses occurred "by means of" – i.e., because of – any specific alleged deception or misrepresentation on the part of Purdue. The State does not allege that every opioid prescription in North Dakota was unlawful. In fact, the State expressly acknowledges that it does not seek an outright ban on the sale of opioids. [DE 34 (State's Response Brief) at 25]. The State acknowledges that "not every sale" of opioids "contributed" to the public health problem. *Id.* at 49. To put it succinctly, the State essentially alleges that there is an opioid problem in North Dakota that has caused the State and its citizens great "financial burden", and that the problem was the fault of Purdue and its marketing, but then completely fails to allege how Purdue's allegedly deceptive marketing actually caused the alleged great "financial burden."

[¶51] The State does not identify any North Dakota doctor who ever received any specific purported misrepresentation made by Purdue, or who wrote a medically

unnecessary prescription because of those alleged statements. The State also does not allege any false statement caused the State to reimburse prescriptions it otherwise would not have reimbursed. Under the State's theory, it can recover for reimbursements under the Consumer Fraud Act even if the State fails to show any such reimbursements were caused by a deception, and even when the State continued to pay for reimbursements with knowledge of the alleged deception.

[¶52] Rather than plead the requisite specifics, the Complaint offers only conclusory allegations that Purdue had "a marketing campaign" since the 1990s, which was "designed to convince prescribers and the public that its opioids are effective for treating chronic pain" and allegedly resulted in the routine prescription of opioids for long-term use. [DE 2 (Complaint) at ¶ 4]. These allegations are unconnected to any particular North Dakota doctor or prescription. Additionally, the State fails to plead how the alleged misstatements, most of which are alleged to have occurred over a decade ago, could have caused specific prescribing decisions to this day.

[¶53] A generalized "fraud-on-the-market" theory does not suffice to establish causation. In cases that assert claims for fraudulent or deceptive pharmaceutical marketing, "a fraud-on-the-market theory cannot plead the necessary element of causation because the relationship between the defendants' alleged misrepresentations and the purported loss suffered by the patients is so attenuated . . . that it would effectively be nonexistent." *In re Actimmune Mktg. Litig.*, 614 F.Sup.2d 1037, 1054 (N.D. Cal. 2009), aff'd, 464 F.App'x 651 (9th Cir. 2011).

[¶54] The State acknowledges that patients may not lawfully obtain Purdue's opioid medications without a valid prescription. [DE 2 (Complaint) at ¶ 11]. The State also

recognizes that doctors themselves have many resources available about Purdue's products, including FDA-approved labeling that discloses the risks Purdue allegedly concealed. *Id.* at ¶¶ 69-70, 72-73, 75-76, 83-84, 88, 93, 97-100, 104, 111-12, 117.

[¶55] Even assuming, for purposes of argument only, that Purdue had failed to disclose these risks, such a failure would not be the "proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004) (internal quotations and citations omitted) (concluding North Dakota would adopt the "learned intermediary" doctrine). The State's theory in this case depends on an extremely attenuated, multi-step, and remote causal chain. The State's claims – no matter how styled – have to account for the independent actor (i.e. doctors) who stands between Purdue's alleged conduct and the alleged harm. *Id.* In the face of information available to physicians, the State has not pleaded facts showing that Purdue's alleged misrepresentations – as opposed to the undisputed multiple layers of individualized decision-making by doctors and patients or other possible intervening causes – led to any relevant prescribing or reimbursement decision.

[¶56] A defendant is not liable for alleged injuries that either result from a superseding, intervening cause, or "if the cause is remote" from the injury. *Moum v. Maercklein*, 201 N.W.2d 399, 403 (N.D. 1972); *see also Price v. Purdue Pharma Co.*, 920 So.2d 479, 485-86 (Miss. 2006) (observing lack of proximate cause for claims of opioid addiction brought against Purdue, because injuries were the result of illegally obtained and improper use of opioids). "A superseding cause is an act of a third person or other force which by its intervention prevents the actor from being liable for harm to

another which his antecedent negligence is a substantial factor in bringing about." *Leistra v. Bucyrus-Erie Co.*, 443 F.2d 157, 163 n.3 (8th Cir. 1971) (internal quotations omitted).

[¶57] *Ashley County, Ark. v. Pfizer, Inc.*, 552 F.3d 659 (8th Cir. 2009), which was decided under analogous facts, is instructive. In *Ashely County*, Arkansas counties brought claims against pharmaceutical companies for, *inter alia*, public nuisance and deceptive trade practices, seeking "compensation to recoup the costs expended by the counties in dealing with the societal effects of the methamphetamine epidemic in Arkansas, with liability premised on the use of the Defendants' products in the methamphetamine manufacturing process. *Id.* at 663. The Eighth Circuit affirmed the dismissal of the complaint for failure to state a claim, and determined that "[p]roximate cause seems an appropriate avenue for limiting liability in this context . . . particularly 'where an effect may be a proliferation of lawsuits not merely against these defendants but against other types of commercial enterprises – manufacturers, say, of liquor, anti-depressants, SUVs, or violent video games – in order to address a myriad of societal problems regardless of the distance between the 'causes' of the 'problems' and their alleged consequences.'" *Id.* at 671-72 (quoting *Dist. of Columbia v. Beretta, U.S.A., Corp.*, 872 A.2d 633, 651 (D.C. 2005)).

[¶58] Similarly, in this case, the connection between the alleged misconduct and the prescription depends on multiple, independent, intervening events and actors. These intervening events and actors include: the doctor's independent medical judgment, the patient's decision whether and how to use the medication, the patient's response to the medication, and the State's own decision to reimburse the prescriptions. Additionally,

it is nearly impossible to trace any of the harms the State alleges back to solely Purdue's own medications, as opposed to other manufacture's opioids and other unlawful opioids. Holding Purdue solely responsible for the entire opioid epidemic in North Dakota is difficult to comprehend, especially given Purdue's small share of the overall market for lawful opioids. It is also difficult to comprehend given the large market for unlawful opioids.

[¶59] The State's claims that Purdue can, should, or should have in the past, "changed the message" regarding opioids to include stronger warnings and labeling is not taken well by the Court. Even if Purdue can and does "change the message," Purdue has absolutely no control over how doctors prescribe the drug and how patients choose to use the drug. Purdue also has no control over how other manufacturers of opioids promote the drugs. Doctors can be loose with their prescribing practices, and patients do not always follow their doctor's orders. The Court does not mean to suggest this is the sole cause of the opioid crisis in North Dakota. But the State has failed to allege facts which, if true, show that Purdue, alone, caused the opioid crisis for which the State seeks compensation. The causal chain the State attempts to allege is simply too attenuated.

[¶60] The State seems to acknowledge its attenuated theory of causation in its Complaint by identifying a number of behaviors that contribute to the opioid crisis, such as "doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment." [DE 2 (Complaint) at ¶ 151]. The State also clearly acknowledges the "high statistic of people that first get addicted after obtaining opioids free from a friend or relative." *Id.* at ¶ 145. These are not Purdue's

acts or misrepresentations, yet the State seeks to hold Purdue solely liable. The State's effort to hold one company to account for this entire, complex public health issue oversimplifies the problem.

[¶61] The Court concludes the State's causal theory is too attenuated and requires dismissal of the State's Consumer Fraud Law Claims as a matter of law. If the State can proceed on the causation it has alleged in this lawsuit against Purdue, it begs the question of how far the causal chain can go. There are a seemingly limitless number of actors who could have "tried harder" under the State's theory and claims. Purdue is no higher up in the causal chain under the facts alleged by the State than any other actor who could be held liable. The State has not pleaded facts that Purdue's alleged misrepresentations caused North Dakota doctors to write medically unnecessary prescriptions or that Purdue's alleged misrepresentation caused the State to reimburse prescriptions.

[¶62] Because the State has failed to adequately plead causation, its Consumer Fraud Law claims fail as a matter of law and must be dismissed.

C. Public Nuisance

[¶63] Purdue additionally argues the State's Third Cause of Action for public nuisance must be dismissed because no North Dakota court has extended the public nuisance statutes to cases involving the sale of goods. Because the State's nuisance claim in this case revolves around the effects of a product (opioids) sold and used in North Dakota, Purdue argues the State's public nuisance claim fails.

[¶64] The State's claim for public nuisance is brought under N.D.C.C. § 42-01-01 *et seq.* (nuisance) and 42-02-01 *et seq.* (abatement of common nuisance). A nuisance is defined by N.D.C.C. § 42–01–01, which provides:

> 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.

[¶65] "A public nuisance is one which at the same time affects an entire community or neighborhood or any considerable number of persons, although the extent of the annoyance or damage inflicted upon the individuals may be unequal." N.D.C.C. § 42–01–06. The N.D.C.C. § 42–01–01 definition of nuisance applies to public nuisance claims. *Kappenman v. Klipfel*, 2009 ND 89, ¶ 36, 765 N.W.2d 716.

[¶66] In response to Purdue's argument on this issue, the State attempts to characterize its claims as focusing only on Purdue's marketing conduct, and not on the actual sale of opioids. The State alleges "[t]he Complaint does not identify Purdue's sale of the opioids as the public nuisance; instead, the nuisance is Purdue's misrepresentations and deceptive promotion of their risks and benefits." [DE 34 (State's Response Brief) at ¶ 73]. This argument, again, ignores the clear allegations in the State's Complaint.

[¶67] The State specifically alleges a public nuisance in this case in that "Purdue's conduct unreasonably interfered with the public health, welfare, and safety of North Dakota residents by expanding the opioid market and opioid use through an aggressive and successful marketing scheme that relied on intentional deception and misrepresentation regarding the benefits, safety and efficacy of prescription opioids." [DE 34 (State's Response Brief) at ¶ 72; and DE 2 (Complaint) at ¶¶ 4, 7, & 9]. The State further alleges that Purdue's conduct "caused and maintained the overprescribing and sale of opioid for long-term treatment of chronic pain at such volumes and degrees as to create an epidemic." [DE 2 (Complaint) at ¶ 201].

[¶68] The State cannot escape the true nature of the nuisance claim it has pleaded. The "overprescribing and sale" of opioids manufactured by Purdue are directly at the heart of the State's nuisance claim, regardless of how it otherwise now tries to characterize its claim.

[¶69] Purdue is correct, as the State concedes, that North Dakota courts have not extended the nuisance statute to cases involving the sale of goods. [DE 34 (State's Response Brief) at ¶ 74; DE 13 (Purdue's Brief in Support of Motion) at ¶ 45]. Such a situation was addressed by the Eighth Circuit Court of Appeals in *Tioga Pub. Sch. Dist. No. 15 of Williams Cty. State of N. Dakota v. United States Gypsum Co.*, 984 F.2d 915, 920 (8th Cir. 1993). Although *Tioga* was a federal case, in the absence of binding North Dakota Supreme Court decisions interpreting North Dakota law, federal court decisions are given deference. *N. Dakota Fair Hous. Council, Inc. v. Peterson*, 2001 ND 81, ¶¶ 20-24, 625 N.W.2d 551, 559 (N.D. 2001).

[¶70] In *Tioga*, the 8th Circuit concluded that the North Dakota Supreme Court would not extend the nuisance doctrine to cases involving the sale of goods. *Tioga*, 984 F.2d at 920. The Court reasoned:

> Tioga has not presented us with any North Dakota cases extending the application of the nuisance statute to situations where one party has sold to the other a product that later is alleged to constitute a nuisance, nor has our research disclosed any such cases. 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

Id. (emphasis added).

[¶71] The State urges this Court to distinguish *Tioga* "because it does not arise from a direct injury to a private individual from the use of the product purchased, and it's not a product liability or warranty type claim." [DE 34 (State's Response Brief) at ¶ 74]. However, the statutory definition of nuisance applies equally to public and private nuisances. Additionally, as the Eighth Circuit warned in *Tioga*:

> [T]o interpret the nuisance statute in the manner espoused by Tioga would in effect totally rewrite North Dakota tort law. Under Tioga's theory, any injury suffered in North Dakota would give rise to a cause of action under section 43–02–01 regardless of the defendant's degree of culpability or of the availability of other traditional tort law theories of recovery. Nuisance thus would become a monster that would devour in one gulp the entire law of tort, a development we cannot imagine the North Dakota legislature intended when it enacted the nuisance statute.

Tioga, 984 F.2d at 921.

[¶72] This Court agrees with the reasoning of the Eighth Circuit in *Tioga*. The State is clearly seeking to extend the application of the nuisance statute to a situation where one party has sold to another a product that later is alleged to constitute a nuisance. *Id.* at 920 (emphasis added). The reality is that Purdue has no control over its product after it

is sold to distributors, then to pharmacies, and then prescribed to consumers, i.e. after it enters the market. Purdue cannot control how doctors prescribe its products and it certainly cannot control how individual patients use and respond to its products, regardless of any warning or instruction Purdue may give.

[¶73] No North Dakota court has extended the public nuisance statutes to cases involving the sale of goods. The Eighth Circuit Court of Appeals, while applying North Dakota law, expressly declined to do so, and this Court declines to do so in this case. The State does not have a cause of action for nuisance against Purdue since its nuisance claim arises from the "overprescribing and sale" of opioids manufactured by Purdue. Therefore, the State's claim for public nuisance must be, and is, dismissed.

CONCLUSION

[¶74] Based upon the foregoing, the Court concludes that the State has not adequately pleaded its causes of action against Purdue. Therefore, for all the reasons stated above, Purdue's Motion to Dismiss is, in all respects, hereby **GRANTED.**

[¶75] Counsel for Purdue is tasked with the responsibility of drafting a judgment consistent with this memorandum.

IT IS SO ORDERED.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated this 10th day of May, 2019.

BY THE COURT:

James S. Hill

James S. Hill, District Judge
South Central Judicial District

cc:

EXHIBIT B

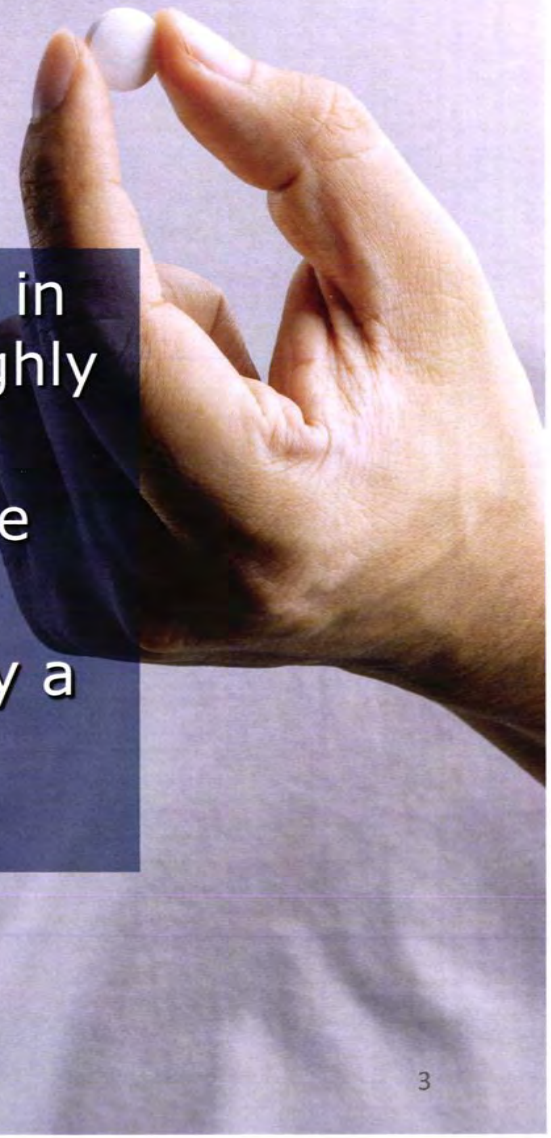
OPIOID EPIDEMIC
IN NEVADA COUNTIES

1

WHAT ARE OPIOIDS?

- A class of drugs that includes heroin and prescription pain relievers such as OxyContin, Vicodin, Codeine and more;
- That interact with opioid receptors on nerve cells in our body and brain;
- They concentrate in brain regions responsible for perception of pain and pleasure;
- They provide both pain relief and euphoria.

WHAT ARE OPIOIDS?



- Because opioids produce euphoria in addition to pain relief, they are highly addictive and are often misused.
- Misuse of opioids leads to overdose incidents and death.
- Long term use (even prescribed by a doctor) leads to dependence and addiction.

What is an opioid overdose?

Taking too many opioids
mixing them with other d
make your breathing slow

TO AVOID AN ACCIDENTAL OPIOID O

- **Avoid mixing your op alcohol, benzodiazep (Xanax, Ativan, Klon Valium), or medicine you sleepy.**
- **Be extra careful if yo change doses, feel ill new medications.**

Now that you have n
Tell someone where it is and how to use it.

Common opioids include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxycodone	Percocet, OxyContin, Roxycodone, Percodan
Morphine	MS Contin, Kadian
Codeine	Tylenol III
Fentanyl	Duragesic
Hydromorphone	Dilaudid
Oxymorphone	Opana
Meperidine	Demerol
Methadone	Dolophine, Methadose
Buprenorphine	Suboxone, Subutex, Buprenex, Butrans

This publication is made possible, in part, by a grant from the Nevada Division of Public and Behavioral Health.

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

JTNN
Join Together Northern Nevada

REGIONAL MEDICAL EXAMINER'S OFFICE

WASHOE COUNTY HEALTH DISTRICT
ENHANCING QUALITY OF LIFE

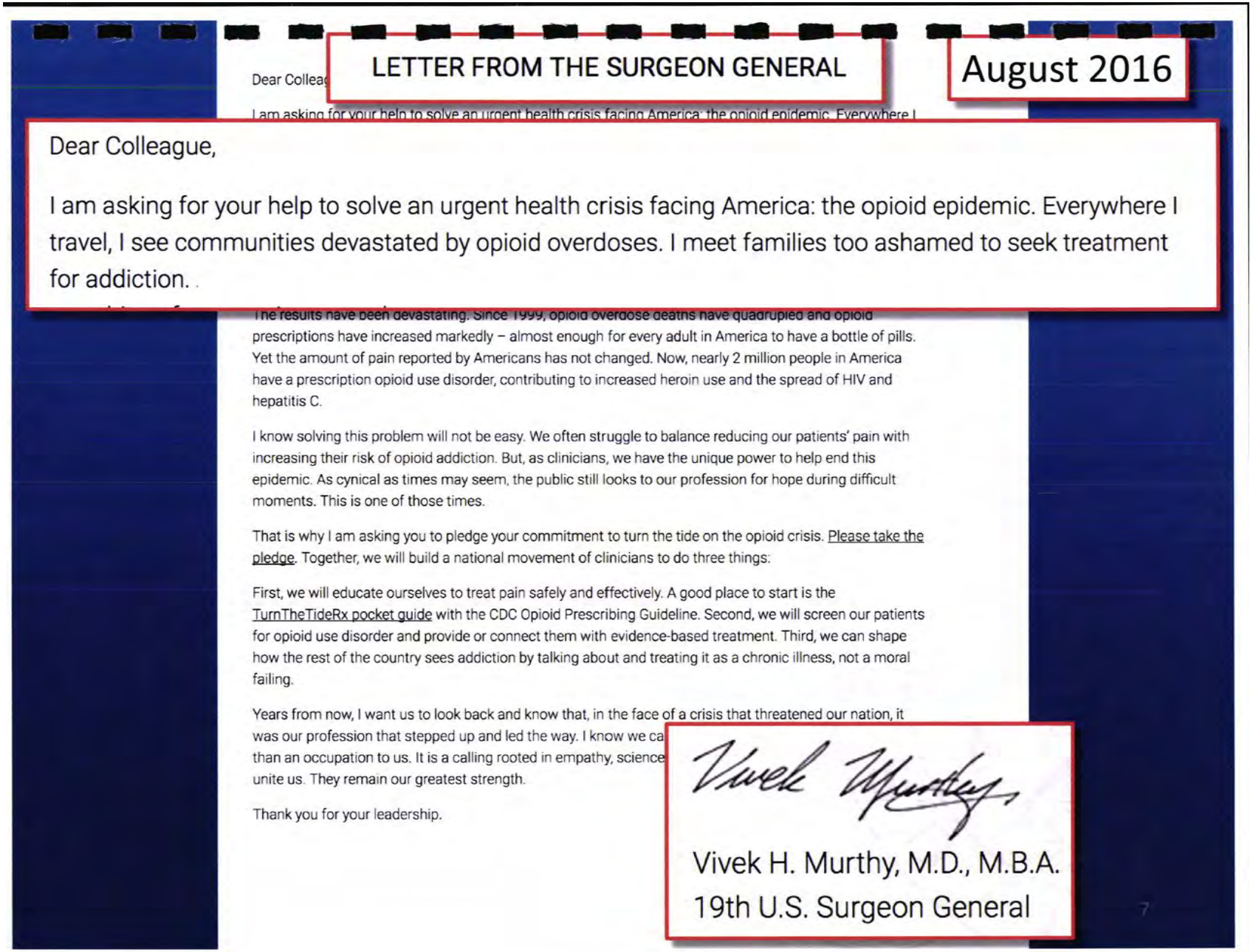
OPIOID EPIDEMIC

- Historically, opioids were considered too addictive for treatment of chronic pain (migraines, back pain, arthritis), and they were used only to treat short term acute pain or for palliative end of life care.
- In the late 1990's, and continuing today, opioids began being prescribed for chronic pain as a result of aggressive marketing campaigns by drug companies.

NEW ENGLAND JOURNAL OF MEDICINE

"...the widespread use of opioid drugs has resulted in a national epidemic of opioid deaths and addictions."

"Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies"
Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D.
N Engl J Med, March 31, 2016; 374:1253-1263



LETTER FROM THE SURGEON GENERAL

August 2016

Dear Colleag

I am asking for your help to solve an urgent health crisis facing America: the opioid epidemic. Everywhere I

Dear Colleague,

I am asking for your help to solve an urgent health crisis facing America: the opioid epidemic. Everywhere I travel, I see communities devastated by opioid overdoses. I meet families too ashamed to seek treatment for addiction. .

The results have been devastating. Since 1999, opioid overdose deaths have quadrupled and opioid prescriptions have increased markedly – almost enough for every adult in America to have a bottle of pills. Yet the amount of pain reported by Americans has not changed. Now, nearly 2 million people in America have a prescription opioid use disorder, contributing to increased heroin use and the spread of HIV and hepatitis C.

I know solving this problem will not be easy. We often struggle to balance reducing our patients' pain with increasing their risk of opioid addiction. But, as clinicians, we have the unique power to help end this epidemic. As cynical as times may seem, the public still looks to our profession for hope during difficult moments. This is one of those times.

That is why I am asking you to pledge your commitment to turn the tide on the opioid crisis. Please take the pledge. Together, we will build a national movement of clinicians to do three things:

First, we will educate ourselves to treat pain safely and effectively. A good place to start is the TurnTheTideRx pocket guide with the CDC Opioid Prescribing Guideline. Second, we will screen our patients for opioid use disorder and provide or connect them with evidence-based treatment. Third, we can shape how the rest of the country sees addiction by talking about and treating it as a chronic illness, not a moral failing.

Years from now, I want us to look back and know that, in the face of a crisis that threatened our nation, it was our profession that stepped up and led the way. I know we ca
than an occupation to us. It is a calling rooted in empathy, science
unite us. They remain our greatest strength.

Thank you for your leadership.

Vivek Murthy

Vivek H. Murthy, M.D., M.B.A.
19th U.S. Surgeon General

LETTER FROM THE SURGEON GENERAL

August 2016

Dear Colleag

I am asking for your help to solve an urgent health crisis facing America: the opioid epidemic. Everywhere I travel, I see communities devastated by opioid overdoses. I meet families too ashamed to seek treatment for addiction. And I will never forget my own patient whose opioid use disorder began with a course of morphine after a routine procedure.

Nearly two decades ago, we were encouraged to be more aggressive about treating pain, often without enough training and support to do so safely. This coincided with heavy marketing of opioids to doctors. Many of us were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.

have a prescription opioid use disorder, contributing to increased heroin use and the spread of HIV and hepatitis C.

I know solving this problem will not be easy. We often struggle to balance reducing our patients' pain with increasing their risk of opioid addiction. But, as clinicians, we have the unique power to help end this epidemic. As cynical as times may seem, the public still looks to our profession for hope during difficult moments. This is one of those times.

That is why I am asking you to pledge your commitment to turn the tide on the opioid crisis. Please take the pledge. Together, we will build a national movement of clinicians to do three things:

First, we will educate ourselves to treat pain safely and effectively. A good place to start is the TurnTheTideRx pocket guide with the CDC Opioid Prescribing Guideline. Second, we will screen our patients for opioid use disorder and provide or connect them with evidence-based treatment. Third, we can shape how the rest of the country sees addiction by talking about and treating it as a chronic illness, not a moral failing.

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unite us. They remain our greatest strength.

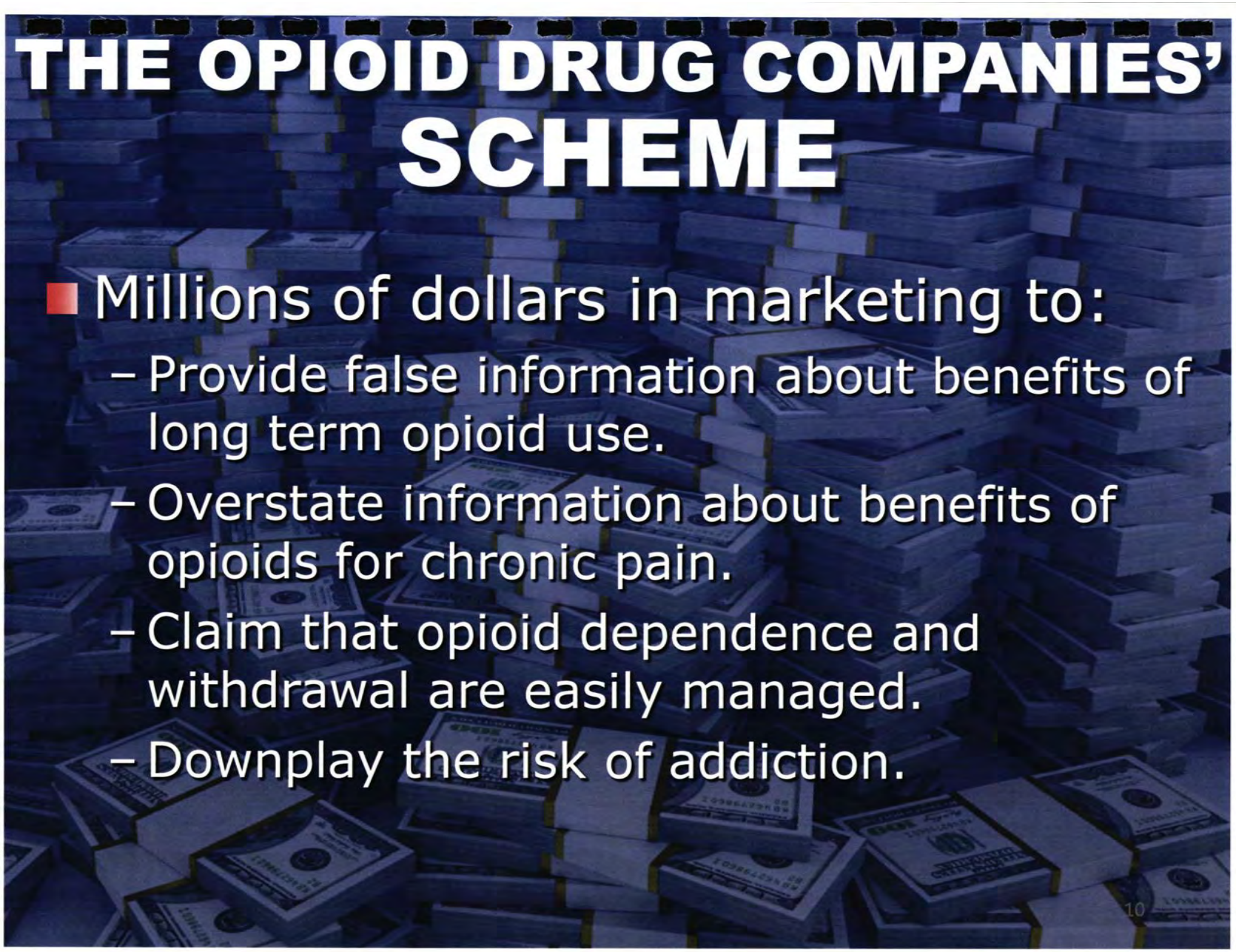
Thank you for your leadership.

Vivek H. Murthy, M.D., M.B.A.
19th U.S. Surgeon General

8

DRUG COMPANIES CAUSED THE OPIOID EPIDEMIC

- Drug companies know that doctors rely on the information that the drug companies provide.
- Drug companies must tell the truth when marketing their drugs and their marketing claims must be supported by medical evidence.
- However, in mid to late 1990s, the opioid manufacturers developed a marketing scheme to persuade doctors and patients to use opioids for chronic pain.
- This scheme allowed the opioids to be prescribed to a much larger group of patients.
- This scheme made the drug companies tens of billions of dollars and caused patients to become addicts.


THE OPIOID DRUG COMPANIES' SCHEME
Millions of dollars in marketing to:
– Provide false information about benefits of long term opioid use.
– Overstate information about benefits of opioids for chronic pain.
– Claim that opioid dependence and withdrawal are easily managed.
– Downplay the risk of addiction.
10

THE OPIOID DRUG COMPANIES' SCHEME

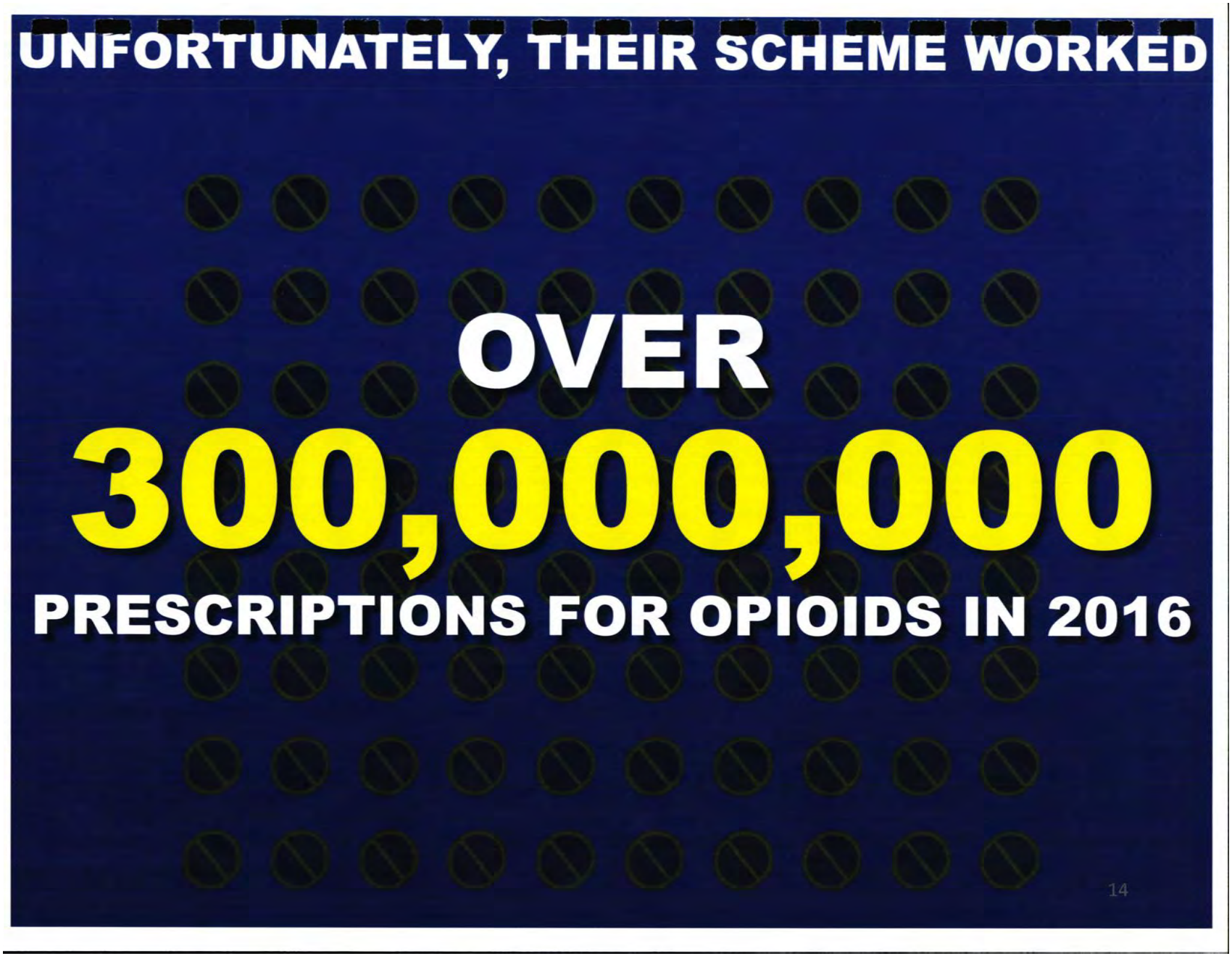
- Disseminated their message through:
  - Sales Reps. (Detailers).
  - Speaker groups (Physicians working for drug company).
  - Key Opinion Leaders (KOL's) working for drug company.
  - Funding and conducting continuing medical education programs (CME), conferences and seminars to promote opioids.
  - "Front Groups" controlled and funded by the opioid companies who created treatment guidelines that favored opioids for chronic pain use.
  - Used "Front Groups" to refute negative articles and fight against regulatory changes that would limit opioid prescribing.

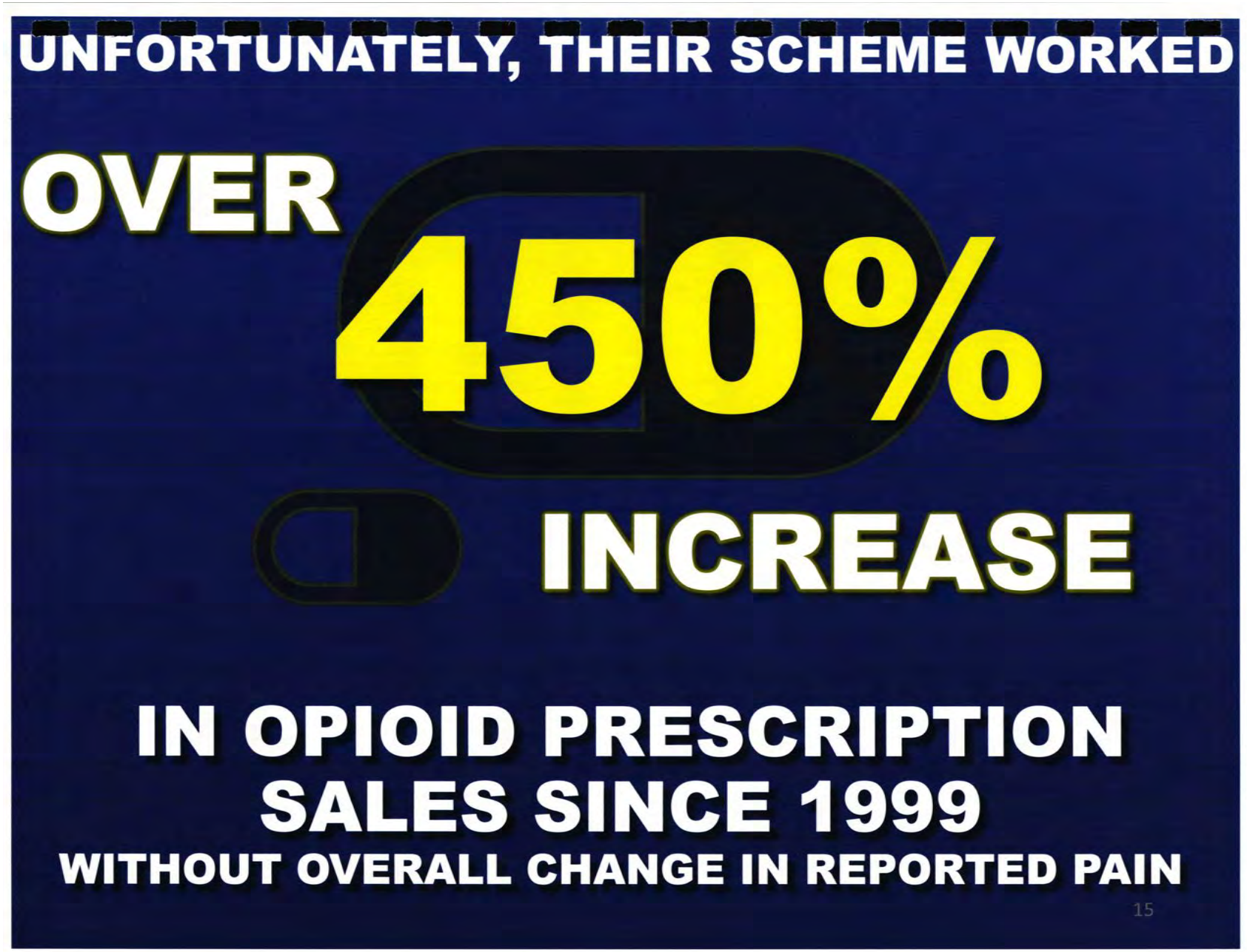
THE OPIOID DRUG COMPANIES' SCHEME

- American Pain Foundation (APF)
  - The most prominent "Front Group" for the opioid drug companies.
  - Received millions of dollars in funding from opioid drug companies.
  - Issued guidelines for patients, policymakers, and physicians which touted the benefits of opioid use for chronic pain.
  - Multi-media campaigns including radio, TV and internet.
  - Launched a campaign to promote opioids for treatment of returning veterans which contributed to high rates of addiction, hospitalizations from adverse events and overdose deaths.
  - In May 2012, APF was investigated by the U.S. Senate Finance Committee to determine their financial links to the opioid drug companies.
  - Within days of being targeted by the U.S. Senate, the APF Board voted to dissolve the organization.

THEIR SCHEME TARGETED VETERANS

- Exit Wounds
  - Book published in 2009 which was sponsored and distributed by an opioid drug company (Purdue Pharmaceuticals).
  - Was written as a "personal narrative" of a veteran.
  - Describes opioids as the "gold standard of pain medication" and that it "increases a person's level of functioning."
  - Minimizes the risk of opioid addiction.
  - The drug company propaganda in Exit Wounds is contrary to the scientific and medical evidence.
  - According to a published study in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids had higher incidence of adverse clinical outcomes, overdoses, and self inflicted injuries than the general population.


UNFORTUNATELY, THEIR SCHEME WORKED
OVER
300,000,000
PRESCRIPTIONS FOR OPIOIDS IN 2016
14


UNFORTUNATELY, THEIR SCHEME WORKED
OVER
450%
INCREASE
IN OPIOID PRESCRIPTION SALES SINCE 1999
WITHOUT OVERALL CHANGE IN REPORTED PAIN
15

UNFORTUNATELY, THEIR SCHEME WORKED

AS MANY AS

1 IN 4

RECEIVING LONG-TERM OPIOID THERAPY (IN PRIMARY CARE SETTINGS) STRUGGLE WITH OPIOID ADDICTION

16

UNFORTUNATELY, THEIR SCHEME WORKED

- In 1997, Purdue pharmaceuticals production quota for OxyContin was 8.3 tons.
- In 2011, Purdue's production quota for Oxycontin rose to 105 tons (1,200% increase).
- In 2012, there were approximately 259 million opioid prescriptions written.
- In 2012, over 2 million Americans were abusing or dependent on opioids.
- In 2014, over 60% of drug overdose deaths involved opioids.
- As of 2016, Purdue Pharmaceuticals had earned as much as $31 billion from the promotion of OxyContin.
- Now, opioid sales account for nearly $10 billion in sales per year (industry wide).


UNFORTUNATELY, THEIR SCHEME WORKED
Prescription
RX # 2054708
OPIOIDS ARE
THE MOST COMMONLY
PRESCRIBED
MEDICATION IN THE U.S.
Source: New England Journal of Medicine
18

DRUG DISTRIBUTORS PARTICIPATED IN THE SCHEME

- In 1970, Congress enacted a law to create a "closed system" for distribution of controlled substances.
- This law prevents drug manufacturers from selling directly to pharmacies and retailers.
- This law requires that drug distributors act as the "gate keeper" between the drug manufacturer and the retailer (pharmacy).
- The drug distributors have a legal duty to identify, investigate and report suspicious orders of opioids to authorities.
- Distributors are legally required to be on alert for suspicious orders by pharmacies, such as unusual:
  - Size of orders
  - Frequency of orders
  - Pattern of orders

THE BIG 3

THERE ARE
OVER 800 REGISTERED WHOLESALE DISTRIBUTORS
IN THE UNITED STATES

BUT **THREE** FORTUNE 500 COMPANIES
OWN 85% OF THE MARKET SHARE

CardinalHealth
AmerisourceBergen
McKESSON
Empowering Healthcare

EACH COMPANY GENERATES
OVER $100 BILLION
IN REVENUE ANNUALLY

THE BIG 3 HAVE FAILED THEIR GATEKEEPER DUTY

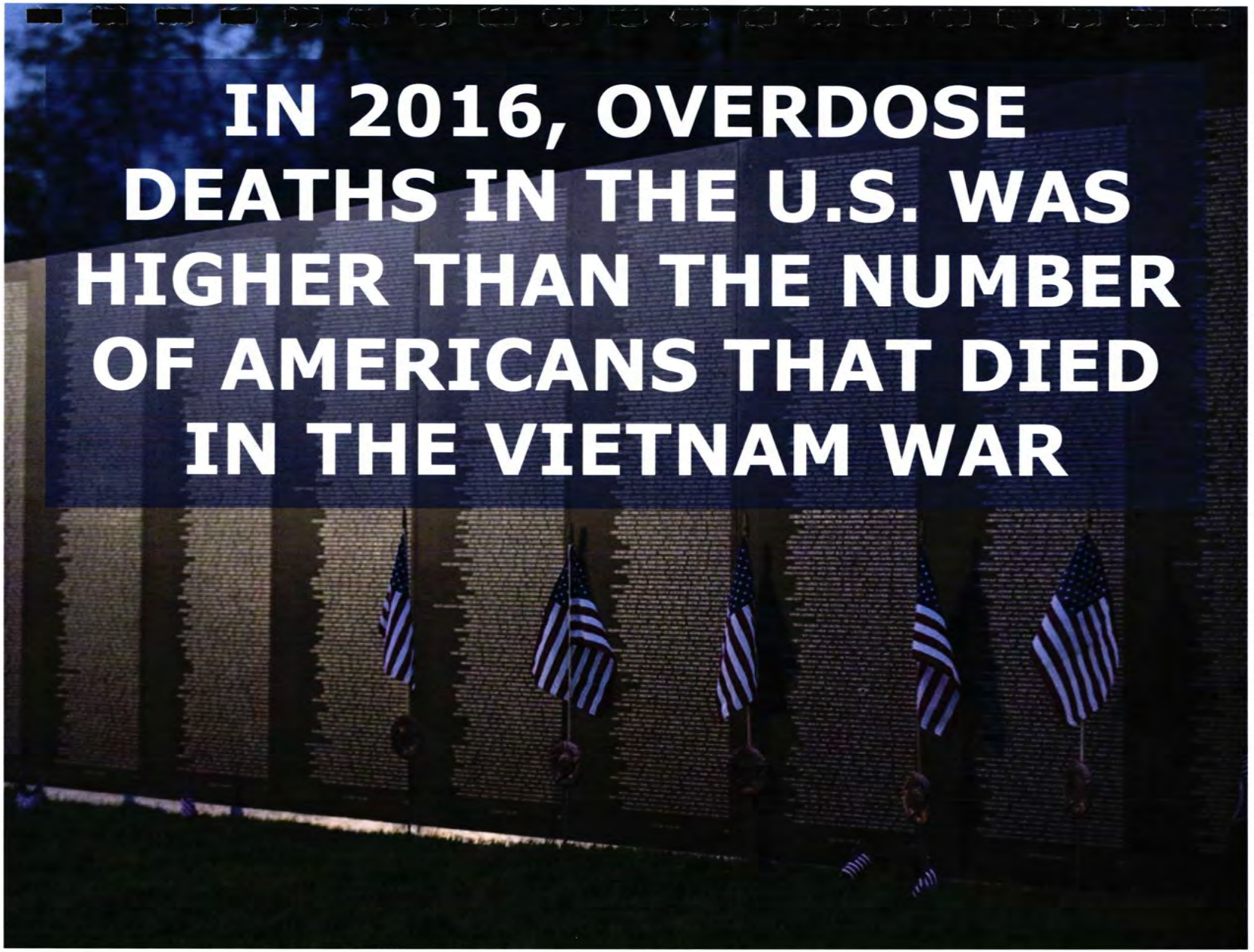
- The drug distributors have not been reporting suspicious opioid orders to the authorities.
- Instead, the distributors have lined their pockets by shipping massive quantities of opioids to our communities.
- For years, the Big 3 have failed to report or stop suspicious orders of opioids, while continuing to funnel millions of pills into U.S. communities.

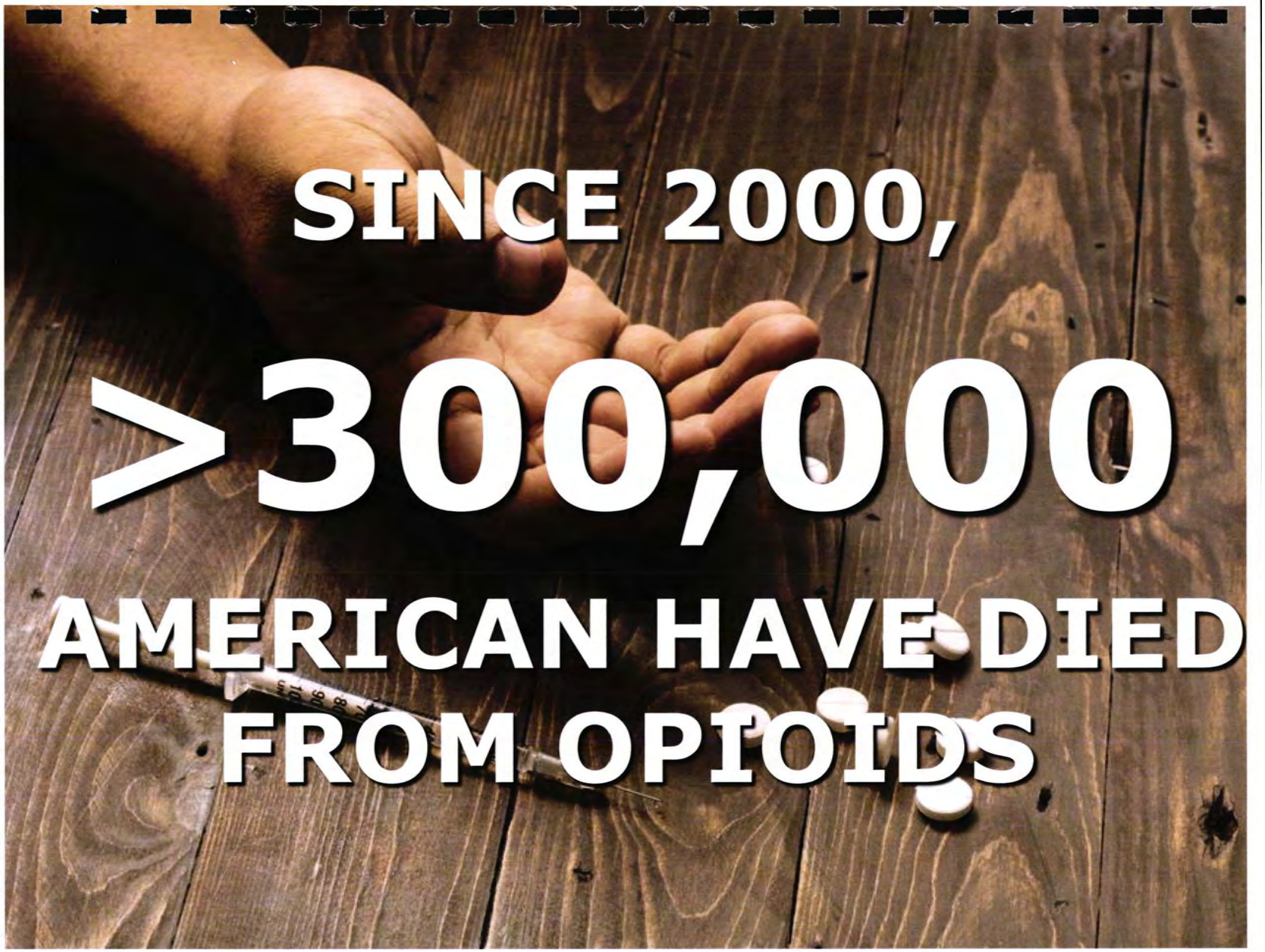
In January 2017 McKesson, the largest drug distributor in the nation, was fined a record **$150 million** by the federal government for its blatant failure to report suspicious orders in violation of federal law. Cardinal Health, another member of the "Big Three" drug distributors, was fined **$44 million** for its own failures to report suspicious narcotic orders to the DEA.


OPIOID ADDICTION
IMPACTS ALL PEOPLE, REGARDLESS OF:
Race
Gender
Socio-economic background
Political affiliation
23

OPIOID CRISIS

- Chances of addiction increases after 3rd day prescribed
- Women addicted to opioids increased 400% from 1999-2010
- Fatally injured drivers who tested positive for opioids rose 700% from 1995-2015
- 60% of all opioid deaths in America involve opioids
- 40x more likely to be addicted to heroin
- 175 people die each day in the U.S. due to opioid and heroin overdose


IN 2016, OVERDOSE DEATHS IN THE U.S. WAS HIGHER THAN THE NUMBER OF AMERICANS THAT DIED IN THE VIETNAM WAR


SINCE 2000,
>300,000
AMERICAN HAVE DIED
FROM OPIOIDS

LETTER FROM THE SURGEON GENERAL

August 2016

Dear Colleag

I am asking for your help to solve an urgent health crisis facing America: the opioid epidemic. Everywhere I travel, I see communities devastated by opioid overdoses. I meet families too ashamed to seek treatment for addiction. And I will never forget my own patient whose opioid use disorder began with a course of morphine after a routine procedure.

It is important to recognize that we arrived at this place on a path paved with good intentions. Nearly two decades ago, we were encouraged to be more aggressive about treating pain, often without enough training and support to do so safely. This coincided with heavy marketing of opioids to doctors. Many of us were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.

The results have been devastating. Since 1999, opioid overdose deaths have quadrupled and opioid

Now, nearly 2 million people in America have a prescription opioid use disorder, contributing to increased heroin use and the spread of HIV and hepatitis C.

increasing their risk of opioid addiction. But, as clinicians, we have the unique power to help end this epidemic. As cynical as times may seem, the public still looks to our profession for hope during difficult moments. This is one of those times.

That is why I am asking you to pledge your commitment to turn the tide on the opioid crisis. Please take the pledge. Together, we will build a national movement of clinicians to do three things:

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Vivek Murthy

Vivek H. Murthy, M.D., M.B.A.
19th U.S. Surgeon General

27

OPIOID USE INCREASES, HEROIN USE INCREASES

NIH National Institute on Drug Abuse

NIH National Institute on Drug Abuse
Advancing Addiction Science

Prescription opioid use is a risk factor for

Prescription opioid use is a risk factor for heroin use

Prescription opioid use is a risk factor for heroin use

Pooling data from 2002 to 2012, the incidence of heroin initiation was 19 times higher among those who reported prior nonmedical pain reliever use than among those who did not (0.39 vs. 0.02 percent) (Muhuri et al., 2013). A study of young, urban injection drug users interviewed in 2008 and 2009 found that 86 percent had used opioid pain relievers nonmedically prior to using heroin, and their initiation into nonmedical use was characterized by three main sources of opioids: family, friends, or personal prescriptions (Lankenau et al., 2012). This rate represents a shift from historical trends.

- **Nearly 80% of new heroin users took prescription opioids before starting heroin.**
- **In 2015, there were 12,990 heroin overdose deaths in the U.S.**

https://www.drugabuse.gov/publications/research-reports/relationship-b...tion-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use Page 1 of 3

28

THE NUMBER OF PRESCRIPTIONS INCREASED

Nevada Substance Abuse Working Group
2017 Report

The Scope of Opioid Abuse

94 painkiller prescriptions for every 100 Nevada residents, 1 in 5 high school students self-reported that they had used a prescription drug that was not specifically written for them.

Nevada Substance Abuse Working Group
2017 Report

January 15, 2017

Adam Paul Laxalt
Attorney General
Chairman

epartment of
in 2014 there
r increase
2013 where there were 16,000 drug related deaths. In Nevada, it was reported
State physicians write 94 painkiller prescriptions for every 100 Nevada
nts self-reported that they had used a
written for them. Ms. Peek testified that
nter for Disease and Control (CDC) to aid
ill be received through 2019 to help

per 5, 2016 Meeting

s of marijuana use among youth. Colorado saw an increase of 20% since
lizing the recreational use of marijuana while the national average fell 4%
ng the same period. Colorado's youth "past month marijuana use" for 2013-
was 74% higher than the national average. The number of highway patrol
diction seizures of Colorado Marijuana increased 37% since the recreational
of marijuana was approved. In terms of budget data, medical and recreational
evenue only accounted for 0.5% of the budget. In all, there are 424 retail
juana stores in Colorado compared to 202 McDonald's and 322 Starbucks
s. DA Jackson testified that it is likely Nevada will see similar increases in
h marijuana and driving fatalities if recreational marijuana is approved by the
rs.

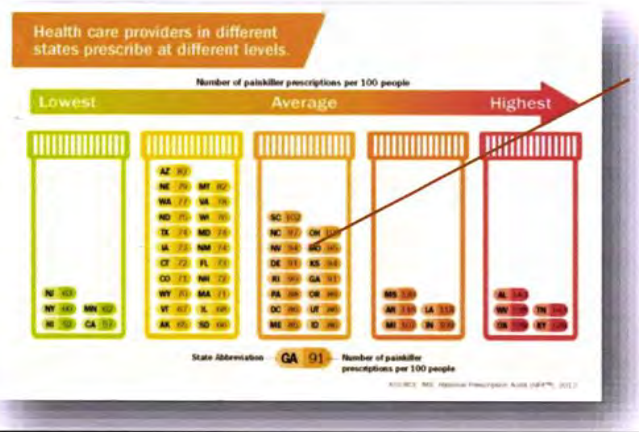
Report on Recreational Marijuana and its Impact on the State

The Honorable Pat Hickey with Nevadans for Responsible Drug Policy,
fied about the numerous unforeseeable consequences the passage of Initiative
tion Two would have on the state. First, he reported that pursuant to the
tion, schools are third in line to receive funding which will mean they will
ve a very small portion of the tax revenue. Second, the language of the petition
nothing to curb the sale, advertisement or use of edible marijuana for youth in
ada. In Colorado, 45% of marijuana is in edible form. Third, the petition fails
ke into account issues in the work force related to testing. Mr. Hickey reported

29

82 PRESCRIPTIONS PER 100 RESIDENTS

The Scope of Opioid Use in Nevada, 2015



Nevada clinicians wrote 94 painkiller prescriptions for every 100 Nevada residents. (2012)

Based on Nevada's Prescription Drug Monitoring Program (PMP), for Hydrocodone, Oxycodone, and Alprazolam prescriptions in 2015:

Total Prescriptions = 2,371,134
Total 2015 population = 2,890,845
Per Capita = 82/100 residents

Prepared by the Nevada Division of Public and Behavioral Health, March 30, 2017.

FACT SHEET >>>

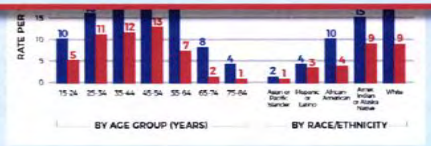
OPIOID EPIDEMIC

RISK FACTORS

Opioid pain relievers, even when legally prescribed, are highly addictive substances putting consumers at risk for addiction. According to the CDC, there are four major risk factors that make someone particularly vulnerable to prescription opioid abuse and overdose, including:

- Obtaining overlapping prescriptions from multiple providers and pharmacies
- Taking high daily dosages of prescription pain relievers
- Having mental illness or a history of alcohol or other substance abuse
- Living in rural areas or having low income.

Although partial agonists (drugs that only have partial efficacy relative to full agonists, such as buprenorphine) may carry a lower risk of dependence, prescription opioids that are full opioid-receptor agonists (nearly all the products on the market) are no less addictive than heroin.



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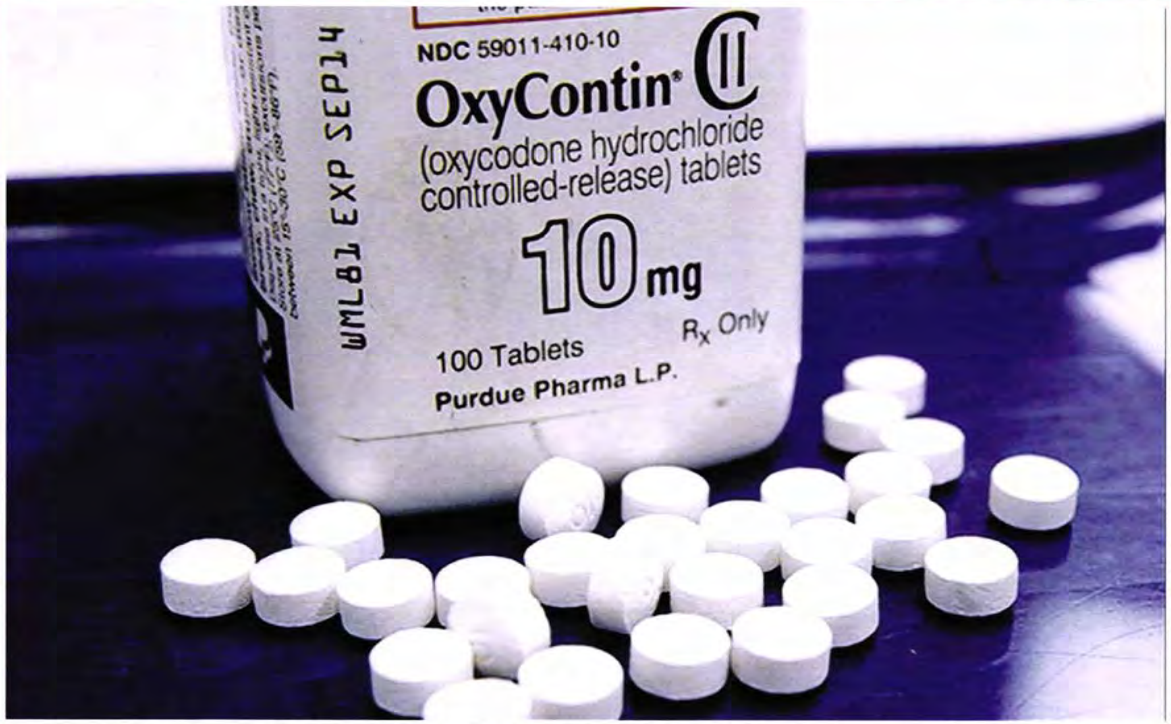


The Nevada Department of Health and Human Services says opioid-related deaths dropped in Nevada in 2016, but hospitalizations and prescription rates rose.

Based on 2016 data, the statewide opioid prescription rate is 87.5 per 100 residents, compared with 66.5 nationwide. That's up from 81 per 100 in 2015 and 78.1 in 2013.

Rates vary by county. Clark County had a prescription rate of 84.3 per 100 in 2016, but in Nye County, it was 155.6 — more than one prescription per person.

https://www.reviewjournal.com/local/local-nevada/opioid-deaths-in-nevada-decline-but-hospitalizations-rise-data-show/

National Governors Association Policy Academy on
Prescription Drug Abuse Prevention

Nevada ranks:

- 2nd highest for hydrocodone (Vicodin and Lortab);
- 2nd highest for oxycodone (Percodan and Percocet);
- 4th highest for methadone;
- 7th highest for codeine.

Furthermore, Nevada consistently has some of the highest rates of drug

Heroin-Related Deaths in Nevada, 2009 - 2013

60

Nevada has the 4th highest drug overdose mortality rate in the United States

2013

ch are

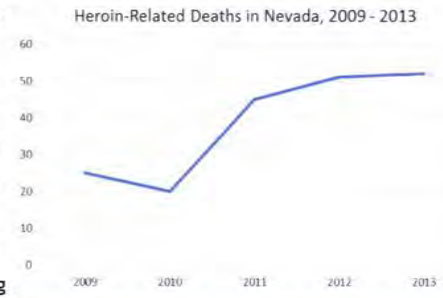
the rate

was 11.5 per 100,000. There has been a substantial increase in heroin-related deaths in Nevada between 2009 and 2013, with over double the number of cases between those years.

As these data illustrate, Nevada is clearly experiencing problems related to prescription drug abuse despite many efforts to prevent and intervene. It is also clear that progress can only be made by working comprehensively and in partnership. There needs to be a systematic and collaborative effort made across disciplines if Nevada wants to see true change in the state.

As a result of the 2014 NGA Prescription Drug Abuse Reduction Policy Academy, the Governor developed a core team to create a plan that would improve community health by reducing prescription drug abuse by 18% by 2018. To achieve this, the core team's plan would change attitudes and behaviors of Nevadans through better coordinate efforts and statewide leadership. In order to accomplish this, the team will hold two stakeholder meetings in 2015 to solicit feedback from all disciplines to identify current efforts, determine ways to prevent duplication of efforts, and establish an effective statewide leadership role focused on four key areas: education,

Furthermore, Nevada consistently has some of the highest rates of drug overdose mortality in the country. Nevada has the 4th highest drug overdose mortality rate in the United States, with 20.7 per 100,000 people suffering drug overdose fatalities, according to a *Prescription Drug Abuse: Strategies to Stop the Epidemic.* According



The number of drug overdose deaths - a majority of which are from prescription drugs - in Nevada increased by 80 percent since 1999

those years.

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FACT SHEET >>>

OPIOID EPIDEMIC

FACT

People addicted to prescription opioids are 40 times more likely to become addicted to heroin.

"Our nation is struggling with a prescription drug epidemic and we must take advantage of every tool at our disposal to address this public health and safety crisis."

R. Gil Kerlikowske – Director, White House Office of National Drug Control Policy

Opioids are a class of narcotics prescribed to treat moderate to severe pain.
Common examples include: codeine, morphine, Lortab (hydrocodone), OxyContin (oxymorphone). More potent preparations include Dilaudid (hydromorphone) and fentanyl, used for severe pain or for anesthesia. Heroin is an illicit opioid that is procured on the streets. It may be used to supplement or replace prescribed opioids.

RISK FACTORS

Opioid pain relievers, even when legally prescribed, are highly addictive substances putting consumers at risk for addiction. According to the CDC, there are four major risk factors that make someone particularly vulnerable to prescription opioid abuse and overdose, including:

- Obtaining overlapping prescriptions from multiple providers and pharmacies
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Although partial agonists (drugs that only have partial efficacy relative to full agonists, such as buprenorphine) may carry a lower risk of dependence, prescription opioids that are full opioid-receptor agonists (nearly all the products on the market) are no less addictive than heroin.

COST

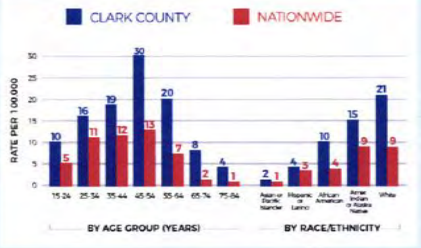
The opioid epidemic creates substantial burden on health care utilization and expenditures. In Clark County, opioid use and misuse were implicated in over 1,700 emergency visits and 1,700 inpatient hospitalizations annually 2013-2015.

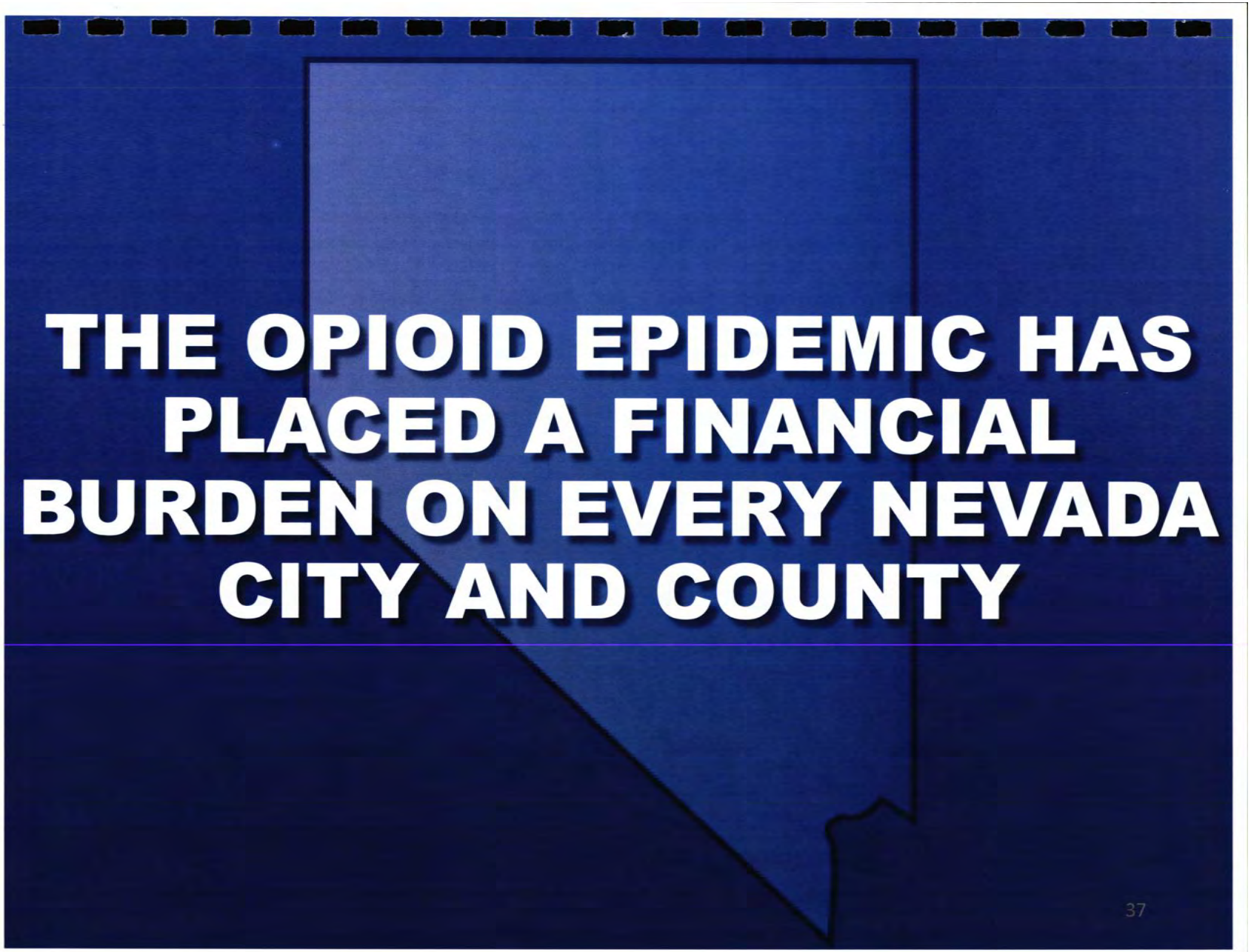
$13 MILLION EMERGENCY DEPT. DISCHARGE CHARGES (SOUTHERN NEVADA, 2015) + **$94 MILLION** INPATIENT DISCHARGE CHARGES (SOUTHERN NEVADA, 2015)

IS EQUIVALENT TO

COST OF PROVIDING MORE THAN 4,200 PEOPLE WITH INPATIENT TREATMENT AT AN AVERAGE-PRICED 28-DAY DRUG AND ALCOHOL REHAB FACILITY
(~$25,000/PER PERSON)

OPIOID-RELATED DEATHS (2005-2015)




THE OPIOID EPIDEMIC HAS PLACED A FINANCIAL BURDEN ON EVERY NEVADA CITY AND COUNTY
37

INCREASED HOSPITAL COSTS IN CLARK COUNTY

OPIOID EPIDEMIC

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SCOPE OF THE OPIOID PROBL
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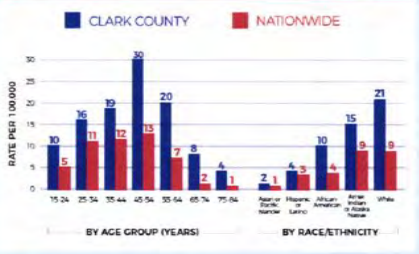


INCREASED COSTS FOR FIRST RESPONDERS AND NARCAN IN RURAL COUNTIES

PUBLIC HEALTH

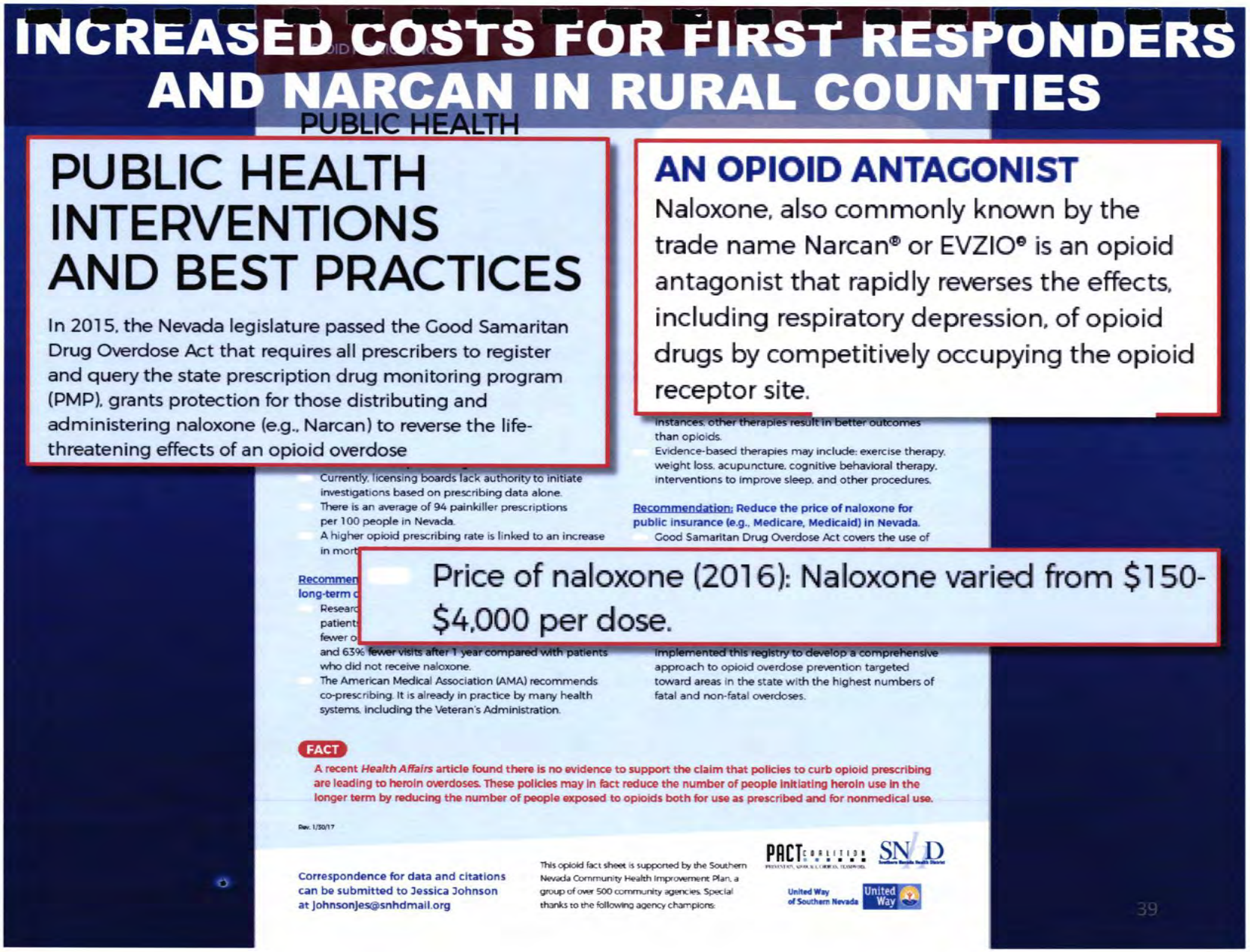
PUBLIC HEALTH INTERVENTIONS AND BEST PRACTICES

In 2015, the Nevada legislature passed the Good Samaritan Drug Overdose Act that requires all prescribers to register and query the state prescription drug monitoring program (PMP), grants protection for those distributing and administering naloxone (e.g., Narcan) to reverse the life-threatening effects of an opioid overdose

AN OPIOID ANTAGONIST

Naloxone, also commonly known by the trade name Narcan® or EVZIO® is an opioid antagonist that rapidly reverses the effects, including respiratory depression, of opioid drugs by competitively occupying the opioid receptor site.

Price of naloxone (2016): Naloxone varied from $150-$4,000 per dose.



INCREASED COSTS FOR FIRST RESPONDERS AND NALOXONE IN RURAL COUNTIES

RHIhub
Rural Health Information Hub

Nevada Rural Opioid Overdose Reversal (NROOR)

Nevada.

Critical Access Hospital (CAH),

appreciated the naloxone training and

...-hospital-kicks-opioid-reversal-project.html)

...s. Rural residents who overdose may not live close enough to a medical facility to receive treatment in time and, prior to October 2015, many basic-level emergency medical services (EMS) personnel did not have access to naloxone, a counteracting drug.

In addition, SB459 allowed for the furnishing of naloxone without a prescription from a physician. While naloxone still needs to be prescribed, a community organization can furnish naloxone kits without having a physician write a prescription for every person who receives a kit from this organization.

NROOR partnered with its state EMS office, which administered naloxone training to EMTs and paramedics around the state. The training covered both intramuscular needle and intranasal naloxone.

NROOR was funded by a Federal Office of Rural Health Policy (FORHP) Rural Opioid Overdose Reversal (ROOR) Grant (https://grants.hrsa.gov/2010/web2External/Interface/Common/PublicWebLinkController.aspx?GrantNumber=D94RH29277&WL_WEBLINK_ID=1) and ended in August 2017.

Services offered

The Nevada Rural Opioid Overdose Reversal Program (https://www.unr.edu/public-health/faculty/karla-wagner/nevada-rural-opioid-overdose-reversal-program):

- Distributed naloxone to EMS agencies staffed only by basic-level EMTs
- Enabled distribution of naloxone to at-risk individuals and family members
- Educated healthcare providers on prescription drug use and abuse as well as legislative changes pertinent to prescribers
- Provided public education and outreach about overdoses

Results

In total, 117 EMTs were trained on the administration of naloxone and details on the new legislation and completed pre-test and post-test evaluations to measure the change in attitudes, knowledge, skills, and beliefs. The NROOR evaluation team found statistically significant improvements in the

EMT services across Nevada reported being satisfied with training and the naloxone kits. Some services never had naloxone on hand before, so they were grateful for NROOR's paying for and providing kits. One volunteer EMT was especially thankful for the training: "Before, when we picked up an OD patient, all we could do was slap an oxygen mask on him, drive fast, and hope he made it."

The best data source available to the NROOR team back in April 2015 was hospital admission data, and the team's distribution plan was based on the number of opioid overdoses that were being reported in rural hospital emergency departments. Rural EMS agencies reported transporting very few suspected opioid overdoses during the two years of the grant period, and there were several doses of naloxone nearing expiration as the program came to a close. Fortunately, the State Chief Medical Officer was able to find urban-based nonprofit organizations to distribute the unused naloxone before it expired.

Barriers

Since NROOR was intertwined with SB459, program coordinators were unable to implement certain parts of the program until the corresponding piece of legislation was solidified.

https://www.ruralhealthinfo.org/community-health/project-examples/937 1/3

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NEVADA HAS MADE COMPREHENSIVE CHANGES

- National Governor's Association Perscription Drug Abuse Reduction Policy Academy co-chartered by Governor Sandoval (2014).
- Task force to research prescription drug abuse (2014).
- SB459
- SB59

IN OUR COMMUNITIES, THE OPIOID DRUG COMPANIES HAVE NOT CHANGED

- They knew their marketing and the way opioids were prescribed was contrary to scientific and medical evidence.
- Their misrepresentations have been confirmed by the FDA and CDC.
- Some drug companies have entered into settlement agreements with public entities which prohibit them from making those false and misleading misrepresentations in those jurisdictions.

In Guilty Plea, OxyContin Maker to Pay $600 Million

MAY 10, 2007

ABINGDON, Va., May 10 — The company that makes the narcotic painkiller OxyContin and three current and former executives pleaded guilty today in federal court here to criminal charges that they misled regulators, doctors and patients about the drug's risk of addiction and its potential to be abused.

That claim became the linchpin of the most aggressive marketing campaign ever undertaken by a pharmaceutical company for a narcotic painkiller.

Purdue Pharma acknowledged in the court proceeding today that "with the intent to defraud or mislead," it marketed and promoted OxyContin as a drug that was less addictive, less subject to abuse and less likely to cause other narcotic side effects than other pain medications.

At one point, the drug accounted for 90 percent of the company's sales.

IN OUR COMMUNITIES, THE OPIOID DRUG COMPANIES HAVE NOT CHANGED

- In our communities, Opioid drug companies continue to misrepresent the risks of long term opioid use and they have not corrected or changed their past misrepresentations.

CIVIL LAWSUITS OFTEN CAUSE CORPORATIONS TO CHANGE THEIR BEHAVIOR

- Eglet Prince has handled complex Civil Litigation against:

EGLET PRINCE

  - Teva Pharmaceuticals- The largest generic drug manufacturer in the world.
  - Takeda Pharmaceuticals– One of Japan's largest drug manufacturers and the makers of Actos (Type 2 diabetes drug)
  - HPN/United Healthcare– HPN is the largest health insurer in Nevada and owned by United Healthcare which is the largest health insurer in the country.

TEVA LITIGATION

- We sued Teva for the HCV outbreak in 2008 under product liability laws.
- Obtained jury verdicts of $505 million and $186 million.
- Teva settled in the middle of the third trial (for a confidential amount).
- As a result of the Teva litigation, policy changes with regard to injection practices occurred throughout the U.S. and large vials of Propofol were removed from out-patient surgery centers.

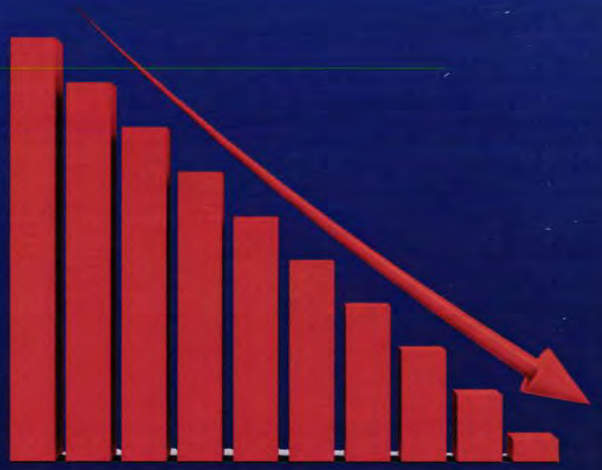
LITIGATION AGAINST TAKEDA

- We sued Takeda for:
  - Failing to warn consumers that Actos (Type 2 diabetes drug) caused bladder cancer.
  - Conducting drug research that they skewed, providing inaccurate and incomplete information to the FDA.
- During the 2nd trial with Takeda, cases settled (for a confidential amount).
- Importantly, Takeda changed their labeling thus informing consumers of the risk of taking Actos.

LITIGATION AGAINST TAKEDA

Takeda

- When Takeda made this labeling change, the number of prescriptions decreased significantly.



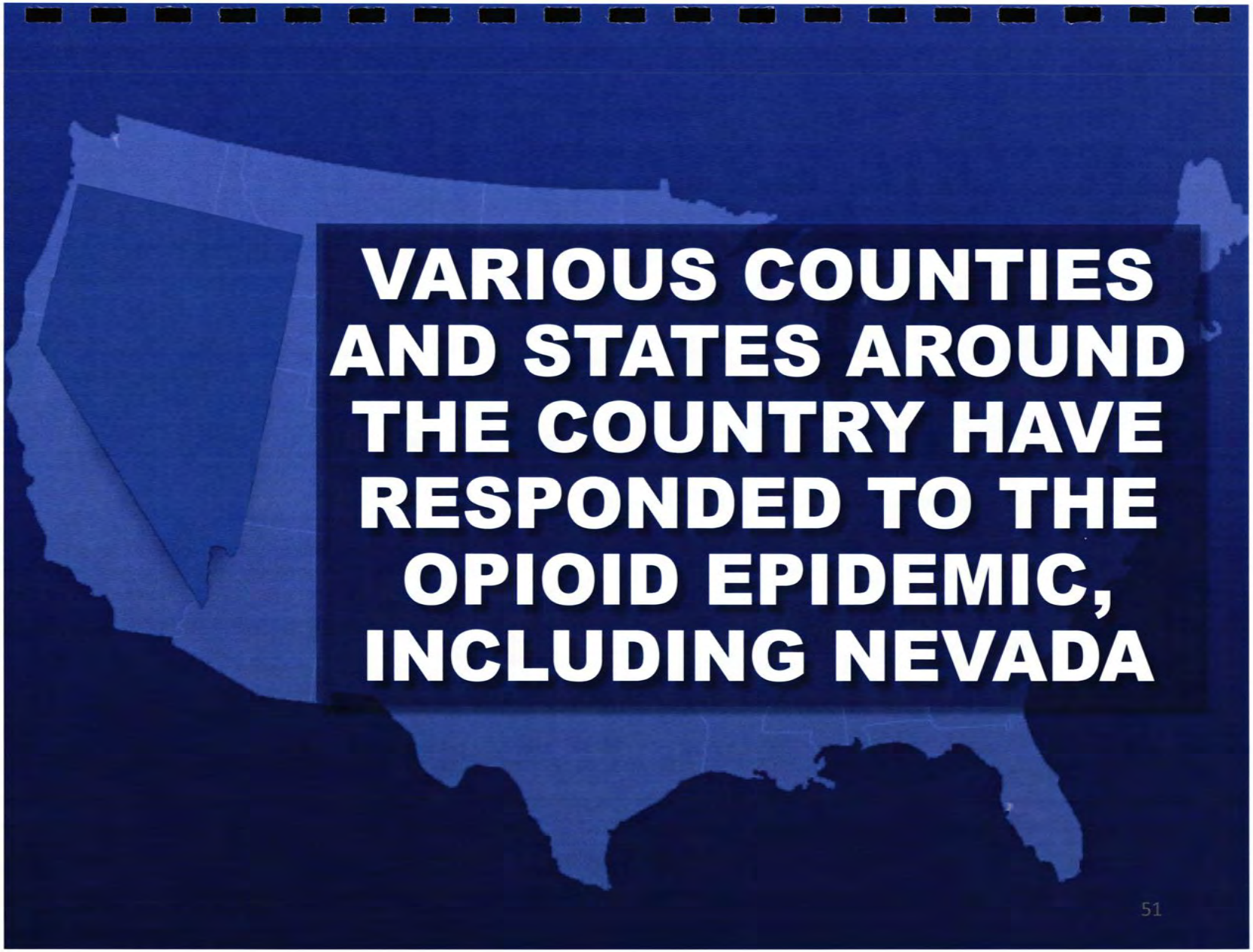
- The lawsuit also made doctors aware of the devastating effects of Actos.

HEALTH PLAN OF NEVADA

LITIGATION AGAINST HPN

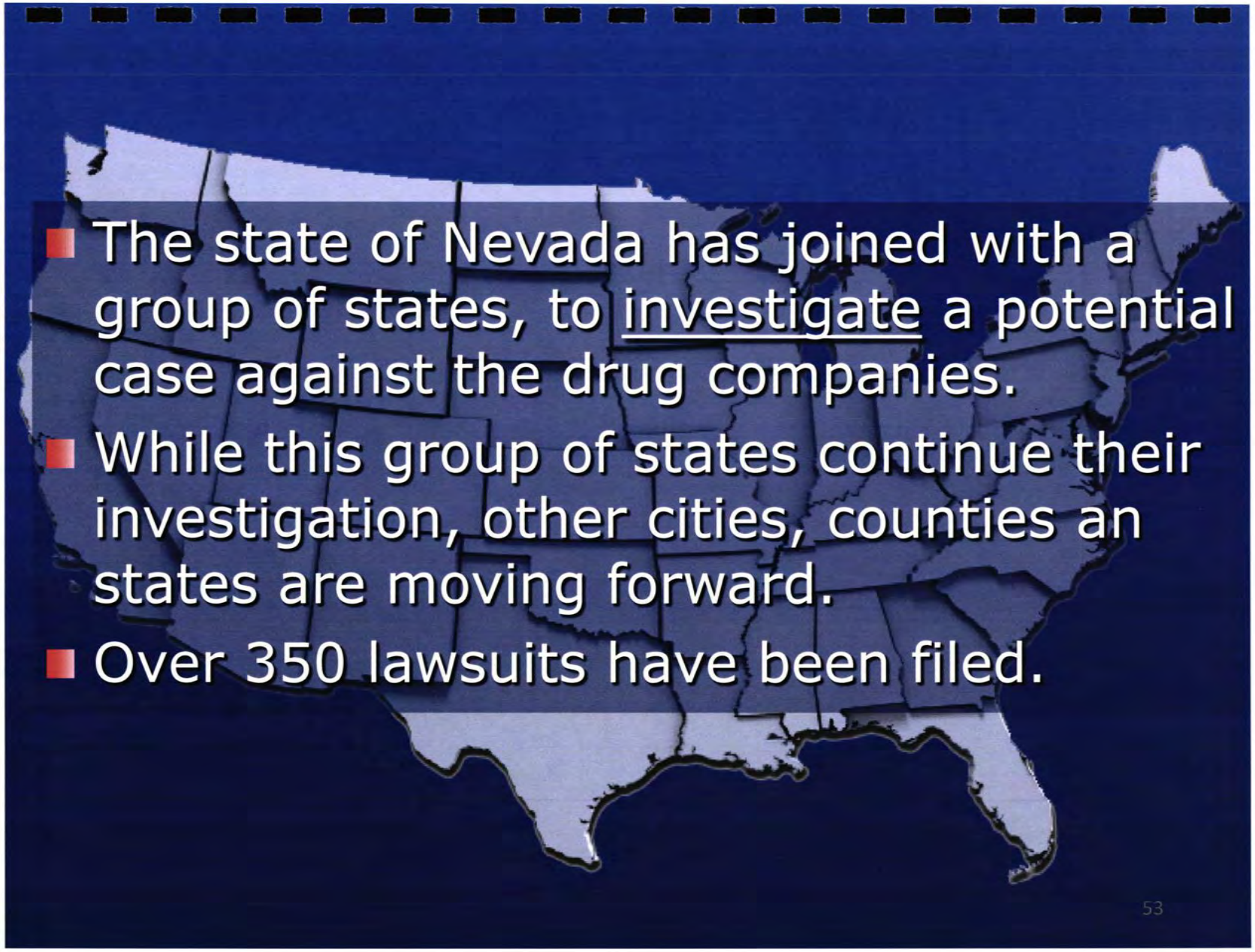
- We sued HPN for faulty credentialing policies, specifically, HPN negligently credentialed Dr. Depak Desai.
- Dr. Desai (together with Teva) was responsible for causing the largest medically caused HCV outbreak in history, which occurred in Clark County.
- Obtained $524 million verdict against HPN.
- HPN settled the cases 6 weeks into the 2nd trial (confidential amount).
- As a result of the HPN litigation, insurance companies and hospitals changed the way they credential healthcare providers, making medical care for their insureds safer.


TO BRING ABOUT CHANGE AND ASSIST IN FUNDING THE FIGHT AGAINST RX DRUG ABUSE, COUNTIES HAVE INITIATED
CIVIL ACTIONS
AGAINST OPIOID DRUG COMPANIES.
50


VARIOUS COUNTIES AND STATES AROUND THE COUNTRY HAVE RESPONDED TO THE OPIOID EPIDEMIC, INCLUDING NEVADA
51

CIVIL ACTIONS

- Brought by cities, counties and states against the drug companies to protect the health, safety and welfare of their citizens have been far more successful than individual lawsuits or class actions.


The state of Nevada has joined with a group of states, to investigate a potential case against the drug companies.
While this group of states continue their investigation, other cities, counties an states are moving forward.
Over 350 lawsuits have been filed.
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STATES THAT HAVE ALREADY FILED CIVIL LAWSUITS

- Alabama
- Alaska
- Washington
- Arizona
- New Mexico
- Mississippi
- South Carolina
- Missouri
- Illinois
- West Virginia
- Ohio
- New Hampshire
- Kentucky