INTERMEDIATE COURT OF APPEALS OF WEST VIRGINIA

A.D.A., as next friend of L.R.A.,
a minor child under the age of 18,
Plaintiff Below, Petitioner,
v. Docket No. 23-ICA-275
Johnson & Johnson, et al.,
Defendants Below, Respondents

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A.N.C., as next friend of J.J.S.,
a minor child under the age of 18,
Plaintiff Below, Petitioner,
v. Docket No. 23-ICA-276
Johnson & Johnson, et al.,
Defendants Below, Respondents

****

Trey Sparks,
Plaintiff Below, Petitioner,
v. Docket No. 23-ICA-307
Johnson & Johnson, et al.,
Defendants Below, Respondents

RESPONSE BRIEF OF THE WEST VIRGINIA BOARD OF PHARMACY

WEST VIRGINIA BOARD OF PHARMCY

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INTRODUCTION AND STATEMENT OF THE CASE

The complaints in the three cases on appeal assert tort claims brought by or on behalf of individuals who allegedly suffer from the effects of Neonatal Abstinence Syndrome ("NAS") due to their birth mothers' use of opioids during their pregnancies with those individuals.[1] The complaints name as defendants certain manufacturers and distributors of prescription opioids, a consulting firm, and the West Virginia Board of Pharmacy.

Defendants in these three cases (and in the 17 other closely-related NAS cases before the WVMLP) moved to dismiss for failure to state a claim on which relief could be granted. The WVMLP heard oral argument on March 24, 2023, **JA 00181**, and granted Defendants' motions to dismiss the complaints with prejudice, by order dated April 17, 2023. **JA 00001-09.** On May 31, 2023, the WVMLP issued an order detailing its bases for dismissal, holding that: (1) Plaintiffs could not establish proximate causation because their alleged injuries were too remote from Defendants' alleged conduct and because, based on Plaintiffs' own allegations, birth mothers' ingestion of opioids was the sole proximate cause of the alleged injuries; (2) Plaintiffs lacked standing to assert claims for public nuisance; and (3) Plaintiffs could not state a claim for negligence because, as a matter of law, Defendants did not owe a duty of care to Plaintiffs. The WVMLP also dismissed Plaintiffs' claims for civil conspiracy, fraud, and punitive damages, and it further ruled that Plaintiffs' claims against the Board of Pharmacy were barred by the public duty doctrine and on grounds of qualified immunity and absolute immunity. **JA 00093-128**. The Complaint in the Sparks case was separately dismissed in a similar Order dated June 2, 2023. **JA 00155-178.**

[1] Three cases are consolidated in this appeal—*A.D.A. v. Johnson & Johnson et al.*, Civil Action No. 21-C-110 MSH, *A.N.C. v. Johnson & Johnson et al.*, Civil Action No. 22-C-73 MSH, and *Sparks v. v. Johnson & Johnson et al.*, Civil Action No. 23-ICA-307. In the *A.D.A.* and *A.N.C.* cases, Plaintiffs are next friends suing on behalf of minor children. In *Sparks*, Plaintiff is no longer a minor and has sued on his own behalf.

I. PROCEDURAL HISTORY

The procedural history is very brief. After the filing of the lawsuits, all defendants filed motions to dismiss. Thereafter the WVMLP Court heard arguments on said motions and issued Orders granting the dismissals. Plaintiffs have timely appealed the WVMLP's rulings.

II. SUMMARY OF ARGUMENT

The WVBOP incorporates by reference and adopts the arguments and positions advanced by the co-defendants in their briefing with respect to Public Nuisance, Prior Settlements, Negligence, Duty of Care, Proximate Cause, Civil Conspiracy, and Fraud, as those arguments, the WVMLP's Order and rulings, and law referenced apply equally to the WVBOP as well. Petitioners have simply failed to make any assertions to proximately connect the WVBOP's alleged conduct to the cause of plaintiffs' injuries and damages.

With respect to defenses specific only the WVBOP, the WVMLP Court was legally correct in dismissing the Petitioners' claims based on clear West Virginia law. First, in determining that the Petitioners' allegations stem from alleged negligence in the performance of certain statutory and/or regulatory duties, the WVMLP Court held that the Public Duty Doctrine was applicable, and that the only exception to the Public Duty Doctrine available to the Petitioners in this matter against the WVBOP, a state agency, is the special relationship exception. Petitioners in their Complaints and in their briefings have failed to even allege this special relationship exception. Petitioners only response to the Public Duty Doctrine dismissal is to mistakenly claim that there is a malicious/wanton exception to the doctrine. However, the WVMLP Court was correct in holding that this particular exception does not apply to state agencies such as the WVBOP, but only political subdivisions per W.VA. Code §29-12A-1, et seq. Petitioners have failed to advance any

argument or case law to counter the WVMLP's decision on the Public Duty Doctrine, or the numerous cases and stare decisis supporting it.

Petitioners have also failed to demonstrate any legal basis to overturn the WVMLP Court's ruling dismissing the WVBOP based upon qualified immunity. Petitioners cannot and have not provided any law, statutes, or other regulations demonstrating any failures of the WVBOP in its performance of its duties. Petitioners baseless arguments concentrate on an allegation of the failure of the WVBOP to investigate suspicious order reports from distributors to pharmacies. As will be demonstrated herein, said allegation is false and there is no specific language in any law or regulation dictating that the WVBOP is to investigate any suspicious order report. The WVMLP Court was further correct in ruling that the Petitioners only offered conclusory allegations regarding legal and regulatory violations, and proximate cause, which said unsupported allegations are insufficient to overcome qualified immunity per clear case law. There are no laws or regulations that require the WVBOP to monitor, analyze, report, and investigate each and every opioid prescription written or opioid dispensed to a pregnant woman, nor is there any duty of the WVBOP to get involved in the physician-patient relationship, or the ability to stop a pregnant woman from ingesting an opioid.

The WVMLP Court additionally properly granted dismissal pursuant to the doctrine of absolute immunity, as plaintiff's false and conclusory allegations related to a duty to review CSMP records or to report those findings to certain review committees were administrative policy-making acts subject to absolute immunity.

III. STATEMENT OF ORAL ARGUMENT

Pursuant to the criteria set forth in Rule 18(a) of the Revised Rules of Appellate Procedure (R.R.A.P.), Respondent believes that the deliberation process would be aided by oral argument in this matter.

IV. STANDARD OF REVIEW

"Appellate review of a circuit court's order granting a motion to dismiss a complaint is *de novo*." Syl. Pt 1, *Tanner v. Raybuck*, 246 W. Va. 361 *; 873 S.E.2d 892 **; 2022 W. Va. LEXIS 280 ***; 2022 WL 1124882; Syllabus Point 2, *State ex rel. McGraw v. Scott Runyan Pontiac-Buick*, 194 W. Va. 770, 461 S.E.2d 516 (1995)." "Where the issue on an appeal from the circuit court is clearly a question of law or involving an interpretation of a statue, we apply a *de novo s*tandard of review." Syl. Pt. 2, *Tanner v. Raybuck*.

V. ARGUMENT

Petitioners allege two assignments of error as it relates specifically to the WVBOP. First, petitioners argue that the Public Duty Doctrine is inapplicable as a defense for the WVBOP. Their second assignment of error argues that the WVBOP is not entitled to Qualified Immunity. The WVMLP Court correctly ruled in holding the Public Duty Doctrine, Qualified Immunity, and Absolute Immunity are applicable in dismissing Petitioners' Complaints as a matter of law.

The WVMLP Court Correctly Ruled in Favor of the WVBOP Which Dismissed Petitioners' Claims Based on the Public Duty Doctrine, Qualified Immunity, and Absolute Immunity

Petitioners' arguments that neither the Public Duty Doctrine nor Qualified Immunity should apply to dismiss their claims rely on incorrect and unsupported factual allegations, conclusory assertions, ignoring years of stare decisis, and misinterpretation of the law. Under both of these legal doctrines which the Court properly applied to dismiss the lawsuits, Petitioners' essentially put forth the same arguments asserting that the WVBOP's actions were willful, malicious, and/or reckless in violating applicable mandatory statutes and laws (citing W.Va. Code § 30-1-1a; § 30-5-6; § 60A-3-301; § 60A-3-303; § 60A-4-401; W.Va. CSR § 15-2-5.1.1.; W.Va. CSR § 15-8-7.7.8) by failing (a) to investigate any suspicious order reports; (b) to identify and

report abnormal or unusual practices of patients; and (c) to ensure that each pharmacy registered maintained effective controls against diversion. Due to these baseless and conclusory assertions, it is necessary in this briefing to furnish and cite the actual law and evidence that the WVMLP court was provided to assist in its ruling, and to address Petitioner's hollow and false allegations.

Petitioners' main argument with respect to their causes of action is that they mistakenly claim that the WVBOP did nothing to investigate suspicious order reports[2] from 2012 to 2017, and further assert, without citing any statutes or law, that the WVBOP is required by law to investigate all suspicious order reports. Petitioners secondary arguments appear to be assertions of failing to generally monitor diversion and dispensing practices of pharmacists/dispensers and/or report CSMP results to certain legislative committees. First, in addressing the actual language of the laws and statutes at issue that Petitioners mistakenly claim, it cannot be disputed that these laws do not contain any language that establish any requirement or duty that the WVBOP must review or investigate suspicious order reports, nor any requirement or duty that the WVBOP investigate or take enforcement actions related to suspicious order reports. *West Virginia Code* § 30-5-6 provides the general powers and duties of the WVBOP. *West Virginia Code* § 60A-3-301, et seq is the Uniform Controlled Substances Act. Finally, *West Virginia Code* § 60A-4-401 prohibits the manufacture, delivery or possession with intent to manufacture or deliver a controlled substance, as well as sets forth the penalties for violating the same. None of these statutes specifically or generally compels an investigation by the WVBOP of a suspicious order report.

[2] Suspicious Order Reports are reports sent by distributors of opioids to dispensers/sellers of opioids indicating, based upon their own algorithms and internal data, that there is something possibly suspicious about the order. However, this does not indicate the order is illegal, improper, or a diversion. The WVBOP plays no role in determining what a suspicious order is, how it is determined, or if the order is shipped, as that is determined by two private business entities.

Specifically, W.Va. Code § 60A-3-303(a) provides that the Board "shall register an applicant to manufacture or distribute controlled substances . . . unless it determines the issuance of that registration would be inconsistent with the public interests." It also enumerates the factors that the Board "shall consider" in "determining the public interest," including "[m]aintenance of effective controls against diversion of controlled substances into other legitimate medical, scientific, or industrial channels, . . . [c]ompliance with applicable state and local law," and "[a]ny other factors relevant to and consistent with the public health and safety." *Id*., Sections 60A-3-303(1), (2), (7). Notably, there is **no** requirement to review or investigate suspicious order reports, and there is **no** requirement to take any enforcement actions upon receipt of suspicious order reports. This is universal for any law, rule, or regulation applicable to the WVBOP.

Likewise, W.Va. Code §30-5-6, merely provides that the WVBOP has the "power" (but not the duty) to "[i]nvestigate alleged violations of the provisions of this article" and to "[i]nstitute appropriate legal action for the enforcement of the provisions of this article. *Id*., Sections 30-5-6(13) and (16). It imposes no requirement the WVBOP must review suspicious order reports, and no requirement that the WVBOP must commence enforcement actions after receiving such reports. See *W.Va. Bd. Of Educ. v. Croaff*, 2017 WL 2172009, at 6 n.2 (Memorandum Decision) (regulatory provisions written in discretionary terms "lack the specificity necessary to avoid application of qualification immunity"). There is no "clearly established law" that required the WVBOP to review or investigate any of the alleged 7,200 suspicious order reports, or to take enforcement actions related to these reports.

Petitioners also generally reference two West Virginia Code of State Rules sections in their briefing. W. Va. Code R. § 15-2-5.1.1., states as follows:

> A registrant shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to

> determine whether a registrant has provided effective controls against diversion, the Board shall evaluate the overall security system and needs of the applicant or registrant.

Further relied upon by Petitioners is W. Va. Code R. §15-8-7.8[3], which states:

> The board shall review records in the CSMP in accordance with parameters set by the Advisory Committee to identify abnormal or unusual practices of patients who exceed those parameters and are therefore outliers in the CSMP data. The board shall issue reports of the results of these searches to the Review Committee for its regular review and action. The board shall communicate with prescribers and dispensers of the patients who exceed the parameters to inform them of each practitioner's patient's activities as demonstrated in the CSMP reports. Reports and communications produced by the board shall be kept confidential by the board and the Review Committee.

Again there is nothing in these rules that relate to suspicious order reports, or that there is some mandatory duty to investigate said reports. In any event, the numerous depositions of David Potters and Mike Goff, clearly establish that the WVBOP did abide by and follow any and all laws and rules asserted by the Petitioners, with its investigations, reliance on the DEA, CSMP analysis and upkeep, doctor/prescriber letters, and inspections. David Potters, who was the executive director and general counsel of the WVBOP from 2007 to 2017, has been deposed numerous times in the various opioid lawsuits and has testified consistently that in 2012 when suspicious order reports were being sent to the WVBOP, that he and the WVBOP investigator "Waggoner" looked at the first couple of reports, decided that they were not helpful or useful as they needed far more data, that the information provided did not trigger any alarms or concerns for the WVBOP, saw no large numbers that would trigger an investigation in all of the suspicious order reports Potters viewed, and that the reports were basically all similar. Mr. Potters further testified that "Waggoner" did investigate some of the suspicious order reports, called the wholesaler, and learned there was

[3] These Committees are separate and distinct from the WVBOP, and are not made up of the WVBOP board members or employees, but are legislatively created.

nothing suspicious and nothing further the WVBOP could do with these suspicious order reports. **JA 01365-01383 and JA 01841-01851**. There are also numerous other areas of monitoring that the WVBOP performs in terms of complying with its statutory and regulatory requirements of addressing potential diversion, illegal opioid dispensing, and investigations, which Petitioners ignore, and which were addressed in the lower court motions. **(see JA 01822-01840, and JA 01395–01422)**[4].

Additionally, the West Virginia legislature created both the CSMP review committee and an advisory committee to review certain data points of the CSMP and look for outliers within the dispensing data. The legislation (W.Va. CSR § 15-2-5.1.1. and W.Va. CSR § 15-8-7.7.8) that created these committees was passed in 2012 and began running in 2014. **JA 01822-01840.** As a result of these legislative committees, the following has occurred in compliance with the law and completely countering Petitioners' baseless and hollow assertions that the WVBOP failed to report data to these committees, did nothing to address or investigate diversion, improper dispensing

[4] •Reliance on the DEA to issue its Controlled Substances Registration for opioid distributors which would require these distributors and registrants to have systems in place to satisfy W. Va. Code R. § 15-2-5.1.1 and §15-8-7.8.
•Employed inspectors (retired pharmacists) to conduct biannual inspections of every pharmacy in West Virginia making sure pharmacies abide by the controlled substances laws required by the DEA as well as reviewing controlled substance prescriptions and dispensing habits, and looking for evidence of diversion
•Inspections have led to pharmacy complaints and investigations, and the taking of licenses. Since 2019, these pharmacy inspections have become annual.
•Requirement that West Virginia pharmacists complete continuing education classes which address controlled substances and diversion.
•Maintaining the Controlled Substances Monitoring Program (CSMP), which contains dispensing data and is designed for practitioners and prescribers to find information on the patient, before prescribing and dispensing opioids, and to help the prescriber and the dispenser make decisions on whether to prescribe and/or refuse to dispense the opioid.
•Worked with the West Virginia Legislature to continue to address and improve the capabilities of the CSMP, all for the benefit of limiting diversion of opioids.
•The CSMP is also used by law enforcement agencies including the DEA and the West Virginia State Police for investigations, all who work with the WVBOP on these investigations on a regular basis.
•Taking complaints from the public or actual pharmacies on issues related to diversion of opioids. Each DEA 106 report of theft or loss that is filed is investigated by the WVBOP. If during this investigation by the WVBOP a criminal issue arose, then it would have been referred to law enforcement, which several have.

practices, or monitoring pharmacies in terms of their controls against diversion[5]. **JA 01822-01840, and JA 01395 – 01422.** Importantly, there is no language in any statute, law, or regulation requiring the WVBOP to investigate, review, evaluate, or probe each and every opioid order, opioid prescription, or opioid dispensing. Moreover, there is also no duty in the applicable laws and statutes mandating that the WVBOP involve itself in the physician-patient relationship.

A. The WVMLP Court Correctly Ruled in Dismissing the Complaints that the Public Duty Doctrine is Applicable to the WVBOP.

Petitioners' Complaint allegations against the WVBOP stem from alleged negligence in the performance of certain statutory and/or regulatory duties. One of the main elements of a negligence action is the existence of a legal duty. The public duty doctrine is a defense based upon the absence of a duty owed to the specific party asserting the negligence claim. *Holsten v. Massey*, 490 S.E.2d 864, 869 (W. Va. 1997). Simply stated, the public duty doctrine holds that a local government entity is not liable for a failure to enforce regulatory or penal statutes. *Rhodes v. Putnam County Sheriff's Dept.*, 207 W.Va. 191, 530 S.E.2d 452 (W. Va. 1999).

Specifically, the public duty doctrine demonstrates that a governmental entity's liability for certain functions may not be predicated upon the breach of a general duty owed to the public as a whole; instead, only the breach of a duty owed to the particular person injured is actionable. *Walker v. Meadows*, 206 W. Va. 78, 521 S.E.2d 801 (W. Va. 1999). Essentially, the doctrine precludes a

[5] •Letters were sent to prosecuting attorneys and law enforcement agencies regarding abnormal prescribing habits of prescribers.
•Letters were sent to prescribers if the CSMP data and parameters used showed potential doctor shoppers by patients or "multiple provider episodes" to make said prescribers aware of issues.
•Letters were sent to physicians advising them of patient overdoses because of opioid.
•Referrals to law enforcement have taken place as a result of the reporting done and the actions taken by these committees (numerous physicians have been referred to law enforcement and licensing boards with some being suspended).
•CSMP Reports have been provided to these committees (including "top prescriber reports" and "drug overdose death data") and leading to thousands of letters being sent out to physicians, prescribers, and licensing boards.
•Letters were sent to various licensing boards if CSMP data showed abnormal prescribing or dispensing by physicians.

department and its officers from being liable based upon a breach of a general duty owed to the public. *Id*. A "government entity can interpose the public duty doctrine as a defense when it perceives a plaintiff is attempting to hold the entity liable for breach of a non-discretionary duty owed to the general public. *Parkulo v. W.Va. Board of Probation & Parole*, 483 SE2d 507, 518 (W.Va. 1996).

The only exception to public duty doctrine is when a special relationship exists between the parties. *Randall v. Fairmont City Police Department*, 412 S.E.2d 737, 748 (W. Va. 1999); citing, *Wolfe v. City of Wheeling*, 387 S.E.2d 307 (W. Va. 1989). There is a four-part test to determine this special relationship exception, and which the plaintiff must prove the following four elements: (1) an assumption by the governmental entity, through promises or actions, of an affirmative duty to act on behalf of the injured party's behalf; (2) knowledge on the part of an agent for a governmental entity that inaction could lead to harm; (3) some form of direct contact between an agent of a governmental entity and the injured party; and (4) the party's justifiable reliance upon the undertaking of the governmental entity. *Id*. The WVMLP Court correctly ruled that the only exception to the public duty doctrine with respect to state agencies is the special relationship exception. **JA 00093-00128.**

In this case, the statutes and regulations relied upon by Petitioners apply to general regulatory duties of the WVBOP of inspecting/investigating certain entities/persons related to the distributing of pharmaceuticals, protecting the public, and/or stopping opioid diversion. As a result, Petitioners' allegations of negligence stem from a breach of a duty owed to the general public, and therefore, the public duty doctrine applies to Petitioner's claims against the WVBOP. Being that the public duty doctrine applies, the WVMLP Court correctly found that Petitioners alleged no facts that relate to establishing a special relationship. In fact, Petitioners do not even

mention a special relationship, let alone cite to any facts that would otherwise establish a special relationship. As a result, based upon the public duty doctrine, WVBOP is entitled to a dismissal of this action and this Court should affirm the WVMLP Court's decision.

Of equal importance is the fact that Federal Judge Polster has already decided this issue in favor of the WVBOP based on the public duty doctrine involving certain cases brought against the WVBOP by cities, towns, and county commissions of West Virginia. Judge Polster, in his Order dated June 8, 2022, ruled that "Plaintiff's Complaints lack an essential element required to state a claim against the BOP – a special relationship between the BOP and the Plaintiffs". He further reasoned that the public duty doctrine barred claims against the WVBOP for alleged failures "to enforce regulations intended to protect the safety and well-being of the public at large" because a "duty to enforce a regulation is exactly the type of a duty that is owed to the general public under the public duty doctrine." ***JA 01384-01394***. For the same reasons articulated by Judge Polster, the WVMLP Court was correct in holding that the public duty doctrine bars all of Petitioners' claims here against the WVBOP, and the WVBOP asks this Honorable Court to do the same.

Understanding that there is no direct communications between the Petitioners/Plaintiffs and the WVBOP, and therefore, no special relationship exception to the public duty doctrine, Petitioners are asking this Court to ignore years of West Virginia case law and *stare decisis* to invoke a "malicious and intentional conduct" "cause of action" and/or exception to the public duty doctrine. First, there is no such recognized "cause of action" for "malicious and intentional conduct" cause of action in West Virginia. See e.g., *Tabor v. Tabor*, No. 2:13-cv-20643, 2013 U.S. Dist. LEXIS 147994, at *3 (S.D. W. Va. Oct. 15, 2013). Additionally, no such "malicious and intentional conduct" exception exists to the public duty doctrine as it relates to "State" entities. In support of this incorrect exception argument, Petitioners rely upon *Massey v. Holstein*, a case

involving political subdivisions and its employees, not a State entity, such as the WVBOP and a Marshall County Circuit Order which was appealed, and where plaintiffs' in that matter agreed to dismiss their claims against the WVBOP following the filing of the appeal.

Massey involved a claim against the Boone County Commission and Boone County Sheriff's Department Deputy Green. Before discussing how the Supreme Court handled these issues on appeal, it is critical to note that the defendants in *Massey* were a political subdivision and an employee of a political subdivision. This is critical because, as discussed infra, there is a specific statute that applies only to political subdivisions and employees of political subdivisions that governs their liability in negligence actions. Simply put, West Virginia Code § 29-12A-1, et seq., which contains the wanton or reckless conduct of an employee exception to the public duty doctrine, does not apply to State agencies such as the WVBOP, and the WVMLP Court was correct to not apply said except in the case at bar. The is demonstrated by the language of the statute which states: "Its purposes are to limit liability of ***political subdivision***s and provide immunity to ***political subdivisions*** in certain instances and to regulate the costs and coverage of insurance available to political subdivisions for such liability." See West Virginia Code § 29-12A-1. The entirety of the statute applies to only political subdivisions and employees of political subdivisions.

On appeal in *Massey*, all Supreme Court did, after discussing the interplay of West Virginia Code § 29-12A-1, et seq. with the public duty doctrine, was acknowledge that West Virginia Code § 29-12A-1 created a statutory change to the public duty doctrine with respect to political subdivisions and employees of political subdivisions. In connection with the statutory changes, the Court noted:

> that the wanton or reckless conduct of an employee exception to immunity found in W. Va. Code, 29-12A-5(b)(2) [1986] is in addition to the special relationship exception to the public duty doctrine. Given that the legislature has authority to abrogate the

> common law, see syllabus, Perry, supra, the only way to reconcile the legislature's express removal of immunity from an employee whose conduct is wanton or reckless with the public duty doctrine is to conclude that W. Va. Code, 29-12A-5(b)(2)[1986] is another exception to the public duty doctrine separate and distinct from the common-law special relationship exception to the public duty doctrine.

Massey, 200 W. Va. at 787, 490 S.E.2d at 876. The Supreme Court then held that "the wanton or reckless conduct exception to an employee's (as the term 'employee' is defined in the Governmental Tort Claims and Insurance Reform Act) immunity under W. Va. Code, 29-12A-5(b)(2) [1986] of the Governmental Tort Claims and Insurance Reform Act is an exception to the public duty doctrine separate and distinct from the common-law special relationship exception to the public duty doctrine." *Id*., 200 W. Va. at 787-88, 490 S.E.2d at 876-77. The *Massey* Court did not extend this statutory exception outside the context of employees of a political subdivision to state agencies. Furthermore, no employee of the WVBOP has been named a defendant. Importantly the language related to this exception mandates that it only applies to political subdivision employees and not state agencies, "(b) An employee of a ***political subdivision*** is immune from liability unless one of the following applies; (2) His or her acts or omissions were with malicious purpose, in bad faith, or in a wanton or reckless manner:" See W. Va. Code, 29-12A-5(b)(2). There is zero reference or applicability of this statutory exception to state agencies.

To date, this willful and wanton exception to the public duty doctrine has never been applied to a State agency, except by a non-binding Order in Marshall County Circuit Court, as referenced in Petitioners' briefing. Importantly, at the time of the Marshall County Circuit Court Order, the Supreme Court has substantively discussed the public duty doctrine six (6) times[6] as it

[6] See *Jeffrey v. W. Va. Dep't of Pub. Safety, Div. of Corr.,* 204 W. Va. 41, 511 S.E.2d 152 (1998); McCormick v. W. Va. Dep't of Pub. Safety, 202 W. Va. 189, 503 S.E.2d 502 (1998); *Tucker v. W. Va. Dep't of Corr.*, 207 W. Va. 187, 530 S.E.2d 448 (1999); *J. H. v. W. Va. Div. of Rehab. Servs.*, 224 W. Va. 147, 151, 680 S.E.2d 392, 396 (2009); *W. Va.*

relates to the State and/or its employees since this Court's decision in *Holsten*. In not a single one of these cases did the West Virginia Supreme Court of Appeals apply the statutory exception of wanton or reckless conduct to a State agency or its employee.

For example, *W.Va. State Police v. Hughes* highlights the fact that the wanton or reckless conduct exception contained in West Virginia Code § 29-12A-1 does not apply to the State and the WVBOP. In *Hughes*, plaintiff sued the West Virginia State Police, alleging that it "recklessly breached a duty . . ." *Id*. (emphasis added). Despite the fact that plaintiffs pled that the State Police defendants "recklessly breached a duty", the WVSCA did not apply the purported wanton or reckless exception to the public duty doctrine. Instead, the Court indicated that "[t]he exception to the public duty doctrine arises when a special relationship' exists between the government entity and a specific individual." *Hughes*, 238 W. Va. at 412, 796 S.E.2d at 199). West Virginia Federal Courts have also followed this longstanding law as it applies to the Public Duty Doctrine. In *Berry v. Rubenstein*, 2008 U.S. LEXIS 34782, 2008 WL 1899907, the United States District Court for the Southern District of West Virginia held that only two exceptions to the doctrine exist, "The first exception occurs where the applicable insurance policy expressly provides that the public duty doctrine does not apply" (citing *Parkulo*); and the second "if a 'special relationship' existed between the state official and the person harmed". *Id*. at 10.

The reason that the West Virginia Supreme Court of Appeals has not discussed the statutory wanton or reckless exception with state agency cases is because the provisions of West Virginia Code § 29-12A-1, et seq. apply exclusively to political subdivisions and employees of political subdivisions. W.Va. Code § 29-12A-2. By definition, West Virginia Code § 29-12A-1, et seq.

Dep't of Health & Human Res. v. Payne, 231 W. Va. 563, 746 S.E.2d 554 (2013); and *W. Va. State Police v. Hughes*, 238 W. Va. 406, 796 S.E.2d 193 (2017).

does not apply to the State or employees, including an Executive Director of a State agency or board. Specifically, West Virginia Code § 29-12A-3(e) defines "State" as follows:

> the State of West Virginia, including, but not limited to, the Legislature, the Supreme Court of Appeals, the offices of all elected state officers, and all departments, boards, offices, commissions, agencies, colleges, and universities, institutions, and other instrumentalities of the State of West Virginia. "State" does not include political subdivisions.

In interpreting West Virginia Code § 29-12A-1, et seq., the Supreme Court has routinely refused to apply the provisions of this statute to State entities or State employees.[7] The WVBOP is asking this Court to follow years of stare decisis, and the unambiguous language of West Virginia Code §29-12A-1, and hold that there is no wanton, reckless, and malicious exclusion to the Public Duty Doctrine as it applies to State agencies, and affirm the WVMLP Court's decision of dismissal.

B. The WVMLP Court Correctly Ruled that the WVBOP is Entitled to Qualified Immunity.

Petitioners' lawsuits were properly dismissed by the WVMLP as a matter of law on the basis of qualified immunity. As this Court is aware, qualified immunity is applicable to bar recovery of monetary damages in a civil action when "an objectively reasonable official, situated similarly to the defendant, could have believed that his conduct did not violate the plaintiff's constitutional rights, in light of clearly established law and the information possessed by the defendant at the time of the allegedly wrongful conduct[.]" *Hutchison v. City of Huntington*, 479 S.E.2d 649, 659 (W. Va. 1996). Qualified immunity "is broad and protects 'all but the plainly incompetent or those who knowingly violate the law.'" *W.Va. State Police v. Hughes*, 796 S.E.2d 193, 198 (W.Va. 2017). "Under the doctrine of qualified immunity, the discretionary actions of

[7] See *Hess v. W. Va. Div. of Corr.*, 227 W. Va. 15, 18 n.6, 705 S.E.2d 125, 128 (2010); *Clark v. Dunn*, 195 W. Va. 272, 275-76, 465 S.E.2d 374, 377-78 (1995); *Coleman v. Sopher*, 201 W. Va. 588, 595 n.7, 499 S.E.2d 592, 599 (1997); *Pruitt v. W. Va. Dep't of Pub. Safety*, 222 W. Va. 290, 298, 664 S.E.2d 175, 183 (2008)

government agencies, officials and employees performed in an official capacity are shielded from civil liability so long as the actions do not violate clearly established law or constitutional duty. *Hughes*, 796 S.E.2nd at 198 (W.Va. 2017). Qualified Immunity shields "discretionary judgments and decisions" that do not violate a "clearly established law, statute, or regulation." *W.Va. Bd. Of Educ. V. Croaff*, No. 16-0532, 2017 WL 2172009, at 6-7 (W.Va. May 17, 2017).

"Qualified immunity provides 'an immunity from suit rather than a mere defense to liability; and like an absolute immunity, it is effectively lost if a case is erroneously permitted to go to trial.'" See J.*H. v. W.Va. Div. of Rehab. Servs.*, 680 S.E.2d 392, 401 n. 12 (W.Va. 2009). (citing *Mitchell v. Forsyth*, 472 U.S. 511, 526 (1985). Additionally, the Court held that "unless the plaintiff's allegations state a claim of violation of clearly established law, a defendant pleading immunity is entitled to dismissal before the commencement of discovery." *See J.H.*, 680 S.E.2d at 401 n. 12. "Because the doctrine seeks to protect government officials from the burdens of trial and preparing for trial, the Supreme Court has 'repeatedly . . . stressed the importance of resolving immunity questions at the earliest possible stage in litigation.'" *Id* (internal citations omitted).

The West Virginia Supreme Court of Appeals has clarified the analysis necessary in order to determine whether qualified immunity applies. First, a court must determine whether the acts or omissions constitute legislative, judicial, executive or administrative policy-making acts *or* whether the acts or omissions involve discretionary governmental functions. *See* Syl. Pt. 10, *West Virginia Regional Jail and Correctional Facility Authority v. A.B.*, 766 S.E.2d 751 (W.Va. 2014). If the act or omission is a legislative, judicial, executive or administrative policy-making act, the State and the official involved are absolutely immune. *Id.* If, on the other hand, the act or omission falls within the category of discretionary functions:

> [A] reviewing court must determine whether the plaintiff has demonstrated that such acts or omissions are in violation of clearly

> established statutory or constitutional rights or laws of which a reasonable person would have known <u>or</u> are otherwise fraudulent, malicious or oppressive . . . . In the absence of such a showing, both the State and its officials or employees charged with such acts or omissions are immune from liability.

Id. at Syl. Pt. 11. Further, "[a] public officer is entitled to qualified immunity for discretionary acts, even if committed negligently." *Maston v. Wagner*, 781 S.E.2d 936, 948 (W.Va. 2015).

In the case at bar, Petitioners' generally assert that the WVBOP neglected its duty to investigate alleged violations of the laws and rules governing pharmacies, wholesalers, manufacturers and other distributors of controlled substances within the State of West Virginia (citing W.Va. Code § 30-1-1a; § 30-5-6; § 60A-3-301; § 60A-3-303; § 60A-4-401; W.Va. CSR § 15-2-5.1.1.; W.Va. CSR § 15-8-7.7.8) by (a) failing to investigate any suspicious order reports pursuant to law; (b) failing to identify and report abnormal or unusual practices of patients; and (c) failing to ensure that each pharmacy registered maintained effective controls against diversion.

Assuming *arguendo* that the acts are not executive or administrative policy-making acts, this Court's next inquiry relates to whether the acts are discretionary. The main thrust of the statutes relied upon by Petitioners relate to inspecting/investigative functions by the WVBOP. Inspecting/investigative functions clearly require the exercise of discretion. Here, the laws cited is a law of generality, not specificity. In other words, it is not clearly established how the WVBOP is to "consider the ... [m]aintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels, in determining whether to renew their registrations annually." W.Va. Code § 60A-3-303. In other words, Petitioners cannot cite to some specific language within this statute and allege a violation of this statute. Instead, Plaintiffs' argument amounts to a conclusory and hindsight argument that, because this happened, there must have been a violation of the law. Such an argument fails to overcome qualified

immunity. *See e.g., W. Va. Dep't of Envtl. Prot. v. Dotson*, 244 W. Va. 621, 630, 856 S.E.2d 213, 222 (2021) (Plaintiffs "fail to cite to any specific provision of SCMRA, or corresponding West Virginia State Rule, to substantiate their general allegations that the DEP's acts or omissions violated SCMRA."). Because the law is not clearly delineated as it relates to the standards for which the WVBOP should consider the purported effective controls or how to conduct inspections/investigations, Petitioners cannot overcome the "clearly established law" ground of qualified immunity.

Finally, in getting to the heart of Petitioners' case against WVBOP, Plaintiff simply asserts unsupported allegations of violating or failing to follow statutes and other laws (specifically failing to investigate suspicious order reports). Petitioners absolutely fail to cite specific language in the laws or regulations that require the WVBOP to perform certain actions that it did not, or assert any allegations specifically citing language in a law of a mandatory duty to perform some specific action or investigation. They failed to cite any specific language because there is no language to support their assertions and claims against the WVBOP. Furthermore, Petitioners' general allegations of failing to perform some type of actions have been demonstrated wrong per the facts and evidence that have existed in the opioid litigation for several years. **JA 01822-01840, and JA 01395–01422.** Finally, while Petitioners assert that the CSMP regulations contain an obligation to review suspicious order reports, these regulations absolutely do not contain any suspicious order review obligations. The CSMP does not contain any information related to suspicious order reports. Asserting otherwise is completely wrong. This Honorable Court should ask Petitioners to produce any regulation, statute, or law that contains language that specifically requires the WVBOP to investigate suspicious order reports.

In the arguments before the WVMLP and somewhat here on appeal, Petitioners' assert that the WVBOP should have done "more." Asserting that a State entity should have done "more" is clearly within the realm of qualified immunity. *See Crouch v. Gillispie*, 240 W. Va. 229, 237 n.21, 809 S.E.2d 699, 707 (2018) ("*See, e.g., Simley v. City of Ferndale*, No. 97-1858, 1999 U.S. App. LEXIS 534, 1999 WL 196504, at 4 (6th Cir. January 13, 1999). The WVBOP at all phases has abided by its legal and regulatory requirements to prevent diversion of opioids.

Turning again to whether the WVBOP violated laws cited by Petitioners, Petitioners offer no factual support to support an alleged violation of these statutory and regulatory duties. This Court must not accept legal conclusions without any factual support. *Hylton v. Bennett*, No. 12-0194, 2012 W. Va. LEXIS 847 (Nov. 16, 2012). Importantly as stated herein, Petitioners' allegations are completely false and have been disproven by the testimony of David Potters and others. **JA 01822-01840, and JA 01395–01422.** In matters where qualified immunity is implicated, "the trial court must insist on heightened pleading by the plaintiff." *Hutchison*, 479 S.E.2d at 659-60. In fact, what the allegations boil down to is an assertion that the WVBOP should have done more and/or a disagreement with the way WVBOP exercised its statutory and regulatory authority. In such instances, the Supreme Court has rejected this theory:

> Also, like *Payne*, in discovery, respondent made the skeletal assertion that if D.H. were properly trained and supervised, the rape would not have occurred. This illusory and languid contention is no more sufficient to overcome the State's immunity in this case than in *Payne:* "Respondents seem to argue simply that if the DHHR defendants were doing their job properly, this incident would not have occurred. . . . Although this overly simplistic analysis may be appealing in light of these tragic events, qualified immunity insulates the State and its agencies from liability based on vague or principled notions [of government responsibility]."

Crouch v. Gillispie, No. 17-0025, 2018 W. Va. LEXIS 75, at 22-23 (Jan. 31, 2018) (quoting *A.B.*, 234 W. Va. at 516 n.33, 766 S.E.2d at 775 n.33). Because the Complaints contain nothing but legal

conclusions without factual support asserting vague principled notions of government responsibility and because Petitioners' have not met the heightened pleading requirement to establish a violation of the implicated statutes and regulations, the WVMLP Court was correct in dismissing the WVBOP pursuant to Qualified Immunity. Plaintiffs' Complaints fail to assert anything remotely close to how the WVBOP's actions proximately caused the birth mothers to ingest opioids or caused any injuries or damages.

Even should this Court believe that the Complaints have factual support to establish a violation of some statute or regulation, Petitioners have not established that the statute or regulation is "clearly established." With respect to whether a law is "clearly established:

> Indeed, some courts hold that an "official may not be charged with knowledge that his or her conduct was unlawful unless it has been previously identified as such." *Warner v. Graham*, 845 F.2d 179, 182 (8th Cir. 1988). But, for a right to be clearly established, it is not necessary that the very actions in question previously have been held unlawful. *Anderson v. Creighton*, 483 U.S. at 640, 107 S. Ct. at 3039.

Hutchison, 479 S.E.2d 649, 659 n.11. Finally, specificity within the law is required. *See Gillispie*, No. 17-0025, 2018 W. Va. LEXIS 75, at *13 (Jan. 31, 2018). Here, Plaintiff cites generally to various statutes and use the term "mandatory" throughout their briefing, without pointing to any language in the statutes that mandate specifically what they believe the WVBOP failed to do. Notably, there is **no** requirement to review or investigate suspicious order reports, and there is **no** requirement to take any enforcement actions upon receipt of suspicious order reports. This is universal for any law, rule, or regulation applicable to the WVBOP.

Petitioner's arguments are similar to those made in *W.Va. Dep't of Envtl. Prot. v. Dotson*, 244, W.Va. 621 (2021), alleging the WVDEP failed to enforce and violated statutory provisions, failed in its "duties to monitor certain mining operations and enforce applicable rules, regulations,

statutes …" which caused flooding; failed "to discharge non-discretionary duties relating to enforcement", "overlooking obvious violation[s] of permit, regulation and law"; and "failed to perform its non-discretionary duties, *Id.* at 217. The West Virginia Supreme Court of Appeals held that plaintiffs failed "to cite any specific provision of the statute, or corresponding West Virginia State Rule, to substantiate their general allegations that the DEP's acts or omissions violated SCMRA", and that they have failed to establish any specific regulatory, statutory or constitutional violation by the DEP concerning its issuing of the permits." *Id.* at 630. The WVSCA dismissed the case based upon Qualified Immunity. In any event, the numerous depositions of David Potters and Mike Goff clearly establish that the WVBOP did abide by the asserted laws and regulations with its investigations, reliance on the DEA, CSMP analysis, upkeep, and reporting, doctor/prescriber letters, and pharmacy inspections. **JA 01822-01840, and JA 01395–01422.** See also *Croaff*, 2017 WL 2172009, at 6 n.2 (regulatory provisions written in discretionary terms "lack the specificity necessary to avoid application of qualified immunity"). There is no "clearly established law" that required the WVBOP to review or investigate any suspicious order reports, or to take enforcement actions related to these reports. Furthermore, with respect to claims associated with the failure to investigate, determinations of when to investigate, and the nature of an investigation, all are subject to qualified immunity. See *Dotson*, 856 S.E.2d at 221.

Beyond the basic qualified immunity analysis, part of the analysis requires that violation of a clearly established law to be the proximate cause of the injury. *See e.g., Crouch v. Gillispie*, 240 W. Va. 229, 237, 809 S.E.2d 699, 707 (2018). Here, the statutes or laws cited at issue does not apply to or regulate behavior by a Plaintiff. As a result, as it is inapplicable to Plaintiffs, there cannot be any proximate cause. In *Crouch v. Gillispie*, the Supreme Court cautioned against

exactly what Plaintiff is attempting to do here – that is, cherry-picking alleged violations of inapplicable statutes to overcome qualified immunity. In *Crouch*, the Supreme Court stated:

> [t]hi*s* analysis essentially adopts the common law tort concept that liability results from the violation of a duty owed *which was a proximate cause of the plaintiff's injury*. We are wary of allowing a party to overcome qualified immunity by cherry-picking a violation of any internal guideline irrespective of whether the alleged violation bears any causal relation to the ultimate injury. Therefore, in the absence of allegations tying the alleged violations to Raynna's death, we are unable to view this case as more than an abstract assertion that DHHR could have investigated more thoroughly."

Id. The WVMLP Court was correct in finding that Petitioners have put forth nothing more than the cherry-picking of a law without any causal relation, or putting forth any assertions that the WVBOP's alleged wrongdoing caused any physician to prescribe opioids, or these pregnant mothers to illegally ingest opioids. The WVBOP is not involved in the physician-patient relationship, or the determination of why a physician prescribed opioids to pregnant mothers. The WVBOP is certainly not involved in a plaintiff's illegal procurement and ingestion of opioids. Importantly, there is no language in any statute, law, or regulation requiring the WVBOP to investigate, review, evaluate, or probe each and every opioid order, opioid prescription, or opioid dispensing. Petitioners have simply "cherry-picked" certain regulations without asserting any legitimate claims to support a proximate cause argument.

With respect to the proximate cause argument, the WVMLP Court correctly held that the alleged injuries suffered by the Minors in utero—after those medicines were prescribed by doctors **(the WVBOP has no duty to monitor or investigate the doctor-patient relationship and each prescription written)**; after those medicines were dispensed by pharmacies **(the WVBOP has no duty to monitor or investigate each and every opioid dispensing)**; after those medicines were used either medically pursuant to a prescription **(the WVBOP has no duty to monitor or**

investigate opioids used for a legitimate medical purpose) or were stolen or sold illegally to third parties **(the WVBOP has no ability to predict criminal conduct)**; and after birth mothers chose to ingest those opioids during pregnancy **(the WVBOP has no duty or ability to investigate or monitor individuals who decide to ingest opioids)**—were too remote from Defendants' alleged conduct to establish proximate causation. **JA 00119.** Importantly, Petitioners cannot reference any language in the applicable statutes, laws, regulations, or otherwise establishing the WVBOP breached any duties or requirements on these paramount causation issues.

Although there is an exception to qualified immunity for actions that are "fraudulent, malicious, or oppressive," *W.Va. Reg'l Jail & Corr. Facility Auth. V. A.B.,* 766 SE2nd 751, 766 (W.Va. 2014), Petitioner's conclusory allegations that the WVBOP's "intentional dereliction of its duties" was "willful" and "malicious", cannot overcome the WVBOP's qualified immunity from suit. The only "willful" and "malicious" conduct alleged is the WVBOP's failure to investigate suspicious order reports. Plaintiff's allegations are thus circular, because the alleged "malicious" and "willful" and/or "intentional dereliction of … duties" is nothing more than the failure to undertake investigations that the Board was not required by law to undertake. See *Hylton v. Bennett*, No. 12-0194, 2012 WL 5834621, at 2 (W.Va. Nov. 16, 2012) (statutory immunity, coextensive with common law qualified immunity, applied where "the Complaint [was] devoid of any factual assertions to support [a] bald claim of malice"); See also *Hughes*, 796 SE2d at 198 ("[a] public officer is entitled to qualified immunity for discretionary acts, even if committed negligently).

For Petitioner'/Plaintiffs' claims to survive, there would have to be some law or regulation that required the WVBOP to review, monitor, analyze, investigate, and report each opioid prescribed and dispensed to a pregnant mother, and to allow the WVBOP to get involved in the

physician-patient relationship. It cannot be disputed that there is no such legal requirement. Furthermore, the regulations/laws cited by Petitioners are irrelevant or are hollow references incapable of creating a proximate cause argument. The WVMLP Court was absolutely correct in dismissing the WVBOP on the grounds of qualified immunity.

C. The WVMLP Court Correctly Ruled that the WVBOP is Entitled to Absolute Immunity.

Absolute Immunity further bars Petitioners' claims against the WVBOP and the WVMLP Court was correct in ruling that even crediting Plaintiffs' conclusory allegations that the WVBOP breached its regulatory duties to review records in the CSMP or to issue reports related to that review, these are "administrative policy-making acts" subject to absolute immunity. See W.Va. Reg'l Jail, 234 W.Va. at 507. **JA 00093-00128.**

D. The WVMLP Court Correctly Ruled in Finding that All Defendants are Entitled to Dismissal Based Upon the Law of Public Nuisance, Prior Settlements, Negligence, Duty of Care, Proximate Cause, Civil Conspiracy, and Fraud.

The WVBOP incorporates by reference and adopts the arguments and positions advanced by the co-defendants in their briefing with respect to Public Nuisance, Prior Settlements, Negligence, Duty of Care, Proximate Cause, Civil Conspiracy, and Fraud, as those arguments, the WVMLP's Order and rulings, and law referenced apply equally to the WVBOP.

VI. CONCLUSION

WHEREFORE, the Respondent WVBOP prays that this Honorable Court affirm the WVMLP Court's Order dismissing Petitioners' claims and lawsuit against the WVBOP and any such other further relief as this Court deems just and proper.

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 19th day of January, 2024, the foregoing **RESPONSE BRIEF OF THE WEST VIRGINIA BOARD OF PHARMACY** was served using the File & ServeXpress system, which will send notification of such filing to all counsel of record.

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