

2016 PA Super 160

THOMAS D. WALTERS AND CLARA M.
WALTERS, HIS WIFE,

Appellants

v.

UPMC PRESBYTERIAN SHADYSIDE;
MAXIM HEALTHCARE SERVICES, INC.,
AND MEDICAL SOLUTIONS L.L.C. D/B/A
MEDICAL SOLUTIONS,

Appellees

IN THE SUPERIOR COURT OF
PENNSYLVANIA

No. 309 WDA 2015

Appeal from the Order Entered February 6, 2015
In the Court of Common Pleas of Allegheny County
Civil Division at No(s): GD-12-018339

LINDA FICKEN AND WILLIAM FICKEN,
HER HUSBAND,

Appellants

v.

UPMC PRESBYTERIAN SHADYSIDE;
MAXIM HEALTHCARE SERVICES, INC.,
AND MEDICAL SOLUTIONS L.L.C. D/B/A
MEDICAL SOLUTIONS,

IN THE SUPERIOR COURT OF
PENNSYLVANIA

Appellees

No. 310 WDA 2015

Appeal from the Order Entered February 6, 2015
In the Court of Common Pleas of Allegheny County
Civil Division at No(s): GD-12-016165

WANDA J. BRAUN AND EDWIN J. BRAUN,
HER HUSBAND,

IN THE SUPERIOR COURT OF
PENNSYLVANIA

Appellants

v.

UPMC PRESBYTERIAN SHADYSIDE;
MAXIM HEALTHCARE SERVICES, INC.,
AND MEDICAL SOLUTIONS L.L.C. D/B/A
MEDICAL SOLUTIONS,

Appellees

No. 311 WDA 2015

Appeal from the Order Entered February 6, 2015
In the Court of Common Pleas of Allegheny County
Civil Division at No(s): GD-12-024324

RONNIE D. MURPHY AND CONNIE E.
MCNEAL, AS CO-EXECUTORS OF THE
ESTATE OF ELEANOR Y. MURPHY, IN
THEIR OWN RIGHT

IN THE SUPERIOR COURT OF
PENNSYLVANIA

Appellants

v.

UPMC PRESBYTERIAN SHADYSIDE,
MAXIM HEALTHCARE SERVICES, INC.,

AND MEDICAL SOLUTIONS, L.L.C. D/B/A
MEDICAL SOLUTIONS,

Appellees

⋮

No. 312 WDA 2015

Appeal from the Order Entered February 6, 2015
In the Court of Common Pleas of Allegheny County
Civil Division at No(s): GD-14-000899

BEFORE: BOWES, MUNDY AND JENKINS, JJ.

OPINION BY BOWES, J.:

FILED JULY 21, 2016

Plaintiffs-Appellants Thomas D. Walters and his wife Clara M. Walters, Linda Ficken and William Ficken, her husband, Wanda Braun and her husband Edwin J. Braun, and Ronnie D. Murphy and Connie E. McNeal, individually and as co-executors of the Estate of Eleanor Y. Murphy, appeal from the trial court's order sustaining preliminary objections in the nature of a demurrer as to their negligence claims against UPMC Presbyterian-Shadyside ("UPMC") and Maxim Healthcare Services, Inc. ("Maxim"). The action was dismissed based upon a finding that neither defendant owed a duty to Plaintiffs. After thorough review, we vacate that portion of the order sustaining the demurrer as to both UPMC and Maxim based on the lack of a common law duty of care, we affirm that portion sustaining the demurrer on the negligence *per se* claim against UPMC, and we remand for further proceedings.

Since we are reviewing the trial court's order sustaining preliminary objections in the nature of a demurrer, we look to the first amended

complaint for the relevant facts, and accept them as true.¹ **Connor v. Archdiocese of Phila.**, 975 A.2d 1084 (Pa. 2009). Radiologic technologist David Kwiatkowski was an employee of Maxim, a medical staffing agency that placed him at UPMC, or in the alternative, an employee of UPMC, which exercised the ability to control and direct his job performance.² First Amended Complaint, 11/30/12, at ¶12. On or about May 7, 2008, a UPMC hospital employee saw Kwiatkowski enter an operating room, lift his shirt, put a syringe in his pants, and leave the room. **Id.** at ¶13. When UPMC confronted Kwiatkowski about the theft, he had three empty fentanyl syringes on his person, an empty morphine syringe in his locker, and tested positive for fentanyl and opiates. **Id.** at ¶14. Further investigation revealed that Kwiatkowski stole the controlled substances, injected himself, substituted water in the used syringes, and placed the syringes on the shelves to avoid detection. **Id.** at ¶13. This practice is known as substitution.

¹ For ease of reference, all citations to the pleadings and the certified record are to the **Walters** case.

² A radiologic technologist is “[a]n individual who is a graduate of a program in radiologic technology approved by the Council on Medical Education of the American Medical Association or who has the equivalent of such education and training. 28 Pa.Code 101.4 (administrative code provision implementing Health Care Facilities Act, 35 P. S. §§ 448.101 -- 448.904).

Plaintiffs pled that, due to the risks associated with improper use and diversion of controlled substances, both the federal and state governments oversee and regulate practitioners such as UPMC, who are registered to possess and dispense controlled substances. **Id.** at ¶17. As a registrant, Plaintiffs pled that, “UPMC had a legal duty to ‘provide effective controls and procedures to guard against theft and diversion of controlled substances’” and notify the DEA “in writing, of the theft or significant loss of any controlled substances within one business day of discovery. 21 C.F.R. § 1301.76(b).” **Id.** at ¶¶19-20. It did not report, and as a healthcare provider, Plaintiffs pled that UPMC “knew or should have known that medical staff such as Kwiatkowski, without intervention, would continue to engage in conduct, including theft of controlled substances in order to satisfy” his addiction. **Id.** at ¶24.

According to Plaintiffs, UPMC did not report Kwiatkowski’s diversion of drugs to the DEA as required by 21 C.F.R. § 1301.76(b),³ or to any other

³ 21 C.F.R. § 1301.76(b) provides in pertinent part:
(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(Footnote Continued Next Page)

law enforcement, governmental, or licensing agencies. As of that date, UPMC banned Kwiatkowski from all UPMC facilities. Appellants pled that both UPMC and Maxim knew or should have known that Kwiatkowski was addicted to drugs, that he was a potential carrier of diseases associated with intravenous drug use, and that without intervention, he would continue to steal and use intravenous drugs, and substitute water or other substances for the drugs. Consequently, “[a]s a direct and proximate result of defendant UPMC’s conduct and/or omissions, Kwiatkowski was able to seek

(Footnote Continued) _____

- (1) The actual quantity of controlled substances lost in relation to the type of business;
- (2) The specific controlled substances lost;
- (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
- (5) Whether the specific controlled substances are likely candidates for diversion;
- (6) Local trends and other indicators of the diversion potential of the missing controlled substance.

and obtain employment with other healthcare facilities, including Hays Medical Center and be in a position to continue to steal and use controlled substances[,] which directly affected the health and well-being of patients,” such as Plaintiffs. **Id.** at ¶46. UPMC failed to report Kwiatkowski’s theft and diversion to law enforcement and take steps necessary to ensure that Kwiatkowski would not continue that practice. **Id.** at ¶46. Specifically, “UPMC knew that Kwiatkowski was a traveling radiologic technician and knew or should have foreseen that thousands of patients around the country would be endangered if UPMC failed to take steps to prevent Kwiatkowski from continuing his illicit conduct.” **Id.** at ¶64.

After the incident at UPMC, Kwiatkowski obtained a Maryland license and secured employment as a radiologic technologist in that state.⁴ Between 2008 and 2010, Kwiatkowski worked at eight other hospitals, including Hays Medical Center in Hays, Kansas, where he encountered Plaintiffs. He started working at that facility on May 24, 2010, and Plaintiffs were patients in the cardiac catheterization unit during his tenure there. Each received intravenously administered medication through a syringe that

⁴ Plaintiffs argue that certification through the American Registry of Radiologic Technologists (“ARRT”) was a prerequisite for the license, and that Kwiatkowski remained certified due to UPMC and Maxim’s failure to report his criminal conduct. **See** American Registry of Radiologic Technologists (ARRT), 28 Pa.Code § 127.5.

Kwiatkowski used to self-administer controlled substances, refilled with water, and replaced for use by unsuspecting staff upon patients. By that time, Kwiatkowski was infected with hepatitis C. Plaintiffs subsequently tested positive for the same strain of hepatitis C as that contracted by Kwiatkowski. Plaintiffs alleged that he transmitted that infection to them and others through contaminated needles. Elizabeth Murphy died due to the infection.

Kwiatkowski was subsequently arrested in New Hampshire and charged with acquiring a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge in violation of 21 U.S.C. § 843(a)(3), and tampering with a consumer product with reckless disregard for the risk to another and placing another in danger of and actually resulting in death or bodily injury in violation of 18 U.S.C. § 1365(a)(3).

Plaintiffs filed the within civil actions, premising liability against UPMC upon several theories of negligence. First, they alleged that UPMC was vicariously liable for the acts of its employee/agent, Kwiatkowski. Second, Plaintiffs pled that UPMC violated the standard of care for hospitals when it failed to take adequate steps to ensure that similar conduct was prevented in the future. Additionally, they maintained that UPMC failed to report, as required by law, Kwiatkowski's theft and diversion of controlled substances to governmental agencies or law enforcement, which would have prevented him from continuing to engage in the theft and diversion of controlled

substances. Finally, Plaintiffs pled that UPMC's violation of federal and state statutes that mandated the reporting of the diversion of controlled substances to the Drug Enforcement Administration ("DEA") constituted negligence *per se*.⁵ Since UPMC was a registrant of controlled substances, Plaintiffs maintained it had a duty to protect healthcare patients who could be injured due to drug tampering. They averred further that, had UPMC complied with the regulations, Kwiatkowski would have been prevented from infecting them in 2010. Plaintiffs characterized UPMC's conduct as malicious, willful, wanton and so recklessly indifferent as to warrant imposition of punitive damages.

The allegations against Maxim, the staffing agency that employed Kwiatkowski, sound exclusively in negligence. According to Plaintiffs, Maxim had a duty to act in accordance with the standard of care of reasonable healthcare staffing agencies. *Id.* at ¶42. Maxim knew of the danger Kwiatkowski presented to the patients at the facilities where he worked and had a duty to ensure that Kwiatkowski would not be able to divert and substitute drugs not only at UPMC, but also at other health care facilities where he would seek employment and access to drugs. First Amended

⁵ Plaintiffs alleged that "at a minimum," the failure to report violated 21 U.S.C. §801 *et seq.*, 21 C.F.R. § 1301 *et seq.*, and 28 Pa.Code § 25 *et seq.* UPMC also was required, upon discovering the theft of controlled substances, to file a DEA Form 106. Plaintiffs' Amended Complaint, 11/30/12, at ¶20.

Complaint, 11/30/12, at ¶67. Maxim breached that duty “by failing to report Kwiatkowski’s theft, use, and/or diversion of controlled substances to any state, federal, or other governmental agency and/or by failing to take adequate steps to ensure that Kwiatkowski would not, in the future, be able to steal, use, or divert controlled substances.” ***Id.*** at ¶68. As a consequence of Maxim’s negligence, Plaintiffs averred they were injured.⁶

Both Maxim and UPMC filed preliminary objections in the nature of a demurrer alleging that, even accepting all well-pleaded facts as true, they had no duty to Plaintiffs that would support a cause of action for negligence. UPMC maintained that, since there was no special relationship between itself and Plaintiffs or itself and Kwiatkowski, no duty could be inferred from the general duty imposed on all persons not to place others at a risk of harm. Furthermore, it warned that imposition of a duty on the facts herein was “not only contrary to established law but would subject hospitals in this Commonwealth to limitless liability.” Preliminary Objections to Plaintiffs’ Amended Complaint, 12/20/12, at ¶19. It contended further that the negligence *per se* claim failed because the statutes cited by Plaintiffs were not designed to protect them, as opposed to the general public, from the harm alleged.

⁶ Plaintiffs voluntarily dismissed claims of negligence against Kwiatkowski’s Kansas employer, Medical Solutions, and hence, those claims are not before us.

Plaintiffs countered that the failure of UPMC and Maxim to report Kwiatkowski's theft and substitution of drugs enabled him to continue working as a radiologic technologist in various hospitals around the country. According to Plaintiffs, due to UPMC's violation of that statute, it was foreseeable that Kwiatkowski would continue to steal and substitute drugs and endanger future patients with contaminated syringes transmitting blood-borne pathogens.

The trial court rejected the Plaintiffs' negligence *per se* claim against UPMC, finding "nothing in the legislation or accompanying regulations suggesting that drug diversion by healthcare employees and its risks to patients are specific subjects that the Controlled Substances Act addressed." Trial Court Opinion, 6/30/13, at 4. Furthermore, the court held that the notice requirements of 21 C.F.R. §1301.76(b) were only intended to protect the general public, not a specific group encompassing Plaintiffs. As to the common law negligence claims against UPMC and Maxim, the court relied upon ***Seebold v. Prison Health Services, Inc.***, 57 A.3d 123 (Pa. 2012), in holding that the law imposed no duty on the part of Defendants. The trial court concluded from ***Seebold*** that

(1) foreseeability is not necessarily the critical factor in deciding whether UPMC shall be liable to plaintiffs for UPMC's failure to report; (2) since UPMC did not create the risk (but only failed to prevent the harm), UPMC is not liable to third persons whom it never treated in the absence of a court-created duty; (3) the default position would avoid the creation of a new duty unless the court is able to see with reasonable clarity the results of the

decision and to determine with reasonable certainty that the change will serve the best interests of society; and (4) the case law which permits recovery where there is no relationship between the plaintiff and the defendant must be narrowly construed because of the Supreme Court's "stated concern about imposing liability upon healthcare providers without limits." [**Seebold,**] 57 A.3d at 1240.

Trial Court Opinion, 6/20/13, at 13. In response to Plaintiffs' insistence that UPMC need only comply with a reporting requirement, which is hardly onerous, the court stated that Plaintiffs' position failed to account for inevitable employee error in reporting, and that UPMC should not be exposed to "potentially limitless liability because of simple employee error." **Id.** at 14. The court held that UPMC's duty extended only to its patients. As to Maxim, the court found no duty to report the information it received from UPMC regarding Kwiatkowski's diversion of drugs. All claims against UPMC and Maxim were dismissed.

Plaintiffs filed the within appeal and they present four questions for our review:

- I. Does a defendant hospital have a duty to protect patients of other healthcare facilities who may come in contact with the hospital's former agent/employee when the defendant hospital knew the agent/employee had diverted drugs while working at its facility, knew or should have known that the agent/employee would engage in the same conduct with subsequent healthcare employers and knew or should have known that drug diversion creates a high degree of risk of causing harm to hospital patients that come in contact with staff who are known to divert drugs?
- II. Does a defendant hospital's violation of a mandatory reporting requirement in a federal regulation intended to

curtail drug diversions in hospital facilities create a statutory duty that the defendant hospital owes to hospital patients who are subsequently harmed because the drug diverter's conduct went unreported and as such, he was able to continue to gain employment in other healthcare facilities, allowing him to continue to engage in drug diversions that created a high degree of risk of causing harm to hospital patients?

- III. Is a hospital patient injured by a health care worker's diversion and substitution of controlled substances part of a class of individuals which the Federal Controlled Substances Act was intended, at least in part, to protect, such that a defendant hospital's violation of a federal controlled Substance Act regulation mandating the reporting of drug diversion constitutes negligence *per se* when a patient is harmed as a direct result of the violation?
- IV. Does a defendant medical staffing agency have a duty to protect patients of healthcare facilities that may come in contact with the agency's former employee when the defendant knew or should have known the employee had diverted drugs while in its employment, knew or should have known that the employee would engage in the same conduct with subsequent healthcare employers and knew or should have known that drug diversion creates a high risk of causing harm to hospital patients that come in contact with staff who are known to divert drugs?

Appellants' brief at 5-6.⁷

⁷ As their premise for imposing a legal duty, Plaintiffs have pled that both UPMC and Maxim were Kwiatkowski's employers, and each knew of Kwiatkowski's diversion and substitution of controlled substances at UPMC and the risk presented. Consequently, we will address together Plaintiffs' first and fourth issues involving the duty question, noting distinctions when the facts warrant different treatment or analysis of UPMC or Maxim. Similarly, since Plaintiffs' second and third issues implicate negligence *per se* generally, we will discuss them together.

Preliminary objections in the nature of a demurrer test the legal sufficiency of the complaint. The trial court considering a demurrer must treat all material facts set forth in the challenged pleadings as true, as well as all inferences reasonably deducible therefrom. The demurrer should be sustained only where it is “clear and free from doubt that the pleader will be unable to prove facts legally sufficient to establish the right to relief.” ***Richmond v. McHale***, 35 A.3d 779, 783 (Pa.Super. 2012). If there is any doubt as to whether preliminary objections in the nature of a demurrer should be sustained, that doubt should be resolved in favor of overruling the preliminary objections. ***Id.***

On appeal from an order sustaining or overruling a demurrer, our standard of review is to determine whether the trial court committed an error of law. Like the trial court, for purposes of our review “all material facts as set forth in the complaint, as well as all inferences reasonably deducible therefrom, must be accepted as true.” ***Bilt-Rite Contractors, Inc. v. the Architectural Studio***, 866 A.2d 270, 272 (Pa. 2005). The issue before us is “whether, on the facts averred, the law says with certainty that no recovery is possible” and any doubt must be resolved in favor of overruling the demurrer. ***Id.*** at 274 (quoting ***MacElree v. Philadelphia Newspapers, Inc.***, 674 A.2d 1050, 1056 (Pa. 1996)).

To establish a common law cause of action in negligence, a plaintiff must demonstrate that the defendant owed a duty of care to the plaintiff,

the defendant breached that duty, the breach resulted in injury to the plaintiff, and the plaintiff suffered an actual loss or damage. ***Lux v. Gerald E. Ort Trucking, Inc.***, 887 A.2d 1281, 1286 (Pa.Super. 2005). "[A] duty or obligation recognized by the law, requiring the actor to conform to a certain standard of conduct[.]" is the first element of negligence. ***Atcovitz v. Gulph Mills Tennis Club, Inc.***, 812 A.2d 1218, 1222 (Pa. 2002). Whether a duty of care exists is a question of law assigned initially to the trial court and subject to plenary review on appeal. ***Winschel v. Jain***, 925 A.2d 782, 796 (Pa.Super. 2007); ***Sharpe v. St. Luke's Hosp.***, 821 A.2d 1215, 1219 (Pa. 2003). Where, however, the plaintiff makes a *prima facie* showing of a duty, the applicable standard of care, whether it was breached, and whether the breach was a cause in fact of the injury are questions of fact for the jury. ***K.H. ex rel. H.S. v. Kumar***, 122 A.3d 1080, 1094 (Pa.Super. 2015).

As our High Court reiterated in ***Althaus ex rel. Althaus v. Cohen***, 756 A.2d 1166, (Pa. 2000):

In determining the existence of a duty of care, it must be remembered that the concept of duty amounts to no more than 'the sum total of those considerations of policy which led the law to say that the particular plaintiff is entitled to protection' from the harm suffered[.] To give it any greater mystique would unduly hamper our system of jurisprudence in adjusting to the changing times."

Althaus, at 1168-69 (quoting ***Sinn v. Burd***, 404 A.2d 672, 681 (Pa. 1979)). The Court went on to quote the late Dean Prosser:

These are shifting sands, and no fit foundation. There is a duty if the court says there is a duty; the law, like the Constitution, is what we make it. Duty is only a word with which we state our conclusion that there is or is not to be liability; it necessarily begs the essential question. When we find a duty, breach and damage, everything has been said. The word serves a useful purpose in directing attention to the obligation to be imposed upon the defendant, rather than the causal sequence of events; beyond that it serves none. In the decision whether or not there is a duty, many factors interplay: The hand of history, our ideas of morals and justice, the convenience of administration of the rule, and our social ideas as to where the loss should fall. In the end the court will decide whether there is a duty on the basis of the mores of the community, 'always keeping in mind the fact that we endeavor to make a rule in each case that will be practical and in keeping with the general understanding of mankind.'

Id.

Recognizing that "the legal concept of duty of care is necessarily rooted in often amorphous public policy considerations, which may include our perception of history, morals, justice and society[,]" the Althaus Court identified five factors that should be weighed in determining whether a duty exists in a particular case. ***Id.*** at 1168. Those factors are:

- (1) the relationship between the parties;
- (2) the social utility of the actor's conduct;
- (3) the nature of the risk imposed and foreseeability of the harm incurred;
- (4) the consequences of imposing a duty upon the actor; and
- (5) the overall public interest in the proposed solution.

Althaus, supra at 1168-69 (citations omitted). Courts are not required to weigh each factor equally and no individual factor is dispositive. ***Id.*** at 1169. "[A] duty will be found to exist where the balance of these factors weighs in favor of placing such a burden on a defendant." ***Phillips v. Cricket Lighters***, 841 A.2d 1000, 1008-09 (Pa. 2003). "Whether a duty exists is ultimately a question of fairness." ***Campo v. St. Luke's Hosp.***, 755 A.2d 20, 24 (Pa.Super. 2000).

Common Law Duty of Care on the Part of UPMC and Maxim

Plaintiffs contend first that, "the utility of imposing a duty [upon UPMC and Maxim] outweighs the costs associated with doing so." Appellants' brief at 24. They cite the compelling public interest in preventing the diversion of prescription drugs, especially from hospitals, as evidenced by federal statutes and regulations requiring hospitals and other drug registrants to secure drugs and report theft. Moreover, substitution, which is the removal of prescription drugs from a syringe often through injection and replacement with water, presents not only the risk that diluted medication will be administered to patients, but that the person diverting and substituting will contaminate the syringe and transmit potentially fatal diseases such as HIV and hepatitis C. Plaintiffs maintain that UPMC knew that Kwiatkowski was diverting and substituting fentanyl yet failed to report it to law enforcement, which would have halted his access to future patients at facilities where Kwiatkowski worked. Maxim knew Kwiatkowski was an addict and knew or

should have known that, without intervention, Kwiatkowski would continue to steal controlled substances to maintain his habit.⁸ According to Plaintiffs, “UPMC and Maxim could and should have foreseen that Kwiatkowski’s diversion of fentanyl, if unchecked and unreported, was likely to cause harm to the class of individuals to which plaintiffs belonged, i.e., those likely to receive care from the drug addict Kwiatkowski if his habit was allowed to continue.” *Id.* at 27.

Plaintiffs point to the nature of Kwiatkowski’s harm-producing conduct at UPMC, which was identical to his conduct at Hays Medical Center, as evidence that it was foreseeable to UPMC and Maxim that Kwiatkowski would seek other health-related employment to facilitate access to prescription drugs, divert them for his own use, and substitute diluted substances for injection through contaminated needles to unsuspecting patients, unless he

⁸ The allegation that Maxim knew of Kwiatkowski’s addiction and diversion of drugs suffices for our purposes of finding a duty. We note further that, in a subsequent filing, Maxim acknowledged that UPMC notified it that Kwiatkowski was terminated “for cause, reason – misconduct[,]” and that it knew the termination was “related to narcotics.” Response in Opposition to Plaintiffs’ Motion for Reconsideration of the Court’s June 20, 2013 Order, 8/12/13, at unnumbered 3. Additionally, Maxim represented that Kwiatkowski worked at a minimum of seven hospitals, not including Hays Medical Center, after being terminated at UPMC, and that Maxim was “not responsible for or associated with Kwiatkowski” or his placement in at least six of those hospitals. *Id.* at unnumbered 7. The reasonable inference to be drawn from the latter statement is that the agency may have placed Kwiatkowski at other healthcare facilities after it knew the reason for his termination by UPMC.

was reported to authorities and denied access. They rely upon ***Moran v. Valley Forge Drive-in Theater, Inc.***, 246 A.2d 875, 878 (Pa. 1968), for the proposition that the type of foreseeability required for imposition of a duty of care is “the likelihood of the occurrence of a general type of risk rather than the likelihood of the precise chain of events leading to the injury[,]” as distinguished from the foreseeability employed in proximate cause analysis that is specific to the particular plaintiff. Plaintiffs contend that the general type of risk presented by Kwiatkowski’s conduct met the foreseeability requirement for imposition of a duty.

Neither UPMC nor Maxim squarely addresses Plaintiffs’ arguments regarding the foreseeability of the harm created by Kwiatkowski’s unchecked drug diversion and substitution and the public interest in imposing a duty. Rather, Maxim focuses on the first factor, the lack of a special relationship between itself and Plaintiffs, as dispositive of the duty question. It relies heavily upon our decision in ***J.E.J. v. Tri-County Big Bros./Big Sisters, Inc.***, 692 A.2d 582, 584 (Pa.Super. 1997), where this Court declined to impose a duty upon Tri-County to plaintiffs based on a statutory failure to report suspected sexual misconduct by one of its Big Brothers upon his Little Brother.⁹ Thereafter, in circumstances unrelated to Tri-County Big Brothers

⁹ Pennsylvania's Child Protection Services Law, 23 Pa.C.S. § 6301 *et seq.*, requires individuals who, in the course of their employment, come into
(Footnote Continued Next Page)

activities, the abuser molested the plaintiffs' minor son. The parents asserted that the Big Brothers national organization was independently and vicariously liable for their son's physical injury and emotional harm, as well as their own emotional distress, due to its failure to report the suspected prior abuse involving the Big Brother.

Noting the absence of any special relationship between Tri-County and the plaintiffs, this Court found the only duty owed by the defendant to the plaintiffs was the general duty imposed on all persons not to expose others to reasonably foreseeable risks of injury. Furthermore, we relied upon the principle that a person is not liable for the criminal conduct of another in the absence of a special relationship imposing a pre-existing duty. **Feld v. Merriam**, 485 A.2d 742, 746 (Pa. 1984); **T.A. v. Allen**, 669 A.2d 360 (Pa.Super. 1995) (same).¹⁰ Since no relationship was alleged between the

(Footnote Continued) _____

contact with children to make a report to the local children and youth agency when they have reasonable cause to suspect, on the basis of their medical, professional, or other training and experience, that a child who has come before them in their professional or official capacity is an abused child. 23 Pa.C.S. § 6311.

¹⁰ Neither UPMC nor Maxim asserts the principle that, generally, one is not liable for the physical harm caused by a third party's criminal conduct, even if the actor's negligent conduct created the situation which afforded the opportunity for the third person to commit the tort or crime, as that intentional tort or crime is a superseding cause of harm. The exception to that rule, however, is the situation where the actor **at the time of his negligent conduct** realized or should have realized the likelihood that such a situation might be created, and that a third person might avail himself of
(Footnote Continued Next Page)

plaintiffs' child and Tri-County National Organization, the latter only owed the general duty imposed on all persons not to place others at risk of reasonably foreseeable harms and did not include a duty to report the abuser. **See *Schmoyer v. Mexico Forge, Inc.***, 649 A.2d 705, 708 (Pa.Super. 1994) (Absent a special relationship, the duty that one person owes to another is "the general duty imposed upon all persons not to expose others to risk of injury which are reasonably foreseeable[."])

Maxim argues that, as in ***Tri-County***, it had no relationship with either Plaintiffs or Kwiatkowski at the time Plaintiffs were exposed to Kwiatkowski and, hence, no duty. Furthermore, it alleges that the consequences of holding it liable for Kwiatkowski's conduct go far beyond the cost of making a telephone call. It characterizes Plaintiffs' position as seeking to hold Maxim liable in perpetuity for injuries caused by any former employee. It advances the same position found persuasive by the trial court: that in the

(Footnote Continued) _____

the opportunity to commit such a tort or crime. **See** Restatement (Second) of Torts § 448 (1965) (Intentionally Tortious Or Criminal Acts Done Under Opportunity Afforded By Actor's Negligence) (emphasis added). Other exceptions include situations where "(a) a special relationship exists between the actor and the third person's conduct, or (b) a special relationship exists between the actor and the other that gives the other a right to protection." **See *Emerich v. Phila. Ctr. for Human Dev., Inc.***, 720 A.2d 1032, 1036 (Pa. 1998) (holding that the special relationship between a mental health professional and his patient may, in certain circumstances, give rise to an affirmative duty to protect and warn patient's intended victim); **see *Feld v. Merriam***, 485 A.2d 742, 746 (Pa. 1984) (holding landlord has duty to protect tenants from the foreseeable criminal acts of third persons).

event of a simple employee error in failing to report, it could be subject to potentially limitless liability.

UPMC, like the trial court, relies upon **Seebold** in refuting the establishment of a new affirmative duty of care on UPMC to protect unknown third parties. It cites **Seebold** for the proposition that it had “no duty to protect or rescue someone who is at risk on account of circumstances the defendant had no role in creating.” **Seebold** at 655 (citing *e.g., Yania v. Bigan*, 155 A.2d 343, 346 (Pa. 1959) and Section 314 of the Restatement of Torts for the proposition that a mere observer has no duty to rescue).

In **Seebold**, a corrections officer sued Prison Health Services (“PHS”), the contractor who provided medical care at the prison, when she contracted a contagious bacterial infection after strip-searching a dozen infected inmates. She alleged that PHS knew or should have known the inmates were infected and should have warned staff and taken precautionary measures. The trial court sustained preliminary objections, finding PHS did not owe a duty to protect the health of a prison staff member; it owed a duty only to its patients.

This Court reversed. We held that physicians treating a patient with a communicable disease had a duty to warn third persons who would be foreseeably likely to contract the contagious skin disease. The Supreme Court reversed this Court, finding first that the standard of care for a physician treating a patient with a communicable disease was to advise the

patient about the nature of the disease, treat the disease, and inform the patient how to prevent its transmission to others. The Court continued that a physician had no duty to third persons outside the doctor-patient relationship. The Court concluded that there was no special relationship between PHS and the plaintiff, and “no duty to protect or rescue someone who is at risk on account of circumstances the defendant had no role in creating” in the absence of such a special relationship. **Seebold**, 57 A.3d at 1246.

According to UPMC, in order to proceed, Plaintiffs’ theory of liability would either have to fall either within an exception to the no-duty rule in rescue scenarios, or the application of the **Althaus** factors would have to militate in favor of creating a new affirmative duty. Appellee UPMC’s brief at 10. Since there was no special relationship between UPMC and Plaintiffs, UPMC maintains there is no applicable exception to the no-duty rule. As to the **Althaus** factors, UPMC argues that the lack of a special relationship between the parties militates against the imposition of a new affirmative duty. Additionally, UPMC takes the position that the social utility of imposing a duty to report upon a health care provider is outweighed by the lack of foreseeability. In response to Plaintiffs’ contention that foreseeability in the duty context need only be of the general type of harm, UPMC downplays the importance of foreseeability in our duty determination. **See Seebold, supra** at 1249 (finding foreseeability alone not determinative of duty).

UPMC characterizes Plaintiffs' attempt to impose a duty to protect all health care patients as "entirely unworkable and overarching." Appellee UPMC's brief at 16.

As to the fourth **Althaus** factor, UPMC argues that the cost of imposing a duty to report includes the consequences: open-ended and limitless liability "unchecked by the passage of time, proximity or scope of harm." Appellee UPMC's brief at 17 (quoting Trial Court Opinion, 6/20/13, at 14). It reiterates the trial court's assumption that, although UPMC intends to comply with all federal reporting regulations, the inevitable employee error could result in onerous consequences.

We find **Seebold** distinguishable as we are not dealing with a physician-patient relationship. **Seebold** presented the issue of whether PHS, a health care provider, owed a duty of reasonable care to warn or otherwise protect a prison guard charged with strip-searching inmates from the dangers of the transmission of MRSA from its patients. Our Supreme Court declined to impose a duty upon a health care provider involved in a physician/patient relationship to warn at-risk third parties, finding that considerations such as physician-patient confidentiality and protection of the physician-patient relationship outweighed considerations favoring imposition of a duty to warn. Our High Court acknowledged that it had imposed a duty upon a health care professional to convey information to a third party that he obtained within the confines of the physician-patient relationship in

Emerich v. Phila. Ctr. for Human Dev., Inc., 720 A.2d 1032 (Pa. 1998) (therapist had a duty to warn his patient's intended victim of the harm but duty limited to readily-identifiable individuals). The Court declined, however, to use ***Emerich***, "unique in many respects," as "a springboard for the imposition of new and broader duties upon health care providers vis-à-vis third party non-patients." ***Id.*** at 1233.

While the ***Seebold*** Court noted other considerations independent of the physician-patient relationship, such as prison order and security, the difficulty in identifying persons at risk in the prison, and access to and the ability to disseminate the information, which weighed against imposition of a duty on the facts therein, the decision turned on the physician-patient relationship. Our High Court refused to impose on physicians engaged **in a physician-patient relationship** "some non-specified affirmative obligation to third-party non-patients relative to communicable diseases," with individual juries deciding what the duty would be.¹¹ Herein, UPMC echoes PHS's argument that policy considerations counteract such an overly expansive exposure of health care providers to unlimited liability.

The fact that Kwiatkowski was an employee of UPMC and Maxim, not a patient, sharply distinguishes the instant case from ***Seebold***. Absent a

¹¹ In his dissenting opinion, then-Justice McCaffrey took the position that any alleged failure to warn was the result of the physicians' failure to properly diagnose MRSA.

physician-patient relationship, we need not be concerned with the policy considerations of privilege and confidentiality flowing from that relationship, and which create a tension with any duty to report, warn, or protect third parties at risk. **See DiMarco v. Lynch Homes-Chester County, Inc.**, 583 A.2d 422 (Pa. 1990) (physician owed duty to his patient, not her boyfriend, to warn and advise about avoiding spread of communicable disease); **compare e.g., Troxel v. A.I. Dupont Inst.**, 675 A.2d 314 (Pa.Super. 1996) (injured third party could maintain action against physician who failed to advise his patient of the dangers of spreading her disease to unborn children of others); **Emerich, supra.**

Secondly, while we agree with UPMC and Maxim that they had no special relationship with Plaintiffs, our inquiry does not end there. Where the defendant stands in some special relationship with the person whose conduct needs to be controlled, a duty may be imposed. **Brezinski v. World Truck Transfer, Inc.**, 755 A.2d 36, 40 (Pa.Super. 2000). Kwiatkowski was allegedly an employee of UPMC and Maxim when the duty to report arose. A special relationship may include a master's duty to control a servant. **See** Restatement (Second) of Torts, § 317 (recognizing master is under a duty in certain circumstances "to exercise reasonable care so to control his servant while acting outside the scope of his employment as to prevent him from intentionally harming others or from so conducting himself as to create an unreasonable risk of bodily harm to them"). In

addition, we have imposed a duty upon those in charge of individuals with dangerous propensities to control those individuals. **See** Restatement (Second) of Torts § 319 (“One who takes charge of a third person whom he knows or should know to be likely to cause bodily harm to others if not controlled is under a duty to exercise reasonable care to control the third person to prevent him from doing such harm.”);¹² **see also Goryeb v. Commonwealth, Dep't of Public Welfare**, 575 A.2d 545, 549 (Pa. 1990) (finding duty to protect "others" who could foreseeably be affected by a wrongful discharge of a mental patient consistent with Section 319 of the Restatement (Second) of Torts and our own prior case law).

UPMC is quick to point out that the master’s duty with regard to a servant only exists where the servant is upon the master’s premises, using the master’s chattel, or upon premises he is privileged to enter only due to his status as the master’s servant, circumstances that it contends are not applicable herein. It does not address a duty under the principles espoused in § 319.

¹² Generally, one is not liable for the physical harm caused by the criminal conduct of a third party unless a special relationship exists between the actor and the third person’s conduct or a special relationship exists between the actor and the other that gives the other a right to protection. **Emerich v. Phila. Ctr. for Human Dev., Inc.**, 720 A.2d 1032 (Pa. 1998); **see Feld v. Merriam**, 485 A.2d 742 (Pa. 1984) (landlord has duty to protect tenants from the foreseeable criminal acts of third persons).

Although there was no relationship between UPMC and Plaintiffs herein, Plaintiffs have pled facts that, if proven, could support a finding of a special relationship between UPMC and Maxim and Kwiatkowski. At the time the alleged duty arose, Kwiatkowski was the employee/agent of Maxim and UPMC, and both entities knew that Kwiatkowski was diverting intravenous drugs that he accessed on UPMC's premises. Kwiatkowski injected himself, replaced the drugs with saline, and placed the contaminated needles and syringes back on the shelf to be used on unsuspecting patients. UPMC communicated the nature of Kwiatkowski's criminal conduct to Maxim, and banned him from its facilities. While Kwiatkowski was in the charge of UPMC and Maxim, both entities knew he was dangerous and likely to cause bodily harm to others if not controlled. Reasonable care, according to Plaintiffs, entailed reporting Kwiatkowski to law enforcement.

We find that Plaintiffs pled facts that could conceivably support imposition of a duty of care upon both UPMC and Maxim to others based on their special relationship with Kwiatkowski. Additionally, application of the **Althaus** factors on the facts as gleaned from the pleadings weigh in favor of imposing a duty to report. Duty is predicated upon the relationship existing between the parties at the relevant time. **Althaus**, at 1169. There was a special relationship between Kwiatkowski and UPMC and Maxim when the alleged duty to report arose, *i.e.*, when Kwiatkowski's theft and substitution of controlled substances were exposed. Additionally, UPMC and Maxim knew

that Kwiatkowski's addiction, diversion, and substitution of drugs presented a danger to patients at facilities where he worked, not just UPMC's patients.

As to the social utility of UPMC and Maxim's conduct, the second **Althaus** factor, it is indisputable that UPMC provides critical health care services and Maxim plays a role in providing the necessary staffing to perform those services. However, imposing a duty to report upon health care providers and staffing agencies will not unduly hinder such entities from performing their vital functions, and in fact, would operate to their benefit in protecting these entities from unwittingly hiring drug-impaired and unreasonably dangerous health care workers. Furthermore, reporting is not such an arduous task as to divert attention or resources from the mission of providing quality health care. UPMC is already required to report the diversion of controlled substances under both federal and state law. Pursuant to 63 P.S. § 422.4, hospitals are required to report impaired physicians to the state board of medicine. **See Cooper v. Frankford Health Care Sys.**, 960 A.2d 134 (Pa.Super. 2008).

The third factor, the risk presented by the diversion, adulteration, and substitution of medications, weighs heavily in favor of imposing a duty. The risk was a serious and foreseeable one to UPMC and Maxim. As Plaintiffs correctly state, foreseeability in the context of duty "means the likelihood of the occurrence of a general type of risk rather than the likelihood of the occurrence of the precise chain of events leading to the injury." **Charlie v.**

Erie Ins. Exch., 100 A.3d 244, 256 (Pa.Super 2014). Plaintiffs pled that, due to the failure of UPMC and Maxim's failure to report Kwiatkowski to the DEA or other law enforcement agencies, he gained access to other health care facilities, exposing the patients in those facilities to the same risk of contaminated needles, and the transmission of life-threatening communicable diseases such as HIV and hepatitis C.

As to the fourth **Althaus** factor, we are not persuaded that the imposition of a duty to report is so onerous as to be "entirely unworkable or overarching" as UPMC contends. Appellee UPMC's brief at 16. Nor do we cower from claims of exposure to "limitless liability unchecked by the passage of time, proximity, or scope of harm" for what could be a mere clerical error. **Id.** Imposition of a duty is but the first step in imposing liability. Recovery hinges on proof of breach and causation, and we recognize that it becomes more difficult to prove the latter with the intervening circumstances that come with the passage of time.

Finally, we find that the fifth **Althaus** factor, consideration of the overall public interest, favors the imposition of a duty of care. It was foreseeable that Kwiatkowski's conduct, if unchecked, would place other hospital patients such as the Plaintiffs at risk for the transmission of an infectious blood-borne disease. The public health interest in preventing the transmission of blood-borne pathogens, especially HIV and hepatitis C, is evidenced by the many statutes and regulations requiring health care

providers to report incidences of these and other communicable diseases. This Commonwealth imposes criminal liability upon a health care practitioner or facility “who treats or examines a person who is suffering from, or who the health care practitioner or health care facility suspects, because of symptoms or the appearance of the individual, of having a reportable disease, infection or condition,” but who fails to report that fact to the Health Department. **See** 28 Pa. Code § 27.21a. “Hepatitis, viral, acute and chronic cases” are among the infections/conditions reportable within five days of being identified. **Id.** at (b)(2); **see** The Disease Prevention and Control Law of 1955, 35 P.S. § 521.1.

UPMC banned Kwiatkowski from its facilities and informed Maxim of his conduct. Such action evidences UPMC’s appreciation of the danger Kwiatkowski posed to its patients. Maxim, despite being fully informed of the danger Kwiatkowski presented, did not report Kwiatkowski to law enforcement. Plaintiffs contend herein that Maxim placed Kwiatkowski at other health care facilities, knowingly and intentionally exposing other patients to the possibility of contagion. The risk of not reporting Kwiatkowski to law enforcement and licensing agencies was that he would seek employment and access to controlled substances to support his addiction at other health care facilities and endanger patients in those settings. His practice of injecting himself and substituting saline for the diverted substances presented an increased risk of serious infection to

patients elsewhere due to contaminated needles and substances. The inference Plaintiffs ask us to draw is that the nature of Kwiatkowski's addiction, as well as his preferred mode of satisfying that addiction, made it both foreseeable and highly likely that patients elsewhere would be exposed to the unreasonable risk of contagion if he was not reported and stopped. The unacceptable health risks involved, the likelihood of transmission of blood-borne pathogens to compromised hospital patients, support the finding of a duty to report.

Were this but a simple drug diversion scenario, where a healthcare professional stole drugs, injected himself, and properly disposed of the needle and syringe, our primary concern would be for the welfare of patients receiving diluted medications followed by overdoses, or being treated by an impaired health care provider. ***See Cassella v. State Board of Medicine***, 547 A.2d 506 (Pa.Cmwlt. 1988) (recognizing that drug-impaired medical practitioners present a clear and obvious danger to the public). The facts herein certainly demonstrate that danger, as well as an even more perilous scenario with far-reaching public health consequences.

Kwiatkowski was engaged in criminal behavior that constituted a serious public health risk. In light of Kwiatkowski's occupation as a health care worker, his addiction to fentanyl, his known diversion and substitution of drugs to conceal his habit, we agree with Plaintiffs that it was highly foreseeable to UPMC and Maxim that, left unchecked, Kwiatkowski would

seek employment and access to drugs at other health care facilities and continue that practice. UPMC and Maxim had a special relationship with Kwiatkowski when his drug diversion and substitution was detected, and they knew and appreciated the danger he presented to patients generally. In these circumstances, we find that Plaintiffs pled facts that could support imposition of a common law duty of care upon both UPMC and Maxim to report Kwiatkowski's criminal conduct to the DEA and/or other law enforcement agencies for prosecution. **See** 21 C.F.R. § 1301.76(b) Supplementary Information ("Lack of prompt notification could prevent effective investigation and prosecution of individuals involved in the diversion of controlled substances.").

II. Negligence *per se* against UPMC

Plaintiffs advance a second theory of liability against UPMC, which was rejected by the trial court. They pled that UPMC is a registrant permitted to possess and dispense controlled substances under the Controlled Substances Act (the "CSA"). Registrants under the CSA have a duty pursuant to 21 C.F.R. § 1301.76(b), to report the diversion of controlled substances to the Drug Enforcement Agency ("DEA") within forty-eight hours of discovery to facilitate investigation and prosecution. Plaintiffs contend that UPMC failed to report Kwiatkowski's diversion of its controlled substances to the DEA and

that the violation of the reporting statute constitutes negligence *per se*.¹³ The trial court disagreed, finding there was “nothing in the legislation or accompanying regulations suggesting that drug diversion by healthcare employees and its risks to patients are specific subjects that the Controlled Substances Act addressed.” Trial Court Opinion, 6/20/13, at 6. Furthermore, the court found the statute was intended to protect the interests of the general public rather than a specific group of persons encompassing Appellants.

Negligence *per se* is defined as “conduct, whether of action or omission, which may be declared and treated as negligence without any argument or proof as to the particular surrounding circumstances.” **Wagner v. Anzon, Inc.**, 684 A.2d 570, 574 (Pa.Super. 1996) (quoting Black's Law Dictionary, p. 933 (5th ed. 1979)). We start with the premise that, since ordinances and statutes regulate conduct, they also may impose legal obligations on individuals. **McCloud v. McLaughlin**, 837 A.2d 541, 545 (Pa.Super. 2003). As this Court stated in **McCloud**, “[n]egligence *per se* is

¹³ Pennsylvania has the Controlled Substance, Drug, Device and Cosmetic Act, 35 P.S. § 780-101 *et seq.*, which like the federal statute classifies substances such as fentanyl as Schedule II substances with a high potential for abuse and dependence. Regulations promulgated pursuant to that legislation require “Persons maintaining stocks or having controlled substances in production areas or on hand for distribution shall provide effective controls and procedures to guard against theft and diversion of substances.” 28 Pa.Code § 25.61(a).

the law's acknowledgement that through an individual's violation of a statute or ordinance, it is possible to show that the individual breached his duty to behave as a reasonable person, i.e., that the individual was negligent." **Id.**

However, a court will not use a statute or regulation as the basis of negligence *per se* where the purpose of the statute is to "secure to individuals the enjoyment of rights or privileges to which they are entitled only as members of the public." ***Centolanza v. Lehigh Valley Dairies***, 635 A.2d 143, 150 (Pa.Super. 1993), *aff'd*, 658 A.2d 336 (Pa. 1995) (quoting Restatement (Second) of Torts, § 288(b) (1965)). Furthermore, before an individual can be held to be negligent *per se*, his violation of the statute or ordinance must "cause harm of the kind the statute was intended to avoid and to a person within the class of persons the statute was intended to protect." **See** Dan B. Dobbs, *The Law of Torts* § 134 (2000). These requirements are calculated to ensure that the policy behind the legislative enactment will be appropriately served by using it to impose civil liability. ***Lutz v. Chromatex, Inc.***, 718 F. Supp. 413, 428 (M.D. Pa. 1989). Even then, negligence *per se* only supplies the first two elements of negligence: duty and breach. ***J.E.J. v. Tri-County Big Brothers***, *supra* at 585; ***Cabiroy v. Scipione***, 767 A.2d 1078, 1079 (Pa.Super. 2001). There can be no recovery absent proof that negligence was the cause of the injury. ***Schemberg v. Smicherko***, 85 A.3d 1071, 1074 (Pa.Super. 2014) (citing ***Mahan v. Am-Gard, Inc.***, 841 A.2d 1052, 1058-1059 (Pa.Super. 2003)).

Thus, to proceed on a negligence *per se* theory, a plaintiff must prove the purpose of the statute, at least in part, was to protect the interest of a specific group of individuals, as opposed to the general public, and that the statute or regulation clearly applied to the defendant's conduct. In order to recover, the plaintiff must also prove that the defendant violated the statute or regulation and that the violation was the proximate cause of injury.

The application of negligence *per se* is illustrated in several recent decisions in this Court. In ***Cabiroy, supra***, we affirmed the trial court's reversal of its grant of a non-suit on a negligence *per se* theory where the plaintiff offered proof that the defendant administered liquid silicone injections that were never approved by FDA, which resulted in harm to the plaintiff. This Court found that the statute that was violated was "designed to protect an individual such as plaintiff from being administered a non-labeled, non-sterile unapproved drug to avoid unexpected negative results." ***Cabiroy, supra*** at 1082. Proof of violation of the statute constituted proof of duty and breach thereof, and it was up to the factfinder to determine if that negligence was the cause of the injury.

In ***Mahan, supra***, plaintiff, a bank teller was shot and injured by an off-duty private detective perpetrating a robbery. She sought and obtained recovery on a negligence *per se* theory against the private detective's employer based on its admitted violation of the fingerprinting requirement of the Private Detective Act, 22 P.S. § 23, in its hiring of the detective. On

appeal, the detective agency argued that the trial court erred first, in admitting evidence that it violated the fingerprinting requirement as a basis for finding negligence *per se*, and second, in permitting the jury to consider whether the violation was the cause of harm to the teller, since the detective had not committed any criminal acts in the past that would have been discovered through fingerprinting. This Court held that the evidence was relevant and properly admitted, but that the agency's failure to abide by the statute was not the proximate cause of the plaintiff's injuries. We acknowledged, based on ***Ford v. Jeffries***, 379 A.2d 111, 115 (Pa. 1977), that the agency could be liable for its negligence despite the detective's superseding criminal acts if, at the time of its negligent conduct, it realized or should have realized the likelihood that such a situation might be created and that the detective might avail himself of the opportunity to commit such a tort or crime. However, the detective's impending criminal conduct was not foreseeable since fingerprinting would not have disclosed any prior criminal acts evidencing that the detective had a criminal propensity.

Appellants contend that the purpose of the CSA's reporting requirement is, "at least in part, to prevent the harms associated with drug diversion from befalling" its likely victims. Appellants' brief at 44. They direct our attention to the Code of Federal Regulations, specifically 21 C.F.R. § 1301.76(b), and the DEA's "Supplementary Information" regarding the

regulations, which addresses the requirement that registrants report drug diversion:

The purpose of immediate notification is to provide an opportunity for DEA, state, or local participation in the investigative process when warranted and to create a record that the theft or significant loss was properly reported. It also alerts law enforcement personnel to more broadly based circumstances to provide an opportunity for DEA, state, or local participation in the investigative process when warranted and to create a record that the theft or significant loss was properly reported. It also alerts law enforcement personnel to more broadly based circumstances or patterns of which the individual registrant may be unaware. This notification is considered part of a good faith effort on the part of the regulated industries to maintain effective controls against the diversion of controlled substances, as required by Sec. 1301.71(a). **Lack of prompt notification could prevent effective investigation and prosecution of individuals involved in the diversion of controlled substances.**

(emphasis added). Plaintiffs maintain that drug diversion affects them and others like them, and UPMC's violation of that reporting requirement was a proximate cause of their injuries.

UPMC counters that none of the statutes or regulations cited by Plaintiffs is intended to protect a group of persons, rather than the public as a whole. Furthermore, the statutes and regulations are not designed to protect against the specific harm at issue: the diversion and substitution of controlled substances by healthcare workers to patients. **See McCloud, supra** (violation of statute must cause harm of the type statute was intended to prevent for negligence *per se* to apply). UPMC directs our attention to **Gonzales v. Oregon**, 546 U.S. 243, 250-51 (2006), where the

United States Supreme Court construed the main objectives of the CSA as “combatting drug abuse and controlling the legitimate and illegitimate traffic in controlled substances.”

Congress enacted the CSA as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C. §§ 801-904). As the United States Supreme Court noted in ***United States v. Moore***, 423 U.S. 122, 132 (U.S. 1975), “the Act was intended to ‘strengthen,’ rather than to weaken, ‘existing law enforcement authority in the field of drug abuse.’ (citing 84 Stat. 1236 (1970) (Preamble); ***see also*** H. R. Rep. No. 91-1444, p. 1. (“This legislation is designed to deal in comprehensive fashion with the growing menace of drug abuse in the United States[.]”).

In enacting the statute, Congress recognized that “(1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.” 21 USCS § 801. Nonetheless, it required “[e]very person who dispenses, or who proposes to dispense, any controlled substance,” to “obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him.” 21 USCS § 822(a)(2).

The regulations require registrants, those entities and persons authorized to manufacture, possess, distribute or dispense controlled substances, to physically secure controlled substances. In addition, they are

not permitted “to employ, as an agent or employee . . . who has access to controlled substances, any person who has been convicted of drug-related felony offense.” 21 CFR § 1301.76(a). Furthermore, a registrant is required to report the diversion of controlled substances to the DEA in certain circumstances. 21 CFR 1301.76(b).

It is apparent that the regulations in question are calculated to ensure that controlled substances in the possession of registrants are properly secured. The prohibition against the employment of convicted drug offenders indicates an awareness of the potential for drug abuse by health care practitioners, workers, researchers, and pharmacists with lawful access to drugs through their employment. The reporting requirement is intended to alert the DEA when legitimately possessed controlled substances are diverted so that it can investigate and prosecute the individuals responsible. We are persuaded that the reporting requirement was intended to protect the public from the dangers associated with the diversion, trafficking, and abuse of controlled substances in the possession of registrants, *i.e.*, hospitals and pharmacies and other licensed persons and entities, by subjecting diverters to criminal prosecution.¹⁴

¹⁴ The CSA also authorizes the DEA to take administrative, civil, and criminal action against any registrant that fails to maintain effective controls against diversion. Administrative actions include a letter of admonition for minor recordkeeping or reporting violations, or hearings for more serious
(Footnote Continued Next Page)

As a registrant under the Act, UPMC was allegedly required to report to the DEA Kwiatkowski's known diversion and substitution of its controlled substances. Its failure to do so in 2008 effectively foreclosed any DEA investigation and prosecution of Kwiatkowski at that time. Such reporting was intended to protect against the harmful consequences of drug abuse, including the type of harm that resulted herein.

Nonetheless, we agree with the trial court that there is no indication in the CSA or its regulations that the reporting requirement was intended to protect a particular group to which Plaintiffs belonged. The CSA's comprehensive enforcement scheme is calculated to protect the public from the dangers resulting from the diversion of drugs and their abuse. We note that the CSA does not expressly provide for a private right of action but that fact is not dispositive of the statute's use as the basis for negligence *per se*. However, absent herein is any indication that the purpose of the statute is to

(Footnote Continued) _____

violations. An order to show cause is usually reserved for a registrant's ongoing failure to maintain controls against diversion, and can result in revocation of registration. The DEA is empowered to pursue civil actions through the U.S. Attorney's office for monetary penalties for violations of the recordkeeping and reporting requirements of the CSA. Registrants are also subject to criminal prosecution for knowing and intentional acts in the unlawful manufacture and distribution of controlled substances. **See** 65 Food Drug L.J. 623, 627-628, for an expansive explanation of possible liability of registrants for violations of the CSA and its regulations.

protect a particular group of individuals encompassing Plaintiffs.¹⁵ **See K.H. ex rel. H.S. v. Kumar, supra** at 1087-90 (citing **J.E.J., supra** at 586, for proposition that while a violation of the Child Protective Services Law (“CPSL”) could serve as the predicate for a negligence *per se* claim, the minor-plaintiff fell outside the class of children protected by the statute as he was not connected to the entity bearing the mandatory reporting obligations). For this reason, we affirm the trial court’s order sustaining the demurrer as to Plaintiffs’ negligence *per se* claim against UPMC.

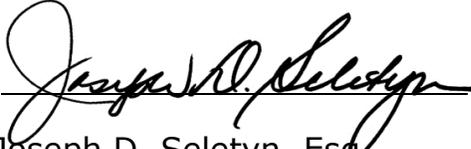
Order affirmed in part and reversed in part. Case remanded for further proceedings consistent with this opinion. Jurisdiction relinquished.

Judge Mundy Joins the Opinion

Judge Jenkins files a Dissenting Opinion.

¹⁵ After a duty has been established, a statute or regulation may be admissible evidence of the requisite standard of care. **See Brogley v. Chambersburg Engineering Co.**, 452 A.2d 743 (Pa.Super. 1982) (sanctioning admission of evidence of OSHA regulation and its violation as probative of employer’s negligence).

Judgment Entered.

A handwritten signature in black ink, appearing to read "Joseph D. Seletyn", written over a horizontal line.

Joseph D. Seletyn, Esq.
Prothonotary

Date: 7/21/2016