No. 2-11-0452

In the

Appellate Court of Illinois

Second Judicial District

ILLINOIS DEPARTMENT OF FINANCIAL
AND PROFESSIONAL REGULATION,

Petitioner-Appellant,

v.

WALGREEN CO.,

Respondent-Appellee.

Appeal from the Circuit Court of the Nineteenth Judicial Circuit,
Lake County, Illinois, No. 10 MR 1760.
The Honorable **David M. Hall**, Judge Presiding.

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1. Whether the Department's Petition to Enforce Administrative Subpoenas was properly dismissed where the underlying subpoenas narrowly sought "incident reports of medication error" and the only responsive documents maintained by Walgreens are confidential STARS reports protected from disclosure as patient safety work product under the Patient Safety Act.

2. Whether the Department has created an issue of fact by impermissibly seeking to expand the scope of its original subpoenas so as to avoid the preemptive force of the Patient Safety Act.

STATUTES INVOLVED

The federal Patient Safety and Quality Improvement Act ("Patient Safety Act"), 42 U.S.C. § 299b-22(a) provides in relevant part:

> **(a) Privilege**
> Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be--
>
> **(1)** subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
>
> **(2)** subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
>
> **(3)** subject to disclosure pursuant to section 552 of Title 5, (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;
>
> **(4)** admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or
>
> **(5)** admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.
>
> **(b) Confidentiality of patient safety work product**
> Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be confidential and shall not be disclosed.

Section 299b-21 of the Patient Safety Act further provides in part:

> **(6) Patient safety evaluation system.**
>
> The term "patient safety evaluation system" means the collection, management, or analysis of information for reporting to or by a patient safety organization.
>
> **(7) Patient safety work product**
>
> (A) In general.
>
> Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements--
>
> (i) which--
>
> (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
>
> (II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or
>
> (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.
>
> …
>
> **(8) Provider**
>
> The term "provider" means--
>
> **(A)** an individual or entity licensed or otherwise authorized under State law to provide health care services, including--
>
> **(i)** a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory,

or health center; or

(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

(B) any other individual or entity specified in regulations promulgated by the Secretary.

42 U.S.C. § 299b-21.

Illinois Supreme Court Rule 191(b) provides in relevant part:

> **(b) When Material Facts Are Not Obtainable by Affidavit.**
>
> If the affidavit of either party contains a statement that any of the material facts which ought to appear in the affidavit are known only to persons whose affidavits affiant is unable to procure by reason of hostility or otherwise, naming the persons and showing why their affidavits cannot be procured and what affiant believes they would testify to if sworn, with his reasons for his belief, the court may make any order that may be just, either granting or refusing the motion, or granting a continuance to permit affidavits to be obtained, or for submitting interrogatories to or taking the depositions of any of the persons so named, or for producing papers or documents in the possession of those persons or furnishing sworn copies thereof.

Sup. Ct. R. 191.

INTRODUCTION

The Illinois Department of Financial and Professional Regulation ("Department") is the state agency charged with regulating pharmacists and pharmacies. There is no dispute that the Department has the general authority to conduct investigations and, where appropriate, discipline licensees for the protection of public health. Rather, the dispute in this case centers upon the limits of the Department's statutory authority to obtain by subpoena documents absolutely privileged under federal law.

This case arose in July 2010 when the Department issued three subpoenas duces tecum to Walgreen Co. ("Walgreens"). C6-11; SA1-6.[1] The Department's subpoenas sought "incident *reports* of medication error" for three Walgreens pharmacists. *Id.* (emphasis supplied). Presumably, the Department intends to use these "incident reports of medication error" to discipline the three pharmacists for allegedly committing prescription dispensing errors.

The notion that a health professional must be punished for committing a medical error is as outdated as it is ineffective. In recent years, a fundamental shift has occurred in the recommended way that medical errors should be addressed. There has also been a corresponding shift in federal law protecting reports of those medical errors from disclosure. As noted below in pp. 8-9, *infra*, Congress enacted the Patient Safety and Quality Improvement Act of 2005 ("Patient Safety Act") to create a

[1] Walgreens includes a Supplementary Appendix with this brief pursuant to Supreme Court R. 342(a). Citations to the Supplementary Appendix are referenced as "SA__".

protected space for providers like Walgreens to voluntarily identify, collect, report, and analyze medication errors without fear of State discipline or discovery.

Walgreens met its burden by establishing the applicability of this privilege. *See* Part II, Section A, *infra*. Conversely, the Department failed to substantively rebut Walgreens' evidence and meet its own burden. *See* Part II, Section B, *infra*. The Department's request that it be given another opportunity to conduct discovery in this matter is futile, and in any event, has been waived. The Department's attempts to chip away at the expansive protections of the federal privilege in this manner should be rejected.

In the end, this case is about whether the Department's statutory authority to obtain certain materials must yield to a comprehensive federal privilege where Walgreens' undisputed evidence shows that the only responsive documents it maintains are privileged. The circuit court rightly answered this question in the affirmative and granted Walgreens' motion to dismiss. This Court should affirm that ruling.

STATEMENT OF FACTS

Supreme Court Rule 341(i) permits an Appellee to include a Statement of Facts to the extent that the Appellant's Statement of Facts is deemed unsatisfactory. Walgreens respectfully submits the following supplementary Statement of Facts as necessary to a full understanding of this case.

A. The Institute of Medicine Report and the Patient Safety and Quality Improvement Act of 2005

In 1999 the Institute of Medicine ("IOM") published a landmark report entitled "TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM" (National Academy Press 1999) ("IOM Report"). C43-65; C89. The IOM report concluded that medical errors, including pharmacy dispensing errors, are most often caused by a convergence of multiple contributing factors. C43-65. The IOM report noted that providers have little to no incentive to report or analyze errors to improve the quality of health care. C89. Accordingly, the IOM Report recommended a move away from a punitive approach to dealing with errors, and a move towards a protected, incentivized peer-review system that encourages voluntary error reporting. *Id.* This new system allows a provider to report and discuss errors openly in a protected environment. *Id.*; C89. By protecting the analysis and reports of errors from disclosure in civil, criminal, and administrative proceedings, providers would have an incentive to report errors and learn from the errors to ensure that a similar error does not reoccur. *Id.*

The IOM Report's key recommendations became law in 2005 when Congress passed and the President signed the Patient Safety and Quality Improvement Act ("Patient Safety Act"). 42 U.S.C. §299b-21, *et seq.* C67-79; C89. The Patient Safety

Act creates a tightly crafted federal privilege for "patient safety work product" reported to a "patient safety organization." 42 U.S.C. 299b-22(a). All "patient safety work product" shall be fully protected from any "Federal, *State*, or local civil, criminal, or *administrative disciplinary* proceeding against a provider." 42 U.S.C. §299b-22 (emphasis supplied). "Patient safety work product" is defined as:

> "**any data, reports, records, memoranda, analyses** (such as root cause analyses), or written or oral statements--
> **(i) which--**
> **(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization**; or
> **(II)** are developed by a patient safety organization for the conduct of patient safety activities;
> and which could result in improved patient safety, health care quality, or health care outcomes; or
> **(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system**.

42 U.S.C. § 299b-21 (emphasis supplied).

By including broad confidentiality and privilege protections in the Act, Congress acknowledged that medical error reporting is compromised when there is a threat of disclosure in litigation or when providers are subject to discipline. *See* S. Rep. No. 108-196, at 4 (2003) ("The purpose of this legislation is to encourage a 'culture of safety' and quality in the U.S. health care system by providing for broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety.").

B. Walgreens' Patient Safety Evaluation System

Walgreens had a comprehensive quality improvement system in place prior to the enactment of the Patient Safety Act. C115; SA7. After the Patient Safety Act went into effect, Walgreens took steps to transform its existing quality improvement system into a patient safety evaluation system as contemplated by the Patient Safety Act. *See* C115-116; SA7-8 (instituting reporting mechanisms and transmitting reports to Patient Safety Organization); 42 U.S.C. § 299b-21(7)(B) (defining "patient safety evaluation system" as "the collection, management, or analysis of information for reporting to or by a patient safety organization."). Walgreens' patient safety evaluation system, known internally as "Continuous Quality Improvement" or "CQI," is "designed to improve patient safety and the quality of health care delivery by promoting accuracy in the dispensing of prescriptions, enhancing the development and training of pharmacy personnel and ensuring consistency in providing pharmaceutical care services." C115-116; SA7-8. "The purpose of the CQI program is to raise awareness about quality related events and provide the means to determine how to prevent such events in the future." *Id.* "Participation in the CQI program is mandatory for all pharmacy staff." *Id.*

Walgreens' CQI system uses a proprietary reporting mechanism, known as the Strategic Reporting and Analytic Reporting System ("STARS"), to track and report external quality events. *Id*. STARS is used to generate confidential, privileged, quality improvement reports, known as "STARS reports." *Id*. Walgreens considers STARS, and STARS reports, along with all peer review reporting, deliberations, and analysis of a provider within STARS, to constitute privileged "patient safety work

product" as defined by the Patient Safety Act. *Id.*; *see also* STARS Report Template at C119; SA11 ("Confidential Peer Review Document – Do Not Print Or Duplicate"). STARS is maintained in electronic format and its data are considered strictly confidential. C115-116; SA7-8.

C. Walgreens Transmits STARS Reports to a Federally-Certified Patient Safety Organization

When a prescription error occurs at Walgreens the pharmacist is required to report the event into STARS as soon as possible and before the end of their shift. C116; SA8. STARS notifies the Walgreens District Pharmacy Supervisor of the STARS report so that it may be reviewed for completeness. *Id.* The Walgreens District Pharmacy Supervisor then transmits the STARS report to the Patient Safety Research Foundation, Inc. *Id.* The Patient Safety Research Foundation, Inc. is a federally certified patient safety organization. *Id.*; SA13; *see also* 42 U.S.C. §299b-24(b)(1) (detailing patient safety organization eligibility). Walgreens has contracted with the Patient Safety Research Foundation to serve as its patient safety organization pursuant to the Patient Safety Act. C116; SA8.

As a federally certified patient safety organization, the Patient Safety Research Foundation "analyzes the information contained in the STARS reports and makes recommendations to Walgreens pharmacies." *Id*. Walgreens relies on these recommendations to "improve the quality of the prescription dispensing process." *Id.* Walgreens transmits its confidential STARS reports to the Patient Safety Research Foundation with the understanding that the reports and information contained therein are privileged patient safety work product as defined in the Patient Safety Act. SA9.

D. Proceedings Before The Circuit Court

After the Department filed its Petition to Enforce the Administrative Subpoenas, Walgreens timely filed a Section 2-619 motion to dismiss. C1-12; C25-41. The motion contained a true and correct copy of a STARS report template to comply with Sup. Ct. R. 201(n). C119; SA11. The primary argument in Walgreens' motion was that the Department's Petition should be dismissed because documents responsive to the subpoenas were privileged under the Patient Safety Act. Walgreens also made two other arguments in support of its motion: that the Illinois Medical Studies Act served as an additional basis to find a privilege, and that the Department's subpoenas were procedurally defective.

In support of its primary argument, Walgreens provided two affidavits from Suzanne Hansen, its Vice President of Pharmacy Services. Ms. Hansen's affidavits established upon personal knowledge that:

- While Walgreens does not have documents specifically entitled "incident reports" pertaining to "medication error," it does maintain STARS reports which contain information about an "improperly processed or filled prescription that is dispensed to the customer"; C115-116; SA7-8.
- STARS reports are transmitted to a federally-certified Patient Safety Organization; C116; SA8.
- Walgreens maintains its STARS reports electronically and considers them to be strictly confidential because they constitute privileged "patient safety work product" as defined by the Patient Safety Act; C117; SA9.

- STARS reports are the only "incident reports" pertaining to medication error in Walgreens' possession and it does not create, maintain, or otherwise have in its possession incident reports pertaining to medication error besides STARS reports; C115-116; C179; SA7-8; SA14.

- Walgreens does not collect or maintain separately any other incident reports pertaining to medication errors outside its STARS reporting system. C179; SA14.

During the hearing on the motion, the circuit court granted the Department leave to file its counter-affidavit. R8. Scott Golden, a Department prosecutor, was the affiant. C251-252; SA16-18. Among other things, Mr. Golden testified that he had "personal knowledge" that Walgreens maintains documents *referencing* "incidents of medication error" separate from STARS. *Id*. Thus, while the Department's subpoenas specifically called for "incident reports," Mr. Golden's affidavit addressed documents that "reference" only "incidents" of medication error.

Mr. Golden's testimony was based upon performance reviews and Loss Prevention statements generated by Walgreens during an internal investigation into an unrelated employee's misconduct. C254-272. These documents became public record when Walgreens filed them in its defense to a federal employment discrimination suit. *See Lindsey v. Walgreen Co.*, 08 C 3547, 2009 WL 4730953 (N.D. Ill. Dec. 8, 2009) *aff'd*, 615 F.3d 873 (7th Cir. 2010). Mr. Golden relied on these documents as proof for him to "dispute" Walgreens' evidence that there "are no other incident reports pertaining to medication error that are collected or maintained separately from

the STARS reporting system." C252; SA17. In contrast, Walgreens submitted clear and uncontradicted evidence that it "did not produce or disclose privileged STARS reports" in *Lindsey*. C180; SA15.

Following extensive argument on whether the Patient Safety Act was a proper basis to dismiss the Department's Petition, the circuit court granted Walgreens' motion. R27-28. The circuit court noted that both parties concede that Walgreens' STARS reports are privileged under the Patient Safety Act. R27. The circuit court also found that "incident reports of medication error" constitute "patient safety work product" under the Patient Safety Act. R.28. The circuit court acknowledged that the Department disagreed with Walgreens as to what documents are or are not part of the STARS system. R27. However, the circuit court focused on the clear and limited language in the subpoenas and found no material evidence in the Department's counter-affidavit which alleged that non-privileged "incident reports of medication error" exist within Walgreens possession. *Id.* The circuit court found that "[e]verything requested in the subpoena as a result is privileged and protected and the motion to dismiss under 2-619 is granted with prejudice, based on those findings." R28. The circuit court issued a written order further specifying the grounds for its decision. C275-276. The Department appealed. C278.

ARGUMENT

I. Introduction and the Standard of Review

The Department's subpoenas in this case seek "incident reports of medication error." C6-11; SA1-6. Walgreens submitted uncontradicted evidence that the only responsive documents are privileged STARS reports. C115-119; C179-180; SA7-9; SA14-15. In an attempt to avoid this privilege, the Department tried to expand the scope of its subpoenas by submitting a counter-affidavit which claims that Walgreens does, in fact, "maintain and/or collect[] documents which reference *incidents* of medication error." C251-252; SA16-18 (emphasis supplied). But that is not what the subpoenas in this case sought. As the circuit court properly found, documents that reference "incidents" of medication error necessarily comprise a much larger universe of documents than actual "incident *reports*" of medication error. Clearly, the latter category of documents are Walgreens STARS reports which are transmitted to a Patient Safety Organization and therefore, by definition, are protected patient safety work product. C115-116; SA7-8.

Recognizing this weakness in its argument, the Department's opening brief incorrectly portrays the circuit court's ruling on the Medical Studies Act as the primary issue on appeal. In doing so, the Department attempts to minimize the applicability of the Patient Safety Act's broad privilege to this case. This re-characterization of the actual reason why the circuit court granted dismissal is an effort to mask the frailties of the Department's counter-affidavit. The Department's brief also tries to distract from the two crucial factual admissions it made below: (1)

that Walgreens' STARS reports are "patient safety work product" protected under the Patient Safety Act; and (2) that the Patient Safety Act preempts the Department's subpoena authority to the extent it calls for "patient safety work product." *See* C16; R27 (conceding STARS reports are protected under the Patient Safety Act); C143; Pet. Br. at 24 n.5 (conceding Patient Safety Act preempts the Department's authority to subpoena patient safety work product).

Walgreens filed a Section 2-619 motion to dismiss the Department's Petition along with affidavits in support. By presenting adequate affidavits supporting the asserted defense, Walgreens satisfied the initial burden of going forward on the motion. *Kedzie & 103rd Currency Exch., Inc. v. Hodge*, 156 Ill. 2d 112, 116-17 (1993); *see also Callaghan v. Vill. of Clarendon Hills*, 401 Ill. App. 3d 287, 291 (2d Dist. 2010). The burden then shifts to the plaintiff. *Id.* The plaintiff must establish that the defense is unfounded or requires the resolution of an essential element of material fact before it is proven. *Id.* The plaintiff may do so by "affidavit[ ] or other proof." *Id.* A counter-affidavit is necessary, however, to refute evidentiary facts properly asserted by affidavit supporting the motion—otherwise the facts are deemed admitted. *Id.* The Department failed to provide any counter-affidavit in its response brief. C134-167. Only after Walgreens pointed out this deficiency in its Reply, see C169-170, did the Department immediately draft and present a motion for leave to file its counter-affidavit. C186-189. The circuit court granted the Department's motion for leave to file its counter-affidavit *instanter* because doing so would allow "a full opportunity for both sides to the present the factual information that they believe is relevant to a determination of the underlying issues…." R8.

If, after considering the pleadings and affidavits of a 2-619 motion, the circuit court finds that the plaintiff has failed to carry the shifted burden of going forward, the motion may be granted and the cause of action dismissed. *Kedzie,* 156 Ill. 2d at 116-117. An appeal from such a dismissal is the same in nature as one following a grant of summary judgment and is likewise a matter given to *de novo* review. *Id.* The appellate court must consider whether the existence of a genuine issue of material fact should have precluded the dismissal or, absent such an issue of fact, whether dismissal is proper as a matter of law. *Id.*

The Court may affirm the circuit court's decision on any basis supported by the record, regardless of the reasoning employed by the circuit court. *In re Marriage of Morreale*, 351 Ill.App.3d 238, 241 (2d Dist. 2004). The Court may also affirm the trial court's decision based upon any admissions in the record and exhibits that are attached to the pleadings. *Pearson v. Lake Forest Country Day Sch*., 262 Ill.App.3d 228, 231 (2d Dist. 1994); *see also Wright v. City of Danville*, 174 Ill. 2d 391, 399 (1996) (section 2–619 dismissal "may be affirmed on any grounds supported by the record, regardless of whether the trial court relied on those grounds or whether its reasoning was correct.").

II. The Patient Safety Act Preempts the Department's Ability to Compel Disclosure of Walgreens' "Incident Reports of Medication Error"

The Patient Safety Quality Improvement Act of 2005 ("Patient Safety Act") provides "sweeping evidentiary protections" for materials used in a health care quality improvement system. *See generally KD ex rel. Dieffenbach v. United States,*

715 F. Supp. 2d 587, 595 (D. Del. 2010). The Patient Safety Act requires that all "patient safety work product" reported to a "patient safety organization" be fully protected from any "Federal, State or local civil, criminal, or *administrative subpoena* or order, including a Federal, State, or local civil or *administrative disciplinary* proceeding against a provider." 42 U.S.C. §299b-22 (emphasis supplied). The Patient Safety Act expressly preempts all contrary state and federal laws. 42 U.S.C. §299b-22(a).

A "provider" covered by the Patient Safety Act is expressly defined to include pharmacists and pharmacies. 42 U.S.C. § 299b-21(8). The Patient Safety Act defines "patient safety work product" as:

> **any data, reports, records, memoranda, analyses** (such as root cause analyses), or written or oral statements--
>
> (i) **which**--
>
> (I) **are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization**; or
>
> (II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or
>
> (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

42 U.S.C § 299b-21(7)(a)(emphasis supplied).

This definition, while sweeping, is not absolute. Walgreens concedes that not "all" documents which could conceivably *relate* to medication errors are privileged under the Patient Safety Act. R20; R24-25. The Patient Safety Act clearly provides

that documents such as patient medical records, billing information, and documents maintained separately from a patient safety evaluation system are not "patient safety work product." 42 U.S.C. § 299b-21(7)(B).

But the Department did not request those types of documents from Walgreens. It sought a very specific classification of documents, namely, "incident reports of medication error." The specificity of the Department's subpoenas here illuminates the applicability of the Patient Safety Act. *See, e.g., Nehring v. First Nat. Bank in DeKalb*, 143 Ill. App. 3d 791, 798 (2d Dist. 1986) (specificity requirement relating to discovery requests exists to (1) enable those from whom discovery is sought to know what is being demanded of them; and (2) to aid the trial court in ascertaining whether the requested material is exempted or privileged from discovery).

The Department's subpoenas seek all "incident **reports** of medication error" for the subject pharmacists. C6-11; SA1-6 (emphasis supplied). The subpoenas, as drafted, target Walgreens' quality analysis and patient safety work product rather than non-privileged factual information concerning alleged medication errors. Walgreens presented uncontradicted evidence that the only documents it maintains which can be construed as "incident reports of medication error" are STARS reports, and that these documents are submitted to a Patient Safety Organization as a part of its patient safety evaluation system. As such, they are privileged under the Patient Safety Act and the circuit court correctly dismissed the Department's petition.

A. Walgreens Met Its Burden in Establishing Its STARS Reports Are Patient Safety Work Product Under the Patient Safety Act.

The Department's subpoenas seek "incident reports" of medication error—a term of art with a very specific meaning. R12. "Incident reports" of medication error in the pharmacy industry contain information such as the patient identifier, the healthcare providers at issue, the drug at issue, what happened, and what caused the error. R12; *see also* C119; SA11 (STARS report detailing Patient Information, Prescription Information, Event Details, and Contributing Factors).

Illinois law recognizes this term of art in the context of pharmacy practice. *See, e.g.,* 77 Ill. Admin Code. § 340.1660 (addressing "incident report" in context of errors and drug reactions in administering medication in Illinois Veterans' Homes Code); 77 Ill. Admin Code § 250.2140(c)(4) (regulation governing Hospital Pharmacy and Therapeutics Committee's review of "medication error and/or other incident reports"); 77 Ill. Admin. Code. § 300.1630 (requiring Illinois skilled nursing facilities to generate an "incident report" of medication errors and drug reactions); 77 Ill. Admin. Code §350.1430(e) (requiring long-term care facilities treating the developmentally disabled to document "incident reports" of medication errors and drug reactions); 77 Ill. Admin Code. § 390.1430 (same for nursing facilities treating children).

Ms. Hansen's affidavit confirms that the only "incident reports of medication error" that Walgreens maintains are in a format known as STARS reports. C179; SA14. The record further confirms Walgreens maintains no "incident reports" of

medication error other than its STARS reports. C115; SA7. And, since its STARS reports are submitted as a matter of course to a federally-certified Patient Safety Organization, *see* C116-117 and SA8-9, then all of Walgreens' STARS reports are protected by the Patient Safety Act privilege. The Department further admitted that (1) Walgreens' STARS reports are privileged under the Patient Safety Act and hence "patient safety work product," *see* R16, R27; and (2) The Patient Safety Act necessarily preempts the Department's statutes which would otherwise authorize it to subpoena "patient safety work product." C143. Taken together, this evidence and the Department's own admissions were sufficient for Walgreens to meet its burden of demonstrating that the Patient Safety Act applies in this case.

B. The Department Failed to Meet Its Burden in Disputing that Walgreens' STARS Reports Are Not Privileged by the Patient Safety Act and Failed to Establish a Genuine Issue of Material Fact

1. The Department's Affidavit Fails to Create a Genuine Issue of Material Fact Because it Does Not Refute Ms. Hansen's Affidavit.

By presenting adequate affidavits supporting the asserted defense, Walgreens satisfied the initial burden of going forward on the motion. *Kedzie*, 156 Ill. 2d at 116-17. The burden then shifted to the Department to establish that the defense is unfounded or requires the resolution of an essential element of material fact before it is proven. *Id.* The plaintiff may do so by "affidavit[ ] or other proof." *Id.* A counter-affidavit is necessary, however, to *refute* evidentiary facts properly asserted by affidavit supporting the motion else the facts are deemed admitted. *Id.* (emphasis supplied). If, after considering the pleadings and affidavits of a 2-619 motion, the

trial judge finds that the plaintiff has failed to carry the shifted burden of going forward, the motion may be granted and the cause of action dismissed. *Id*. That is precisely what occurred in this case. The circuit court considered the affidavits presented and found that the Department was not able to meet its shifted burden regarding the applicability of the federal Patient Safety Act privilege.

Contrary to the Department's belief that Mr. Golden's Affidavit "contradicts" Ms. Hansen's affidavit, in fact they address two entirely different types of information:

Department's Subpoenas	Department's Counter-Affidavit
"incident <u>reports</u> of medication error" C6-C11; SA1-6 (emphasis supplied).	**"<u>incidents</u> of medication error"** and **"<u>references</u> to medication error"** C252; SA17 (emphasis supplied).

Mr. Golden's affidavit does not address "incident reports." C252; SA17. Instead, Mr. Golden's affidavit merely "disputes" Ms. Hansen's testimony by speculating that there *may* be other "documents which reference *incidents* of medication error separate from Walgreens' electronic STARS reporting system." C251-52; SA16-17. Mr. Golden's hypothesis does not contradict Ms. Hansen's affidavit. "When supporting affidavits have not been challenged or contradicted by counter-affidavits or other appropriate means, the facts stated therein are deemed admitted." *Zedella v. Gibson*, 165 Ill. 2d 181, 185 (1995); *see also People v. 1515 Coolidge Ave., Aurora, Ill.*, 308

Ill. App. 3d 805, 812 (2d Dist. 1999) (applying same standard to 2-619 motion). Walgreens affidavits were correctly deemed admitted and unopposed and the Department's evidence fails to create any issue of material fact.

The circuit court considered the existence of performance reviews and loss prevention reports which were at issue in the *Lindsey* case (*see* C254-272), but it ultimately determined that these were immaterial because they were not "incident reports of medication error." In granting the 2-619 motion, the circuit court implicitly found Walgreens evidence on the issue of the Patient Safety Act privilege to be persuasive and sufficient to meet the initial burden. The circuit court correspondingly found that the Department failed to carry the shifted burden of going forward. With these conditions met, dismissal under Section 2-619 was correct. *Van Meter v. Darien Park Dist.*, 207 Ill. 2d 359, 377 (2003).

2. Mr. Golden's Affidavit Is Speculative and Inappropriately Attempts to Expand the Scope of the Department's Subpoena

To be valid, affidavits must not contain conclusions but only evidentiary facts to which the affiant is capable of testifying. *Gassner v. Raynor Mfg. Co*., 409 Ill. App. 3d 995, 1005 (2d Dist. 2011). Unsupported assertions, opinions, and self-serving or conclusory statements do not comply with the rule governing affidavits. *Id.*, *see also* Ill. S.Ct. R. 191(a). Here, the Department's affidavit is self-serving and based upon unsupported assertions and opinions. It also fails to create a genuine issue of fact because the witness expands impermissibly the plain language of what was actually requested in the subpoenas.

The affiant, Mr. Golden, is a prosecutor employed by the Department. C251; SA16. Mr. Golden asserts that "Walgreens maintained and/or collected documents which reference **incidents** of medication error separate from Walgreens' electronic STARS reporting system." C252; SA17 (emphasis supplied). His affidavit does not address "incident *reports* of medication error"—what the subpoenas actually sought and what the Department is trying to enforce. *Cf.* C. 251-52; SA16-17 *with* C2; C6-11; SA1-6.

The Department continued to impermissibly try to expand the scope of its subpoenas during oral argument on the motion to dismiss. *See, e.g.*, R15 ("any documents that reference medication error"); R16 ("a reference of medication error" and "an incident of medication error"); R17 ("an incident of medication error" and "it's a medication error and it is an incident in a document that the Department is seeking"); R18 ("examples of medication errors in documents). The Department also mischaracterized precisely what the subpoenas request. *See* R21 ("They request incident [sic] of medication error"). The Department omitted any reference that the subpoenas, in fact, request "incident *reports*" of medication error. C6-10; A1-6 (emphasis supplied). The Department may wish to avoid preemption under the Patient Safety Act, but it simply cannot do so by ignoring the language in its own subpoenas.

Documents referencing individual "incidents" of medication error are significantly different from "Incident *Reports*." Walgreens position in this case is that the latter are privileged by the Patient Safety Act. As previously discussed, the Department concedes that STARS reports are privileged. R16, R27. Mr. Golden's

affidavit was based solely upon documents Walgreens used to defend itself in an unrelated employment discrimination matter in federal court. Mr. Golden's repeated allegations that Walgreens "*may*" maintain incidents of medication errors outside its STARS reporting system is pure speculation and completely unsupported by personal knowledge. C252; SA17 (emphasis supplied). Those averments should be deemed to not have been made upon Mr. Golden's personal knowledge (as is required by Sup. Ct. R. 191), but rather on his information and belief. Indeed, the most that Mr. Golden could reasonably testify to would be that Walgreens filed certain documents to defend itself in the *Lindsey* case—the only fact within his personal knowledge because he apparently reviewed the federal electronic docket. Mr. Golden does not have any personal knowledge about Walgreens STARS reports or other records, and therefore his affidavit contains improper speculation and conclusions which should be disregarded under Supreme Court Rule 191(a). *See Estate of Blakely v. Fed. Kemper Life Assur. Co*., 267 Ill. App. 3d 100, 105 (2d Dist 1994) (court must disregard self-serving conclusions in affidavits).

Under these circumstances, the circuit court was correct to find the Department's purported evidence was immaterial and insufficient to warrant denial of the motion to dismiss. *See Luciano v. Waubonsee Cmty. Coll.*, 245 Ill. App. 3d 1077, 1084-85 (2d Dist. 1993) (Plaintiff's affidavit premised solely upon belief as to circumstances regarding Defendant's employment and conjecture was insufficient to rebut positive averments of facts, and thus no question of fact existed); *see also Millsaps v. Bankers Life Co*., 35 Ill.App.3d 735, 741 (2d Dist. 1976) (affidavit filed in support of complaint based on information and belief insufficient as against defendant's

uncontradicted affidavit filed in conjunction with section 2-619 motion to dismiss); *Gassner v. Raynor Mfg. Co*., 409 Ill. App. 3d 995, 1005 (2d Dist. 2011) (unsupported assertions, opinions, and self-serving or conclusory statements do not comply with the rule governing affidavits).

The *Lindsey* documents speak for themselves. They do not include STARS reports. C180. The *Lindsey* documents only make limited references to medication errors and include loss prevention and employment evaluation reports. Walgreens acknowledges that the *Lindsey* documents are not patient safety work product and therefore not protected by the Patient Safety Act.

In contrast to Mr. Golden's speculative and self-serving affidavit, Walgreens evidence is based on personal knowledge of a witness qualified to testify about Walgreens patient safety evaluation system and STARS reports. Walgreens "does not create, maintain, or otherwise have in its possession incident reports pertaining to medication error other than STARS reports." C179; SA14. Moreover, "[t]here are no other incident reports pertaining to medication error that are collected or maintained separately from the STARS reporting system." *Id.* The Department is attempting to create an issue of fact where none exists.

Interestingly, Mr. Golden did not testify that Walgreens may have "incident reports of medication error"—precisely the phraseology used in the three subpoenas at issue in this litigation. C6-11; SA1-6. This crucial factual discrepancy dooms the Department's attempt to create an issue of material fact sufficient to avoid dismissal under Section 2-619. The circuit court found that the Department's evidence simply

failed to rebut the facts established by Walgreens which demonstrated that the only documents it maintains responsive to the three subpoenas are STARS reports. Mr. Golden's speculation about what other documents Walgreens "may" have is not enough. "[U]nsupported conclusions, opinions, or speculation are insufficient to raise a genuine issue of material fact." *Outboard Marine Corp. v. Liberty Mutual Insurance Co.*, 154 Ill.2d 90, 132 (1992).

Walgreens has demonstrated, and the Department has conceded, that its STARS reports are transmitted to a federally-certified Patient Safety Organization and are patient safety work product. Accordingly, these documents are protected by the Patient Safety Act and privileged from disclosure. The Department failed to meet its counter-burden to show otherwise. The circuit court was correct to grant Walgreens' Section 2-619 motion.

C. The Department's Belated Request to Conduct Discovery Was Waived, and in Any Event, Would be Futile.

In its brief, the Department contends the circuit court's granting of the 2-619 motion was premature because it did not have the opportunity to conduct discovery about the documents in Walgreens' possession. Dept. Br. at 29. The Department has waived this opportunity because it neither moved for a continuance in the circuit court nor filed a Supreme Court Rule 191(b) affidavit attesting that it needed to conduct discovery to response to the motion to dismiss. The Department's request for discovery comes too little, too late.

Supreme Court Rule 191(b) specifies the procedure to be followed where

additional discovery is needed to resolve issues raised in a section 2-619 proceeding. *Kensington's Wine Auctioneers and Brokers, Inc. v. John Hart Fine Wine, Ltd.*, 392 Ill.App.3d 1, 11 (1st Dist. 2009). Supreme Court Rule 191(b) provides in relevant part:

> **(b) When Material Facts Are Not Obtainable by Affidavit.**
>
> If the affidavit of either party contains a statement that any of the material facts which ought to appear in the affidavit are known only to persons whose affidavits affiant is unable to procure by reason of hostility or otherwise, naming the persons and showing why their affidavits cannot be procured and what affiant believes they would testify to if sworn, with his reasons for his belief, the court may make any order that may be just, either granting or refusing the motion, or granting a continuance to permit affidavits to be obtained, or for submitting interrogatories to or taking the depositions of any of the persons so named, or for producing papers or documents in the possession of those persons or furnishing sworn copies thereof.

Sup. Ct. R. 191.

Consequently, if the Department wished to conduct discovery below, it simply had to submit an affidavit claiming that additional discovery was required. Rule 191(b) then authorizes the circuit court to grant a continuance to permit additional discovery to proceed, including procuring additional affidavits, submitting interrogatories, depositions of witnesses, or producing documents. As this Court has recognized, Rule 191(b) is the procedure by which a circuit court could compel the production of such information. *Burks Drywall, Inc. v. Washington Bank & Trust Co.*, 110 Ill. App. 3d 569, 577 (2d Dist. 1982), citing R. 191(b); *see also Saladino v. Team Chevrolet, Inc.*, 242 Ill. App. 3d 735, 742 (2d Dist. 1993) (rejecting belated request

for discovery where plaintiff failed to comply with Rule 191(b) and to inform the trial court of the names and probable testimony of any witnesses who would be deposed). The record contains no evidence of the Department filing a Rule 191(b) affidavit. Accordingly, the Department waived discovery in this case. *Cordeck Sales, Inc. v. Construction Systems, Inc.*, 382 Ill.App.3d 334, 372 (1st Dist. 2008) (party cannot argue on appeal summary judgment order must be reversed because it required additional discovery where party failed to request additional discovery and attach a Rule 191(b) affidavit); *Kleiber v. Freeport Farm & Fleet, Inc.,* 406 Ill. App. 3d 249, 261 (3d Dist. 2010), *appeal denied*, 949 N.E.2d 659 (Ill. 2011) (noting plaintiff's failure to request continuance for summary judgment hearing and failure to file Rule 191(b) affidavit forfeited its argument that granting of motion was premature so that discovery could proceed); *Rogers v. Robson, Masters, Ryan, Brumund & Belom*, 74 Ill. App. 3d 467, 471 (1st Dist. 1979), aff'd sub nom. *Rogers v. Robson, Masters, Ryan, Brumund, & Belom*, 81 Ill. 2d 201 (1980) ("Plaintiff did not comply with [Rule 191(b)] and having failed to do so, he cannot now complain of an inability to conduct discovery before summary judgment was ordered"); *Kimbrough v. Jewel Companies, Inc.*, 92 Ill. App. 3d 813, 819-20 (1st Dist. 1981) ("Were we to allow a plaintiff to avoid a motion for summary judgment by simply alleging that unknown witnesses might testify in some unspecified favorable way in the future, we would defeat the whole purpose of the summary judgment procedure since we would force the movant and the court to waste time and money to try the case in a full trial although there is no showing that plaintiff has even a prima facie case") (emphasis supplied).

Even supposing that the Department had not waived discovery, its argument that

it must conduct discovery now lacks merit since it had ample time to do so. The Department first engaged in discovery in this case in July, 2010, when it issued the initial subpoenas. C6-11; SA1-6. The Department's statute provides it with an array of discovery devices with which it may conduct investigations. 20 ILCS 2105/2105-105(a). It may, as it elected to here, issue subpoenas *duces tecum* to obtain "any books, papers, records, or other documents" that the Department's Director deems relevant or material to its investigation. *Id.* The Department may also issue subpoenas to secure the attendance of witnesses; it may administer oaths to witness them and "take evidence" from them. Witnesses who ignore the Department's subpoenas are subject to misdemeanor criminal liability prosecuted by the Attorney General. *Id.* Yet, the Department did not conduct any discovery aside from issuing the three subpoenas.

Walgreens submits that the Department did not do so because no amount of additional discovery would have changed the uncontroverted fact that the STARS reports are the only "incident reports of medication error" in Walgreens' possession and are protected from disclosure under the Patient Safety Act. Remanding this case to conduct discovery would be an exercise in futility.

D. The Department's Mistaken Interpretation of the Patient Safety Act is Contrary to Congressional Intent and, If Adopted, Would Have a Chilling Effect Upon Providers' Willingness to Voluntarily Report Errors to Patient Safety Organizations.

The Department also argues that patient safety work product which is "*also* maintained separately from a patient safety evaluation system" loses its privileged status. Pet. Br. at 26 (emphasis supplied). By misinterpreting the Patient Safety Act,

the Department persists in speculating that there *might* be the "possibility" that a STARS report is also maintained in a separate location so as to attempt to create an issue of material fact. C252; SA17. The Department's argument fails for two reasons.

First, its argument is moot because the record confirms that Walgreens does not maintain patient safety work product "separate" from its privileged STARS reports. C115-117; SA7-9; C179-180; SA14-15. Such rampant speculation is simply not enough to meet the Department's counter-burden in avoiding dismissal. The Department is essentially arguing that Walgreens must meet an enhanced burden of proof to perfect its privilege under the Patient Safety Act. Neither the Patient Safety Act nor its regulations require any such enhanced burden.

The Department points to the *Lindsey* documents as alleged proof that Walgreens "maintains" other documents responsive to the subpoenas at issue. *See* C254-272. The internal corporate investigation in *Lindsey* focused on a former employee's failure to comply with mandatory company policy of completing STARS reports—it was not an investigation into event that precipitated the STARS report or the STARS reports themselves. *Id.* Instead, Walgreens' Loss Prevention personnel independently sought and obtained evidence from non-privileged sources at Walgreens in an effort to investigate Ms. Lindsey. *Id.* Tellingly, no STARS reports were admitted or otherwise disclosed in the record of *Lindsey*. C180; SA15.

Second, the Department's argument also fails because its interpretation would render the Patient Safety Act meaningless. The Patient Safety Act focuses on the purpose for a document's collection to invoke the privilege, not the precise location

where the document is maintained. This distinction, and the Department's confusion, was illustrated at oral argument on the motion to dismiss. The Department argued that information written "on a napkin" could not be patient safety work product. R22. However, under the Patient Safety Act's regulations, a patient safety evaluation system is merely "the mechanism through which information can be collected, maintained, analyzed and communicated." 73 Fed. Reg. at 70,738. To this end, a system need not be formal—like Walgreens proprietary STARS system—but "exists whenever a provider engages in patient safety activities for the purpose of reporting to a Patient Safety Organization or a Patient Safety Organization engages in these activities with respect to information for patient safety purposes." *Id*. So, if a hypothetical provider used napkins as a means to collect, maintain, analyze, or communicate patient safety work product which would ultimately be transmitted to a Patient Safety Organization, then those napkins would remain privileged. R22-23. While documentation of a patient safety evaluation system is considered a "best practice," it is not required by law. 73 Fed. Reg. at 70,738.

The Department also argues that Walgreens "waives" its privilege under the Patient Safety Act by maintaining STARS reports outside of its quality improvement system. Dept. Br. at 26-27. This further illustrates the Department's fundamental confusion about the Patient Safety Act's purpose and application. Regardless of whether patient safety work product is disclosed properly or impermissibly, the Patient Safety Act's privilege and confidentiality protections remain in full force. 42 C.F.R. §3.208(a). The penalty for an improper disclosure is financial, not a waiver of the privilege. 42 U.S.C. §2996-22(f). Accordingly, even if Walgreens "failed to

quarantine" its STARS reports, maintained them separately, disclosed them improperly, or otherwise engaged in the conduct as alleged by the Department, the documents responsive to the three subpoenas would remain privileged under the Patient Safety Act.

These protections exist for a reason. Congress sought to "facilitate an environment in which health care providers are able to discuss errors openly and learn from them." H.R. Rep. 109-197, at 9 (2005), C89; *see also* Final Rule, Dep't of Health & Human Servs., *Patient Safety and Quality Improvement*, 73 Fed. Reg. 70732 (Nov. 21, 2008), 2008 WL 4948973 at *70732 (noting privilege provides "protections [that] will enable all health care systems, including multi-facility health care systems, to share data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers"). C112-113. The goal is to create a voluntary reporting system where providers are encouraged to share information without fear of liability. C112.

In construing the Patient Safety Act, a Court's "task is to give effect to the will of Congress, and where its will has been expressed in reasonably plain terms, that language must ordinarily be regarded as conclusive." *Italia Foods, Inc. v. Sun Tours, Inc*., 110350, 2011 WL 2163718 at *2 (2011). "Thus, in construing a statute, a court must not focus exclusively on a single sentence or phrase, but must view the statute as a whole. The court may consider the reason for the law, the problems sought to be remedied, and the purposes to be achieved." *Id.* The circuit court correctly recognized Congressional intent and the reasons for the Patient Safety Act's enactment in

rejecting the Department's arguments. R26-27. It was therefore correct in dismissing the Department's Petition and its decision should be affirmed.

III. The Court's Observation that the Medical Studies Act Applies to Pharmacies and Pharmacists Was Merely *Obiter Dictum*, Which Need Not Be Addressed On Appeal

The circuit court's decision below was rooted in the strong preemptive force of the Patient Safety Act. R26-28. "As an aside," the circuit court also noted that the Medical Studies Act applies to the peer review activities of pharmacists and pharmacies. R28; C275; *see* 735 ILCS 5/8-2101. It is abundantly clear that the Medical Studies Act did not form the basis of the circuit court's decision, and its reference to the Act was merely *obiter dictum* which this Court need not address on review. *See Exelon Corp. v. Dep't. of Revenue,* 234 Ill. 2d 266, 277 (2009) (*obiter dictum* is "a remark, an aside, concerning some rule of law or legal proposition that is not necessarily essential to the decision…."). Walgreens will therefore not unnecessarily lengthen this brief with discussion of that point, which was neither central to the decision below nor necessary to its affirmance by this Court.

CONCLUSION

For all of the foregoing reasons, Walgreen Co. respectfully requests the Court affirm the circuit court's decision dismissing the Department's Petition for Enforcement of Administrative Subpoenas.

Dated: September 16, 2011

Respectfully Submitted,

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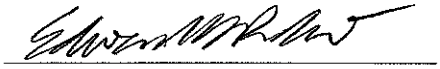
CERTIFICATE OF COMPLIANCE

I certify that this brief confirms to the requirements of Illinois Supreme Court Rules 341(a) and (b). The length of this brief, excluding the pages containing the Rule 341(d) cover, the Rule 341(h)(1) statement of points and authorities, the Rule 341(c) certificate of compliance, the certificate of service, and those matters to be appended to the brief under Rule 342(a) is 35 pages.



Edward D. Rickert

SUPPLEMENTARY APPENDIX

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STATE OF ILLINOIS

DEPARTMENT OF FINANCIAL & PROFESSIONAL REGULATION

SUBPOENA DUCES TECUM

DEPARTMENT OF FINANCIAL & PROFESSIONAL REGULATION Of the State of Illinois, Complainant	)	
v.	)	Case No: **2005.01990**
BRIAN L. KAMHOLZ, Respondent License No. **051.037671**	)	

TO: **Dwayne A. Pinon, Esquire**
Walgreen Co.
Corporate and Regulatory Law
104 W. Wilmot Road, 4th Floor
Mail Stop 1447
Deerfield, IL 60015

Pursuant to the Pharmacy Practice Act, 225 ILCS 85/35.5 and the Code of Civil Procedure, 735 ILCS 5/8-8021, the Department commands you to personally surrender on or before **August 11, 2010** to Dr. Yashwant Amin, Pharmacy Coordinator and Director of Drug Compliance for the Department of Financial & Professional Regulation of the State of Illinois, 9511 Harrison Street, Suite A-171, Des Plaines, IL 60016-1563 or any other agent the Pharmacy Coordinator sees fit to designate, certain documents and records for its inspection, copying, and verification, said documents and records being:

All incident reports of medication error involving Brian L. Kamholz from 3/1/05 through 7/1/10.

Pursuant to HIPAA Privacy Rule 45 CFR 164.512(f)(1)(ii)(C) this information may be released to the Department, a law enforcement official as defined in 45 CFR 164.501. The information sought in this subpoena is relevant and material to a legitimate law enforcement inquiry, and the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought.

And this you will in no wise omit under penalty of the laws made and provided in these instances.

SEAL

WITNESS:
Department of Financial and Professional Regulation
Brent E. Adams, Secretary

Alison R. Pearson

Donald W. Seasock, Acting Director of the
Division of Professional Regulation,
and the seal thereof,

This 1st day of July, 2010.

EXHIBIT
A-1

C00006

SA-1

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Dwayne A. Pinon, Esquire
Walgreen Co.
Corporate and Regulatory Law
104 W. Wilmot Road, 4th Floor
Mail Stop 1447
Deerfield, IL 60015

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SA-2

STATE OF ILLINOIS

DEPARTMENT OF FINANCIAL & PROFESSIONAL REGULATION

SUBPOENA DUCES TECUM

DEPARTMENT OF FINANCIAL & PROFESSIONAL REGULATION Of the State of Illinois, Complainant	)	
v.	)	Case No: **2009.11146**
THOMAS JOSEPH KWASIBORSKI, Respondent License No. **051.028800**	)	

TO: **Dwayne A. Pinon, Esquire**
Walgreen Co.
Corporate and Regulatory Law
104 W. Wilmot Road, 4th Floor
Mail Stop 1447
Deerfield, IL 60015

Pursuant to the Pharmacy Practice Act, 225 ILCS 85/35.5 and the Code of Civil Procedure, 735 ILCS 5/8-8021, the Department commands you to personally surrender on or before **August 11, 2010** to Dr. Yashwant Amin, Pharmacy Coordinator and Director of Drug Compliance for the Department of Financial & Professional Regulation of the State of Illinois, 9511 Harrison Street, Suite A-171, Des Plaines, IL 60016-1563 or any other agent the Pharmacy Coordinator sees fit to designate, certain documents and records for its inspection, copying, and verification, said documents and records being:

All incident reports of medication error involving Thomas Joseph Kwasiborski from 10/31/07 through 7/1/10.

Pursuant to HIPAA Privacy Rule 45 CFR 164.512(f)(1)(ii)(C) this information may be released to the Department, a law enforcement official as defined in 45 CFR 164.501. The information sought in this subpoena is relevant and material to a legitimate law enforcement inquiry, and the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought.

And this you will in no wise omit under penalty of the laws made and provided in these instances.

SEAL

WITNESS:
Department of Financial and Professional Regulation
Brent E. Adams, Secretary

Alison R. Peirce

Donald W. Seasock, Acting Director of the
Division of Professional Regulation,
and the seal thereof,

This 1st day of July, 2010.

EXHIBIT
A-2

C00008

SA-3

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Dwayne A. Pinon, Esquire
Walgreen Co.
Corporate and Regulatory Law
104 W. Wilmot Road, 4th Floor
Mail Stop 1447
Deerfield, IL 60015

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) [illegible] C. Date of Delivery 7-6-10

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☒ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7009 1680 0001 7332 8540

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

7009 1680 0001 7332 8540

U.S. Postal Service
CERTIFIED MAIL™ RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)
For delivery information visit our website at www.usps.com®
OFFICIAL USE

Postage	$ .44
Certified Fee	2.80
Return Receipt Fee (Endorsement Required)	2.30
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$ 5.54

Prof. Reg. Desplaines
Postmark Here
7/01/10

From: Nash Amin
Des Plaines DC

Sent To: Dwayne A. Pinon - Walgreens
Street, Apt. No.; or PO Box No.: 104 W. Wilmot Rd. - 4th Fl.
City, State, ZIP+4: Deerfield, IL 60015

PS Form 3800, August 2006 See Reverse for Instructions

C00009

SA-4

STATE OF ILLINOIS

DEPARTMENT OF FINANCIAL & PROFESSIONAL REGULATION

SUBPOENA DUCES TECUM

DEPARTMENT OF FINANCIAL & PROFESSIONAL REGULATION Of the State of Illinois, Complainant	)	
v.	)	Case No: **2009.08238**
MARY J. OLIMSKI SPRIGGS, Respondent License No. **051.287908**	)	

TO: **Dwayne A. Pinon, Esquire**
Walgreen Co.
Corporate and Regulatory Law
104 W. Wilmot Road, 4th Floor
Mail Stop 1447
Deerfield, IL 60015

Pursuant to the Pharmacy Practice Act, 225 ILCS 85/35.5 and the Code of Civil Procedure, 735 ILCS 5/8-8021, the Department commands you to personally surrender on or before **August 11, 2010** to Dr. Yashwant Amin, Pharmacy Coordinator and Director of Drug Compliance for the Department of Financial & Professional Regulation of the State of Illinois, 9511 Harrison Street, Suite A-171, Des Plaines, IL 60016-1563 or any other agent the Pharmacy Coordinator sees fit to designate, certain documents and records for its inspection, copying, and verification, said documents and records being:

All incident reports of medication error involving Mary J. Olimski Spriggs from 1/1/08 through 7/1/10.

Pursuant to HIPAA Privacy Rule 45 CFR 164.512(f)(1)(ii)(C) this information may be released to the Department, a law enforcement official as defined in 45 CFR 164.501. The information sought in this subpoena is relevant and material to a legitimate law enforcement inquiry, and the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought.

And this you will in no wise omit under penalty of the laws made and provided in these instances.

SEAL

WITNESS:
Department of Financial and Professional Regulation
Brent E. Adams, Secretary

Alison R. Peirce

Donald W. Seasock, Acting Director of the
Division of Professional Regulation,
and the seal thereof,

This 1st day of July, 2010.

EXHIBIT
A-3

C00010

SA-5

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Dwayne A. Pinon, Esquire
Walgreen Co.
Corporate and Regulatory Law
104 W. Wilmot Road, 4th Floor
Mail Stop 1447
Deerfield, IL 60015

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) [illegible] C. Date of Delivery 7-6-10

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☒ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7009 1680 0001 7332 8540

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

U.S. Postal Service™
CERTIFIED MAIL™ RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)
For delivery information visit our website at www.usps.com®

7009 1680 0001 7332 8540

Postage	$ .44
Certified Fee	2.80
Return Receipt Fee (Endorsement Required)	2.30
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$ 5.54

Postmark Here: 7/01/10

Prof. Reg. Resplaines

From: Yash Amin Des Plaines DFS

Sent To: Dwayne A. Pinon - Walgreens
Street, Apt. No., or PO Box No.: 104 W. Wilmot Rd. - 4th Fl.
City, State, ZIP+4: Deerfield, IL 60015

PS Form 3800, August 2006 See Reverse for Instructions

C00011

SA-6

IN THE CIRCUIT COURT OF THE NINETEENTH JUDICIAL CIRCUIT, LAKE COUNTY, ILLINOIS

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION, Petitioner, v. WALGREEN CO. Respondent.	Case No. 10 MR 1760

AFFIDAVIT

I, Suzanne Hansen, being first duly sworn on oath, deposes and states that if called as a witness to testify in the above-captioned cause, I am competent to testify and would testify as follows:

1. I am currently employed as Vice President, Pharmacy Services, at Walgreen Co. ("Walgreens").

2. I have reviewed the Department's Petition and subpoenas in this litigation. I am familiar with Walgreens records which could be considered responsive to the subpoenas.

3. Walgreens does not create, maintain, or otherwise have in its possession documents which are specifically entitled "incident reports" pertaining to "medication error."

4. Prior to April 29, 2005, Walgreens had in effect a comprehensive quality improvement program referred to as "CQI" (Continuous Quality Improvement). The CQI program is designed to improve patient safety and the quality of health care delivery by promoting accuracy in the dispensing of prescriptions, enhancing the development and training of pharmacy personnel and ensuring consistency in providing pharmaceutical

care services. The purpose of the CQI program is to raise awareness about quality related events and provide the means to determine how to prevent such events in the future. Participation in the CQI program is mandatory for all pharmacy staff.

5. The CQI Program uses Walgreens' proprietary Strategic Tracking and Analytical Reporting System ("STARS") to track and report external quality events. An external quality event is defined as an improperly processed or filled prescription that is dispensed to the customer. A true and correct copy of the STARS report template is attached hereto and incorporated herein as Exhibit 1.

6. Pursuant to the CQI program policies and procedures, for each external event a STARS report must be created. The pharmacist is required to report the event into the STARS system as soon as possible and before the end of his/her shift. Once the pharmacist enters the event into the STARS system, the District Pharmacy Supervisor is notified to review the report. The District Pharmacy Supervisor then submits the completed STARS report to The Patient Safety Research Foundation, Inc. ("PSRF"). PSRF analyzes the information contained within the STARS reports and makes recommendations to Walgreens pharmacies which are designed to improve the quality of the prescription dispensing process. I have no reason to believe that Walgreen polices and procedures were not followed with respect to the three pharmacists identified in the subpoenas referenced herein.

7. On January 9, 2009, PSRF was listed as a federally certified component patient safety organization ("PSO"). The listing was effective on January 14, 2009, for a period of three years. A true and correct copy of the PSRF's certification document is attached hereto and incorporated herein as Exhibit 2.

8. Walgreens has contracted with the PSRF to serve as its component PSO pursuant to the Patient Safety and Quality Improvement Act of 2005.

9. As defined in the CQI program policies and procedures, Walgreens considers the STARS reports to constitute privileged "patient safety work product" pursuant to the Patient Safety and Quality Improvement Act of 2005. The STARS system is maintained electronically and all reporting through the system is considered strictly confidential.

10. STARS reports generated by Walgreens pharmacies in Illinois are maintained for one year from the date they are reported to PSRF.

Further your affiant saith not.

Suzanne Hansen, VP Pharmacy Service

Suzanne Hansen
Vice President, Pharmacy Services

Sworn and subscribed to before me
this 24th day of January, 2011

Mayra P. Villafan
Notary Public

OFFICIAL SEAL
MAYRA P VILLAFAN
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:08/02/14

Exhibit 1

STARS External Event Information

Event #:
Store #:
Fill Date:

Event Type:
Medication Taken:
Doses Taken:
Alleged Patient Health Condition:

Patient Information

Name: Address: Gender:
DOB: Phone

Prescription Information

RX #: Last Refill: Original Date:
Drug ID: DAW: Substitute:
Manufacturer: Quantity:
Directions: Qty Dispensed:
Drug Expiration:
Days Supply: Refills: Refills Before: Qty Remaining:
Prescriber: Prescriber ID: NDC:
Prescriber Phone:

Event Recap

Comment History

Event Details

Drug Entered Into IC+:
Was the drug that was entered into IC+ the drug prescribed:
Was the drug that was entered into IC+ the drug dispensed:
Directions Entered Into IC+:
Were the directions that were entered into IC+ the directions prescribed:
Were the directions that were entered into IC+ the directions dispensed:

Root Cause Analysis for: Incorrect Drug

Contributing Factors

Workstation Detail

Station	Patient Entry (PE)	Script Entry (SE)	Filling (FILL)	Up-Front Verification (UFV)	Product Review (PR)	Out Window (OW)	Consultation RPh (CRPh)	Immunizing RPh (IRPh)
Staff								
Reviewed								

Follow-up Actions

Patient Returned Incorrect Medication:
Correct Medication given to Patient:
Doctor Contacted:
MD Comments:

Improvement Action Plan

Suggestions for Improvement

Exhibit 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare
Research and Quality

540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

January 9, 2009

Thomas P. Lawlor, RPh
The Patient Safety Research Foundation, Inc.
200 Wilmot Road, MS #2194
Deerfield, IL 60015-4681

Dear Mr. Lawlor:

The Agency for Healthcare Research and Quality (AHRQ) has processed your application and is pleased to notify you of The Patient Safety Research Foundation, Inc.'s listing as a Patient Safety Organization (PSO) by the Secretary of the Department of Health and Human Services (HHS). Your organization's listing will be effective on January 14, 2009 and will be effective for a period of three years, until midnight on January 13, 2012. Furthermore, your AHRQ-assigned PSO number is P0043, and your listing will be published within the next week on AHRQ's PSO Web site at www.pso.ahrq.gov. You will receive an additional letter from AHRQ shortly detailing the technical assistance services that are available to all listed PSOs.

To remain listed as a PSO, the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) requires each PSO to have two bona fide contracts during each successive 24-month period, beginning with the initial date of listing. In your case, this requirement must be met no later than midnight on January 13, 2011. To facilitate program administration, as reflected in the final rule (section 3.102(d)(1)), the Secretary will need to receive a notice from a PSO at least 45 days before the deadline attesting whether or not the PSO has met this requirement. Please use the form entitled *Attestation Regarding the Two Bona Fide Contracts Requirement* for this purpose. To obtain and complete the form, please visit AHRQ's PSO Web site at http://www.pso.ahrq.gov/listing/psoforms.htm#contrfm. AHRQ encourages PSOs to submit this form as soon as they have met this requirement; the list of PSOs on the Web site will identify when a PSO has met the requirement.

The Patient Safety Act also requires a PSO to file a disclosure statement regarding certain specified types of relationships with each provider with whom the PSO has entered a contract. To determine if any disclosure statements will be expected from your organization, please review the requirements outlined in the final rule (section 3.102(d)(2)). If you are required to submit a disclosure statement, please note that the applicable form is available on AHRQ's PSO Web site at http://www.pso.ahrq.gov/listing/psoforms.htm#contrfm. To review the final rule sections referenced above, you can access the rule on AHRQ's PSO Web site at http://www.pso.ahrq.gov/regulations/finalrule.htm.

If you have any questions regarding AHRQ's policies and procedures for PSOs, please contact the PSO Office via email at PSO@ahrq.hhs.gov or toll free at (866) 403-3697 or (866) 438-7231 (TTY).

Sincerely,

William B. Munier, M.D.

C00121

SA-13

IN THE CIRCUIT COURT OF THE NINETEENTH JUDICIAL CIRCUIT, LAKE COUNTY, ILLINOIS

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION, Petitioner, v. WALGREEN CO. Respondent.	)	Case No. 10 MR 1760

SUPPLEMENTAL AFFIDAVIT

I, Suzanne Hansen, being first duly sworn on oath, deposes and states that if called as a witness to testify in the above-captioned cause, I am competent to testify and would testify as follows:

1. I am currently employed as Vice President, Pharmacy Services, at Walgreen Co. ("Walgreens") and submit this Supplemental Affidavit in further support of Walgreens' Motion to Dismiss.

2. Walgreens does not create, maintain, or otherwise have in its possession incident reports pertaining to medication error other than the STARS reports referenced in my original affidavit. There are no other incident reports pertaining to medication error that are collected or maintained separately from the STARS reporting system.

3. As previously stated, STARS reports generated by Walgreens pharmacies in Illinois are maintained for one year from the date they are reported to The Patient Safety Research Foundation, Inc. ("PSRF"). All existing STARS reports that are responsive to the Department's subpoena were reported to PSRF after the date of certification (January 9, 2009).

4. I have reviewed the Declaration filed by Walgreens in the case of *Katie Lindsey v. Walgreen Co.;* which is cited by the Department in its response. Walgreens did not produce or disclose privileged STARS reports in that employment action.

Further your affiant saith not.

Suzanne Hansen
Vice President, Pharmacy Services

Sworn and subscribed to before me
this 24th day of March, 2011

Mayra P. Villafan
Notary Public

OFFICIAL SEAL
MAYRA P VILLAFAN
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:08/02/14

IN THE CIRCUIT COURT OF THE NINETEENTH JUDICIAL CIRCUIT
LAKE COUNTY, ILLINOIS

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION,	)	
Petitioner,	)	Case No. 10 MR 1760
v.	)	
WALGREEN CO.,	)	
Respondent.	)	

AFFIDAVIT OF SCOTT GOLDEN

I, Scott Golden, as agent for the Illinois Department of Financial and Professional Regulation, being first duly sworn on oath, deposes and states that if called as a witness to testify in the above-captioned cause, I am competent to testify and would testify as follows:

1. I am currently employed as Prosecutor in the Division of Professional Regulation within the Illinois Department of Financial and Professional Regulation and submit this Affidavit in opposition to the Supplemental Affidavit of Suzanne Hansen attached to Walgreen Co.'s ("Walgreens") Reply in Support of Its Motion to Dismiss.

2. I have personal knowledge of the facts stated herein.

3. I have reviewed certain documents (the "Documents") maintained in a public electronic case file in *Lindsey v. Walgreen Co.*, No. 08 C 3547 (N.D.Ill. Dec. 2009) filed by Walgreens in support of a Motion for Summary Judgment in that case, attached hereto as Exhibits 1 through 6.

4. After my review of the Documents, I have determined that as of August 18, 2009, the date on which the documents were filed in the *Lindsay* case, Walgreens maintained and/or

collected documents which reference incidents of medication error separate from Walgreens' electronic STARS reporting system.

5. Specifically, as of August 18, 2009, Walgreens maintained documents titled "Pharmacy Manager Performance Review," which include the performance category "Quality Assurance" and which allow for the input of comments regarding a pharmacist's performance in this area and may note a "high number of incidents" as noted in Pharmacy Manager Performance Review filed in *Lindsey v. Walgreen Co.*, NO. 08 C 3547 (N.D.Ill. Dec 08, 2009). *See* Ex. 1 at p. 1.

6. Also, as of August 18, 2009, Walgreens maintained documents titled "Case Inquiry Report" that may include references to medication error in the "Case Description" and "Facts" portion of the Case Inquiry Report, as indicated in the Case Inquiry Report filed in *Lindsey v. Walgreen Co.*, NO. 08 C 3547 (N.D.Ill. Dec 08, 2009). *See* Ex. 2 at pp. 3-4.

7. Also, as of August 18, 2009, Walgreens maintained documents titled "Loss Prevention Statements" that may include references to medication error as in the Loss Prevention Statement of LaTanya Russell, Catherine Okorie, Pamela Scuefield and Brandy Jackson filed in *Lindsey v. Walgreen Co.*, NO. 08 C 3547 (N.D.Ill. Dec 08, 2009). *See* Exs. 3-6.

8. I have also reviewed the Supplemental Affidavit of Suzanne Hansen attached to Walgreen Co.'s ("Walgreens") Reply in Support of Its Motion to Dismiss and attached hereto as Exhibit 7.

9. Based on my review of the Documents, I dispute the averment of Suzanne Hansen that "[t]here are no other incident reports pertaining to medication error that are collected or maintained separately from the STARS reporting system."

FURTHER AFFIANT SAYETH NOT.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

By: _____
Scott Golden, Prosecutor,
Division of Professional Regulation

Subscribed and sworn to before me
this 15 day of April, 2011.

_____
NOTARY PUBLIC

OFFICIAL SEAL
DANIEL ARON KELBER
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:03/28/12