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IN THE
COURT OF APPEALS OF INDIANA

A.B. Doe, a minor child by and through her parent(s); individually and on behalf of all others similarly situated,
Appellant-Plaintiff,

v.

Jerome Adams, M.D., in his capacity as the Indiana State Health Commissioner, and Victoria Buchanan, in her capacity as the Director of the ISDH Genomics and Newborn Screening Program,¹

April 19, 2016
Court of Appeals Case No.
49A04-1505-CT-326

Appeal from the
Marion Superior Court

The Honorable
Heather A. Welch, Judge

Trial Court Cause No.
49D01-1409-CT-31867

¹ After this appeal was filed, Jerome Adams, M.D. was substituted for William C. Vanness II, M.D. as the current Indiana State Health Commissioner (“Commissioner”) and Victoria Buchanan was likewise

Appellees-Defendants.

Kirsch, Judge.

[1] A.B. Doe, a minor child, by and through her parents (“Doe”) brought an action against the Indiana State Health Commissioner and the Director of the Indiana State Department of Health Genomics and Newborn Screening Program, in their individual and official capacities, and the Indiana State Department of Health (collectively, “ISDH”), alleging violations of the United States and Indiana constitutions and state law for retaining her newborn dried blood spot sample without permission.² The trial court granted ISDH’s Indiana Trial Rule 12(B)(6) motion to dismiss, and Doe appeals, raising three issues, of which we

substituted for Bob Bowman as the current Director of the ISDH Genomics and Newborn Screening Program (“Director”).

² The trial court dismissed the claims against the Commissioner and the Director in their individual capacities. Doe does not appeal those portions of the trial court’s decision. Claims against the Commissioner and the Director in their official capacities remain, although the individuals named in the original complaint have been substituted with the current Commissioner and Director. The trial court also dismissed ISDH, finding that it was not a “person,” and could not be sued under 42 U.S.C. § 1983. Doe also does not appeal that determination. Thus, the remaining claims are those against the current Commissioner and Director in their official capacities, which, for simplicity, we will continue to refer to, collectively, as “ISDH.”

find the following one dispositive: whether the trial court erred when it determined that Doe had not sustained, nor was she in immediate danger of sustaining, a direct injury as a result of the storage of her dried blood spot sample, and, therefore, she lacked standing.

[2] We affirm.³

Facts and Procedural History

[3] Doe was born in 2006. At the time of her birth, a small amount of blood was collected from Doe, pursuant to Indiana’s newborn screening program, which is codified at Indiana Code chapter 16-41-17. Indiana’s newborn screening program is a public health measure aimed at identifying, treating, and preventing serious conditions and diseases in infants, such as phenylketonuria, hypothyroidism, sickle cell anemia, cystic fibrosis, critical congenital heart disease, and other serious disorders. Indiana Code section 16-41-17-8 requires hospitals to take a blood sample from every infant born under their care. The blood is obtained from the infant, usually by a heel-stick test, before he or she leaves the hospital or within one week of birth, if born outside of a hospital. The blood is collected in five circles on a newborn screen card, which is referred to as a “DBS sample,” and the DBS sample is transported to a designated laboratory for testing. Ind. Code § 16-41-17-7. The Genomics & Newborn

³ We held oral argument in this case on March 15, 2016, at the Indiana Court of Appeals courtroom in the Indiana Statehouse. We commend counsel on the quality of their oral and written advocacy.

Screening Program division of ISDH is responsible for carrying out the testing prescribed by the legislature. The laboratory performs the screen by punching out small pieces from the DBS sample. If the test results indicate anything of concern, the laboratory contacts the newborn's doctor. Sometimes the laboratory may repeat a screening test, but often, not all of the five DBS circles on the newborn screen card are used. Nothing in the newborn screening program statutes directs if and how the ISDH may store the DBS samples. However, from approximately 1991 to June 2013, ISDH retained and stored that portion of the newborn screen card that contained the DBS sample taken from each infant.⁴

[4] In June 2013, ISDH changed its storage and retention policies:

As of June 2013, parents or guardians of newborns indicate whether or not to allow their child's DBS to be made available for medical research purposes. If a parent or guardian chooses to have their child's DBS saved, it will be stored and made available for medical research purposes for a period of three years and then destroyed. Although saved DBS, as of June 2013, will be available for medical research, no identifiable information about your baby will ever be released. If a parent or guardian indicates they do not want a baby's DBS used for medical research, then the DBS is kept for 6 months to ensure additional screening is not necessary and then destroyed.

⁴ Doe maintains that from 1991 to June 2013, it was ISDH's policy to keep the DBS samples "indefinitely," *Appellant's Br.* at 1. However, during the course of the litigation, ISDH submitted evidence that the DBS samples were retained for twenty-three years. *Appellant's App.* at 81-82.

See <http://www.in.gov/isdh/20215.htm> (last visited Mar. 23, 2016).

- [5] On September 25, 2014, Doe filed a Class Action Complaint and Request for Emergency Declaratory and Injunctive Relief (“Complaint”) against ISDH. The proposed class is defined as “[a]ll individuals who had a blood sample taken pursuant to IC 16-41-17-8 that has been or will be stored by the [ISDH] for more than six months without any documentation of consent.” *Appellant’s App.* at 37. Doe brought the action “pursuant to 42 U.S.C. § 1983 for violations of the Fourth, Fifth, and Fourteenth Amendments to the United States Constitution, for violations of the Indiana Constitution, and violations of Indiana State Law.” *Id.* at 30. The Complaint referred to Indiana’s Newborn Screening Program statutes, including Indiana Code section 16-41-17-8, as well as the ISDH website. *Id.* at 32 (Complaint citing to <http://www.in.gov/isdh/20215.htm>). In her Complaint, Doe asserted the following facts: ISDH took and stored blood samples from her; her blood samples continue to be stored “at an undisclosed location”; her blood samples or information derived therefrom “was shared with unauthorized third parties”; neither she nor her guardians were informed that her blood samples may be used for medical research or may be provided to any third parties; and neither she nor her guardians were notified that ISDH “continues to store her blood samples.” *Id.* at 32-33. She alleged that the storage of her blood samples without her knowledge or permission was an unreasonable search and seizure, was a taking of private property for public use without just compensation, and the conduct deprived her of life, liberty, or property without due process of law.

She claimed violations of 42 U.S.C. §§ 1983 and 1988 and asked for an award of attorneys' fees.

[6] On October 1, 2014, Doe filed a Motion for Class Certification. A few weeks later, on October 20, 2014, Doe filed her Plaintiff's Motion for Preliminary Injunction, requesting that the trial court enjoin ISDH from sharing any data or information obtained through the DBS samples of Doe and others similarly situated with any third party, including local, state, and federal law enforcement. Doe also requested that the trial court order ISDH to disclose the identity of every third party, including law enforcement agencies, that has received information related to the blood sample of any proposed class member.

[7] On November 19, 2014, ISDH filed a Response in Opposition to Motion for Preliminary Injunction ("ISDH's Opposition") and attached thereto, among other things, the affidavit of Bob Bowman ("Bowman Affidavit"), who at that time was the Director of the Maternal and Child Health Division for the ISDH, and prior to that, was the Director of Genomics and Newborn Screening within the Maternal and Child Health Division. The Bowman Affidavit averred, among other things, that the blood is collected in five circles on the newborn's screening card; the screening cards are perforated and one section contains the DBS sample and an identification number, but "no information about the identity of the newborn is contained with the [DBS] sample"; and the DBS samples are stored at the Indiana University Newborn Screening Laboratory. *Id.* at 79. The Bowman Affidavit also addressed ISDH's policy regarding retention of the DBS samples. The original policy "required the DBS samples

to be stored for 23 years,” but in 2013, the ISDH changed the retention policy “and the samples are now only stored for three years prior to destruction,” if the child’s parents consent to use for medical research; if the parents do not so consent, the sample is destroyed in six months. *Id.* For those parents whose babies were born before June 2013, “[T]hey may request that the DBS sample be destroyed” by completing an ISDH form and returning it to ISDH. *Id.* at 80. Under the new June 2013 policy, parents may also complete an available form requesting that the DBS sample be stored for medical research purposes. ISDH attached the referenced forms, such as the “Request for Destruction of Dried Blood Spot,” as exhibits. *Id.* at 83, 87-90.

[8] Also attached to the Bowman Affidavit was the “After Newborn Screening” pamphlet, published by ISDH and distributed to parents at their child’s birth. *Id.* at 84-85. The pamphlet provides this explanation as to why DBS samples are retained:

There are several reasons why dried blood spots are kept. First, good laboratory practices require that samples (such as DBS) be kept for a period of time after testing is done, in case a test needs to be checked or repeated. DBS are also used by Indiana’s newborn screening laboratory to help develop tests for newborn screening and to make sure that equipment is working correctly.

Id. at 85. The After Newborn Screening pamphlet advises parents that “you don’t have to allow your child’s DBS to be used for medical research.” *Id.* at 84. The pamphlet also states that DBS samples that were collected pre-June 2013 – and thus “before parents/guardians were asked to decide whether a

child's DBS sample could be used for medical research" – are "*NOT available*" for use in research. *Id.* at 85 (emphasis in original). The ISDH website likewise states that "[i]f your baby was born before June 1, 2013, your baby's DBS has not been made available for medical research."

<http://www.in.gov/isdh/20215.htm> (last visited Mar. 23, 2016).

[9] Presumably in response to Doe's allegations in her Complaint that her DBS sample had been "shared with unauthorized third parties," Bowman stated in his Affidavit that, in his review of records retained by the laboratory, "there have been only two instances in which a DBS sample has been released to a third party without signed authorization[.]" *Id.* at 33, 79-80. One was pursuant to a request from the Allen County Coroner as provided by Indiana Code section 16-49-3-5, regarding an investigation by the Child Fatality Review Team, and the other was a request by a doctor who needed the sample to conduct pre-natal genetic testing at the parents' request.

[10] The next day, on November 20, 2014, ISDH filed Defendants' Motion to Dismiss, pursuant to Indiana Trial Rule 12(B)(6), asserting that Doe's Complaint failed to state a claim upon which relief could be granted. ISDH argued that ISDH was not a "person" subject to suit under 42 U.S.C. § 1983 and should be dismissed, and that Doe did not allege any personal involvement by the Commissioner and Director, and they should be dismissed in their individual capacities. ISDH also argued that: (1) Doe lacked standing as she has suffered no injury in fact; (2) the declaratory action is improper given the availability of an administrative remedy, namely completion of a form

requesting destruction of her DBS sample; and (3) the injunctive relief request is moot given the changes in ISDH's policy regarding retention and storage of the DBS samples. ISDH also filed a motion for an extension of time to respond to Doe's motion for class certification, which the trial court granted.

[11] On February 25, 2015, the trial court held a consolidated hearing on both Doe's Motion for a Preliminary Injunction and on ISDH's Motion to Dismiss. At the hearing, counsel for each party presented argument, but presented no witnesses or new documentary evidence. However, Counsels' arguments addressed the materials that ISDH had attached to its Opposition to Doe's request for a preliminary injunction, including Bowman's Affidavit, the After Newborn Screening pamphlet, and the available ISDH forms that allow a parent to request destruction of his or her child's DBS sample. Counsel also discussed the contents of the ISDH website, to which Doe had cited in her Complaint.

[12] On March 25, the trial court issued Findings of Fact, Conclusions of Law, and Order denying Doe's Motion for a Preliminary Injunction ("Findings and Conclusion"). The trial court's Findings and Conclusions included, but were not limited to, the following determinations: the newborn screening laboratory released DBS samples to a third party without signed authorization on only two occasions (Allen County Coroner statutory request and a doctor request related to genetic testing), neither of which involved Doe; parents/guardians of children born between 1991 and June 2013 can at any time request destruction of their child's DBS sample by filling out a form; DBS samples for children born between 1991 and June 2013 have not been and will not be used for medical

research and those samples are stored for 23 years. Although Doe claimed that the storage of the DBS samples and possible release to law enforcement and other third parties created an irreparable harm, and that the trial court should enjoin ISDH from turning over DBS samples to law enforcement and other third parties, the trial court determined Doe had an available adequate remedy at law, namely requesting that the DBS sample be destroyed, and, therefore, was not entitled to a preliminary injunction.

[13] The trial court's Findings and Conclusions also addressed Doe's claim that the storage "of DBS samples for infants born between 1991 and May 31, 2013" violates the Fourth Amendment to the United States Constitution and Article 1, Section 11 of the Indiana Constitution. The trial court determined that the initial taking of the blood for newborn screening is lawful and that "the subsequent storing of those DBS samples, for a definite period of time, is not a "search" under the Fourth Amendment, and the storage "satisfies Article 1, Section 11 because it is reasonable under the totality of the circumstances." *Appellant's App.* at 26-28. Doe did not seek interlocutory appeal of the trial court's Findings and Conclusions, which denied her request for a preliminary injunction.

[14] After the trial court denied Doe's request for a preliminary injunction, Doe filed a motion on April 6, 2015, seeking an opportunity to conduct expedited discovery, specifically to conduct discovery with regard to the Child Fatality Review Team. ISDH opposed Doe's request and sought a stay of discovery.

On April 16, 2015, the trial court granted ISDH’s motion to stay discovery, pending its ruling on ISDH’s Motion to Dismiss.

[15] Thereafter, on April 27, 2015, the trial court issued an Order Granting the Defendants’ Motion to Dismiss (“Order”). The Order found: (1) Doe lacked standing because (a) she had not sustained and was not in imminent danger of sustaining some direct injury as a result of the act of storing her DBS sample, (b) she had not made any request for destruction of her DBS sample that had been denied by ISDH, and (c) any injury is “completely speculative”; (2) her claim for declaratory relief was improper because an administrative remedy was available, namely that Doe could request that ISDH destroy her DBS sample; and (3) her request for equitable relief was moot because in June 2013 ISDH modified its storage policy. *Id.* at 12-14. Doe now timely appeals the trial court’s Order.

Discussion and Decision

I. Preliminary Matters

[16] We begin by briefly clarifying what Doe is *not* claiming. Doe does not challenge the propriety of taking of her blood for testing. She does not assert that the newborn screening program statutes are unconstitutional. She does not raise any issue with regard to the records made pursuant to the testing, or the storage of those records. Rather, Doe challenges the continued storage of her DBS sample, after the time that the statutorily-mandated testing of the DBS samples is complete. She summarizes:

With neither consent nor authority, the State of Indiana has retained the blood samples of almost every single baby born within its boundaries between 1991 and June 1, 2013. In other words, the State has complete control over and unfettered access to over two million unique DNA samples. The dangerous ramifications of this are obvious and are the subject of [Doe's] lawsuit.

Appellant's Br. at 3.

A. Class Certification

[17] Doe's general position, explaining why and how the trial court erred, presupposes the existence of a plaintiff class of persons similarly situated to her. For instance, Doe argues, "The State's serious and ongoing violations of the Constitutional rights of over two million individuals born in Indiana (including Miss Doe) are unlawful and profoundly injurious," and although she could request destruction of her DBS sample, millions of others who do not know to request destruction of his/her DBS sample face continuing irreparable harm and violation of his/her constitutional rights. *Appellant's Br.* at 5, 15.

Defendants argue, however, "[N]o class has been certified and only Doe's claims are at issue." *Appellees' Br.* at 7-8, 10. Accordingly, we find that a brief discussion of the status and effect of Doe's request for class certification is warranted.

[18] In September 2014, Doe filed her Complaint as a class action, and in October 2014, she filed a Motion for Class Certification. The trial court granted ISDH's request for an enlargement of time to respond to Doe's motion for class

certification “until and including twenty days after [ISDH] receive[s] notice that the Motion to Dismiss has been [d]enied.” *Appellant’s App.* at 3, 9. As ISDH’s Motion to Dismiss was granted, it appears that ISDH never filed a response to Doe’s motion for class certification, the trial court did not rule on Doe’s motion, and it remains pending.

[19] On appeal, Doe challenges the storage of her own blood sample, as well as that of millions of others whose blood was taken and stored. To the extent that she suggests that her action proceed as a class, prior to certification, we find this is not consistent with Indiana law. The general approach in Indiana is that “[b]efore certification, a purported class action is essentially an individual action in which the plaintiff wishes to assert claims as a class representative.” *Arthur and Withered*, 11 Ind. Prac., Civil Trial Practice §18.4 (2015). “Without certification of action as a class action and identification of class, action is not properly a class action.” *Id.* at n.1 (citing *Baxter v. Palmigiano*, 425 U.S. 308 (1976)). This court has recognized that principle, stating, “[I]n the case before us[,] the ‘Class’ has not been certified. The complaints are merely ‘proposed’ class actions.” *Alexander v. PSB Lending Corp.*, 800 N.E.2d 984, 991-92 (Ind. Ct. App. 2003) (rejecting plaintiffs’ argument that standing may be determined on classwide basis), *trans. denied*. We thus agree with ISDH that, as no class has been certified, only Doe’s claims are at issue.⁵

⁵ We note that the record before us reflects that the trial court likewise rejected Doe’s suggestion that her case should proceed as a class action although no class yet had been certified. *Tr.* at 27-29.

B. Procedural Posture and Standard of Review

[20] Doe appeals the trial court's decision granting ISDH's Indiana Trial Rule 12(B)(6) Motion to Dismiss, which sought dismissal of Doe's complaint on the following grounds: (1) Doe lacks standing because she has not sustained and is not in immediate danger of sustaining a direct injury and Doe's fear of possible expropriation of her DBS sample is speculative; (2) a declaratory action is not proper because she has an available administrative remedy (asking ISDH to destroy her DBS sample); and (3) her request for injunctive relief is moot because ISDH changed its retention policies, now asking parents for consent to store the sample for three years for possible medical research and providing a form for the destruction of a DBS sample taken before June 2013. Following a consolidated hearing, the trial court granted ISDH's motion. *Appellant's App.* at 7-14. Doe asserts on appeal that ISDH failed to meet the stringent burden to show that Doe's complaint fails to state a claim upon which relief can be granted; therefore, the trial court's dismissal was in error. We review a grant of a motion to dismiss as follows:

The standard of review on appeal of a trial court's grant of a motion to dismiss for the failure to state a claim is *de novo* and requires no deference to the trial court's decision. The grant or denial of a motion to dismiss turns only on the legal sufficiency of the claim and does not require determinations of fact. A motion to dismiss under Rule 12(B)(6) tests the legal sufficiency of a complaint: that is, whether the allegations in the complaint establish any set of circumstances under which a plaintiff would be entitled to relief. Thus, while we do not test the sufficiency of the facts alleged with regards to their adequacy to provide recovery, we do test their sufficiency with regards to whether or

not they have stated some factual scenario in which a legally actionable injury has occurred.

Bellows v. Bd. of Comm'rs of Cnty. of Elkhart, 926 N.E.2d 96, 110 (Ind. Ct. App. 2010) (internal citations and quotation omitted); *Schulz v. State*, 731 N.E.2d 1041, 1044 (Ind. Ct. App. 2000) (“A complaint cannot be dismissed under 12(B)(6) unless it appears to a certainty that the plaintiff would not be entitled to relief under any set of facts.”), *trans. denied*.

[21] In their Appellees’ Brief, ISDH observes that the trial court’s Order referred to and relied on the contents of Bowman’s Affidavit, the attached ISDH forms, and the ISDH website. Thus, ISDH suggests, the trial court effectively treated its Motion to Dismiss as one for summary judgment. *See Appellees’ Br.* at 9-10, 17. Although our review of a Rule 12(B)(6) motion to dismiss and a motion for summary judgment is the same, *i.e.*, *de novo*, the legal standard necessary to succeed on each of those two motions is different, and we deem it appropriate to address whether we are reviewing a decision on a motion to dismiss or one granting summary judgment.

[22] We turn to Indiana Trial Rule 12(B), which provides, in pertinent part:

If, on a motion, asserting the defense number (6), to dismiss for failure of the pleading to state a claim upon which relief can be granted, matters outside the pleading are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56. In such case, all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56.

A trial court's failure to give explicit notice of its intended conversion of a motion to dismiss to one for summary judgment is reversible error only if a reasonable opportunity to respond is not afforded a party and the party is thereby prejudiced. *Azhar v. Town of Fishers*, 744 N.E.2d 947, 950 (Ind. Ct. App. 2001).

[23] After ISDH raised the matter in its Appellees' Brief, Doe responded in her Reply Brief and maintained that the trial court's decision was, in fact, a ruling on a motion to dismiss, noting the decision was entitled, "Order Granting the Defendants' Motion to Dismiss" and that the Order specifically cited the standard of review for a motion to dismiss. *Appellant's App.* at 7. Doe also argues that ISDH did not attach any materials to its Motion to Dismiss and thus did not actually *present* "matters outside the pleading" to the trial court as is contemplated by Rule 12(B). However, we are not persuaded by these arguments, as our court has recognized that what the trial court titles the order and whether the defendant actually submitted the outside materials with its motion to dismiss is not necessarily determinative. *See Milestone Contractors, L.P. v. Ind. Bell Tel. Co.*, 739 N.E.2d 174, 176-77 (Ind. Ct. App. 2000) (finding that trial court's order reflected that it considered matters outside pleadings that had been included in other briefs and discussed at hearing, and trial court thereby effectively treated defendant's Rule 12(C) motion for judgment on the pleadings as motion for summary judgment), *trans. dismissed*.

[24] Here, a review of the trial court's Order reveals that the trial court relied on content from Bowman's Affidavit and the exhibits attached thereto. For

instance, in finding that Doe “failed to demonstrate immediate danger of sustaining some direct injury” as the result of the storage of her DBS sample, the trial court’s Order recognized: the screening cards are perforated; the section with the DBS sample includes only an identification number; and “Defendants do not know the identity of Doe.” *Appellant’s App.* at 10, 12. That information was derived from Bowman’s Affidavit. *Id.* at 79. The trial court also recognized that “Doe’s complaint does not allege that . . . a request was made to destroy her/his sample and that the ISDH refused.” *Id.* at 12. The information concerning the availability of a form by which an individual may request destruction of his or her DBS sample was derived from the ISDH website, as well as the ISDH form itself, which was an exhibit to Bowman’s Affidavit. The trial court also referred to content from the ISDH website that “no samples collected before June 2013 were released for medical research purpose[.]” *Id.* at 12. Given this, we find that matters outside the pleadings were considered and not excluded by the trial court. Accordingly, we find that the trial court treated ISDH’s Motion to Dismiss as one for summary judgment.

[25] Although maintaining that the trial court’s ruling was one on a motion to dismiss, Doe alternatively argues that, if it was a ruling on a motion for summary judgment: “[T]he trial court precluded [Doe] from taking discovery and thus denied her any opportunity to present pertinent material,” and therefore, “[she] was prejudiced[.]” *Appellant’s Reply Br.* at 2-4. Finding as we do that the trial court’s Order was a grant of a motion for summary judgment, we thus next consider whether Doe was prejudiced. There are at least several

considerations pertinent to a determination of whether a trial court's failure to give express notice deprives the non-movant of a reasonable opportunity to respond with Trial Rule 56 materials:

First, we consider whether the movant's reliance on evidence outside the pleadings should have been so readily apparent that there is no question that the conversion is mandated by T.R. 12(B). Second, we consider whether there was ample time after the filing of the motion for the non-movant to move to exclude the evidence relied upon by the movant in support of its motion or to submit T.R. 56 materials in response thereto. Third, we consider whether the non-movant presented "substantiated argument" setting forth how she "would have submitted specific controverted material factual issues to the trial court if [she] had been given the opportunity."

Azhar, 744 N.E.2d at 950-51 (internal citations omitted). In *Azhar*, the plaintiff contended that the trial court committed reversible error because she was surprised by the trial court's action in converting a Rule 12(B)(6) motion into a motion for summary judgment and that she was not given the opportunity to put forth evidence to show the existence of a genuine issue of material fact. *Id.* The *Azhar* court rejected her claim and found that, in that case, the movant's reliance on evidence outside the pleadings – which were documents attached to its motion to dismiss – was readily apparent and "unmistakable." *Id.* The *Azhar* court observed, "[G]iven the mandatory wording of T.R. 12(B), *Azhar* should have known that the trial court was compelled to convert the motion to a summary judgment motion." *Id.* The court also found that the three-month period between the motion to dismiss and the hearing thereon provided "ample

time” within which Azhar could have moved to exclude the evidence or submit Indiana Trial Rule 56 materials in response. *Id.*

[26] Here, ISDH filed its Motion to Dismiss on November 20, 2014; ISDH did not attach to the Motion any exhibits or documents, but referred to and incorporated some content from the ISDH website.⁶ The prior day, ISDH had filed its Opposition to Doe’s Motion for a Preliminary Injunction and attached to that Opposition: Bowman’s Affidavit as well as other ISDH documents, including ISDH’s retention policy, the After Newborn Screening pamphlet, and ISDH forms to request storage or destruction of one’s DBS sample. Doe did not seek to strike or in any other way oppose ISDH’s submitted evidence. For her part, Doe submitted a copy of a 2009 decision rendered by a federal Texas district court, but did not file any other evidence in support of her Motion for Preliminary Injunction or in opposition to ISDH’s Motion to Dismiss. Approximately three months later, in February 2015, the trial court held a combined hearing on Doe’s Motion for Preliminary Injunction and on ISDH’s Motion to Dismiss. The content of ISDH’s attachments and documents were discussed by counsel for both parties at the hearing, as well as Doe’s cited Texas district court case.

[27] Applying the three *Azhar* considerations to the present case, we conclude that ISDH’s reliance on the outside materials was “readily apparent.” 744 N.E.2d

⁶ Doe’s Complaint cites to the ISDH website and includes some of the website’s content in her complaint. *Appellant’s App.* at 32.

at 950. Furthermore, ISDH filed its materials, including Bowman’s Affidavit and the After Newborn Screening pamphlet in November, several months before the hearing. Doe did not conduct any discovery or submit materials of her own in response, or otherwise seek to oppose or strike ISDH’s evidence. The combined hearing was held in February 2015. We find there was “ample time” after the filing of ISDH’s motion and materials for Doe to move to exclude the evidence relied upon by the movant in support of its motion or to submit Trial Rule 56 materials in response thereto. *Id.* at 951. Lastly, our review of the record before us does not reveal that Doe presented “substantiated argument” setting forth how she “would have submitted specific controverted material factual issues to the trial court if [she] had been given the opportunity.” *Id.* While she contends that she sought and was denied the chance to conduct discovery, the record indicates that her request for expedited discovery came in April 2015, which was *after* the trial court had denied her motion for preliminary injunction, and further, it was limited in scope to seeking depositions and materials from and about the Child Fatality Review Team, which involved a matter not related to Doe. Based on the record before us, we find that Doe was not prejudiced by the fact that the trial court treated ISDH’s motion to dismiss as one for summary judgment.

[28] When reviewing a grant of summary judgment, our standard of review is the same as that of the trial court:

Considering only those facts that the parties designated to the trial court, we must determine whether there is a “genuine issue

as to any material fact” and whether “the moving party is entitled to judgment as a matter of law.” In answering these questions, the reviewing court construes all factual inferences in the non-moving party’s favor and resolves all doubts as to the existence of a material issue against the moving party. The moving party bears the burden of making a prima facie showing that there are no genuine issues of material fact and that the movant is entitled to judgment as a matter of law; and once the movant satisfies the burden, the burden then shifts to the non-moving party to designate and produce evidence of facts showing the existence of a genuine issue of material fact.

The party appealing from a summary judgment decision has the burden of persuading this court that the grant or denial of summary judgment was erroneous. Where the facts are undisputed and the issue presented is a pure question of law, we review the matter de novo.

Bellows, 926 N.E.2d at 113-14 (internal citations omitted); *see also Reel v. Clarian Health Partners, Inc.*, 873 N.E.2d 75, 78 (Ind. Ct. App. 2007), *trans. denied*. A trial court’s ruling on a motion for summary judgment reaches this court clothed with a presumption of correctness. *Hibler v. Conseco, Inc.*, 744 N.E.2d 1012, 1018 (Ind. Ct. App. 2001). When reviewing the trial court’s ruling we will affirm on any theory supported by the material properly designated to the trial court. *Id.*

II. Standing

[29] Turning to the merits of the case, we address Doe’s claims that the trial court erred when it determined that she lacked standing. “Standing is a fundamental, threshold, constitutional issue that must be addressed by this, or any, court to

determine if it should exercise jurisdiction in the particular case before it.”

Alexander, 800 N.E.2d at 989.

The main purpose of standing is to [e]nsure that the party before the court has a substantive right to enforce the claim that is being made in the litigation. The standing requirement restricts the courts to real controversies in which the complaining party has a demonstrable injury. To possess standing, a plaintiff must demonstrate a personal stake in the outcome of the lawsuit and must show that he *has sustained or was in immediate danger of sustaining some direct injury* as a result of the conduct at issue.

Schulz, 731 N.E.2d at 1044 (internal citations omitted) (emphasis added). If properly challenged, when a plaintiff fails to establish standing in the pleadings, the court must dismiss the complaint. *Alexander*, 800 N.E.2d at 989. The question of whether a party has standing is purely one of law and does not require deference to the trial court’s determination. *Wood v. Walden*, 899 N.E.2d 728, 731 (Ind. Ct. App. 2009).

[30] The trial court’s Order determined, as is relevant here, that Doe lacked standing because (a) she had not sustained and was not in imminent danger of sustaining some direct injury as a result of the act of storing her DBS sample, (b) she had not made any request for destruction of her DBS sample that had been denied by ISDH, and (c) any injury is “completely speculative.” *Appellant’s App.* at 11-13. Doe argues that the trial court’s determination in that regard was in error and that she has standing because “ongoing governmental violations of the Fourth, Fifth, and Fourteenth Amendments to the Constitution constitute an

immediate danger of sustaining some direct injury[.]” *Appellant’s Br.* at 7.⁷ Doe’s premise is that she has a reasonable privacy interest in her DBS sample, which contains her DNA, and the ISDH’s continued storage beyond the time necessary to conduct the screening tests violates the Fourth Amendment’s protections against unreasonable searches and seizure.⁸ She explains that “the essential question . . . is whether the person asserting a violation has a reasonable expectation of privacy in the material examined.” *Id.* at 10. She urges that, as soon as the screening tests on a DBS sample are completed, “The State’s legal right to possess that blood ended, and its continued control over the blood constituted trespass.” *Id.* at 9.

[31] Indiana’s body of case law concerning an individual’s privacy interests in biological samples exists primarily, if not entirely, in the context of criminal law, which we recognize presented different issues, but we nevertheless find the discussion of the constitutional privacy interests at stake relevant to the matter at hand. For instance, Indiana courts have recognized that the taking of a biological sample, such as a DNA sample, constitutes a “search” for purposes

⁷ Doe argues, “[T]he State’s serious and ongoing violations of the Constitutional rights of over two million individuals born in Indiana (including Miss Doe) are unlawful and profoundly injurious.” *Appellant’s Br.* at 5. However, as we have determined, only Doe’s rights are at issue here.

⁸ We note that Doe’s arguments on the issue of standing, presented both in her written briefs as well as at oral argument, focus on Fourth Amendment search and seizure analysis. *See Appellant’s Br.* at 7-12. Although the language of Article 1, Section 11 is nearly identical to its federal counterpart, “Section 11 is interpreted independently and separately” from the Fourth Amendment. *State v. Washington*, 898 N.E.2d 1200, 1205-06 (Ind. 2008). Doe, having failed to present a separate analysis under the Indiana Constitution, has waived her claim that ISDH’s storage of her DBS sample constitutes a violation under Article 1 Section 11 of the Indiana Constitution. We likewise find that, having failed to present argument under the Fifth and Fourteenth Amendments to the United States Constitution, Doe has abandoned or waived those claims as well.

of the Fourth Amendment. *Balding v. State*, 812 N.E.2d 169, 172 (Ind. Ct. App. 2004) (citing *Patterson*, 742 N.E.2d at 9). The Fourth Amendment prohibits searches and seizures that are unreasonable. *Id.* As such, the Fourth Amendment “does not protect all subjective expectations of privacy, but only those that that society deems as ‘reasonable.’” *Id.* at 173. Our Supreme Court in *Smith v. State*, 744 N.E.2d 437, 439 (Ind. 2001), had occasion to examine the issue of a criminal defendant’s Fourth Amendment privacy interest in his hair, blood, and saliva samples. Smith was arrested and charged with rape, and he was ordered to provide hair, blood, and saliva samples, which were used to create a DNA profile. Smith’s DNA profile was compared to those from unsolved cases, and it matched DNA from a prior unsolved rape. Smith moved to suppress the DNA evidence on the grounds that it violated the Fourth Amendment and Article 1, Section 11. His claim essentially was that “the information must be destroyed after the investigation that analyzed it is concluded, or at least cannot be used in a subsequent investigation.” *Id.* The *Smith* Court rejected that contention, holding that a defendant has “a legitimate expectation of privacy in his body and blood samples at the time they [are] taken[,]” but once the DNA is used to create a profile, the profile becomes the property of the Crime Lab, and the defendant “has no possessory or ownership interest in it.” *Id.*; see also *Patterson v. State*, 742 N.E.2d 4, 11 (Ind. Ct. App. 2000) (once blood sample is lawfully obtained, defendant did not have reasonable expectation of privacy in his blood sample and reuse of his DNA sample in subsequent unrelated criminal investigation did not trigger Fourth Amendment protections), *clarified on reh’g*, 744 N.E.2d 945, 947 (Ind. Ct. App.

2001) (“[S]ociety is not prepared to recognize as reasonable an individual’s expectation of privacy in a blood sample lawfully obtained by police.”), *trans. denied, cert. denied*, 534 U.S. 961 (2001).⁹

[32] Applying such reasoning to the present case, it is debatable whether Doe has a constitutionally-protected privacy interest in the continued storage of her lawfully-obtained DBS sample. However, assuming without deciding that she does possess such an interest, Doe still has to show that she has suffered, or is in immediate danger of suffering, some direct injury in order to have standing. We find that she has not done so.

[33] In seeking dismissal of Doe’s complaint, ISDH presented evidence that (1) the stored DBS samples, including Doe’s, have not been released without authorization for medical research and will not be released (per the ISDH website and the After Newborn Screening pamphlet); and (2) there have been only two instances when a DBS sample was released to other third parties without authorization (per Bowman’s Affidavit), and neither instance involved Doe. Bowman’s Affidavit also stated that the portion of the screening cards that are stored only have an identification number on them; consequently, ISDH argues, the stored samples are not a “treasure trove of potential DNA evidence,” as Doe suggests. *Appellees’ Br.* at 14. ISDH also presented evidence

⁹ We note that, in its Findings and Conclusions that denied Doe’s request for a preliminary injunction, the trial court relied, in part, on *Patterson v. State* when it determined that the storage of Doe’s DBS sample did not constitute a “search” under the Fourth Amendment. *Appellant’s App.* at 25-26.

that Doe could at any time request that her sample be destroyed via the available ISDH form (attached to Bowman’s Affidavit).

[34] With regard to what direct injury she has suffered as a result of the storage of her DBS sample, Doe asserts that she has a reasonable fear “that the blood samples, including hers, might be misused.”¹⁰ *Appellant’s Br.* at 8. In support of the proposition that “a reasonable fear arising out of and related to [] unlawful conduct,” is “enough for injury in fact,” Doe cites, in part, to *Friends of the Earth, Inc. v. Laidlaw Environmental Services, Inc.*, 528 U.S. 167, 184-85 (2000). There, a company discharged pollutants into a waterway in excess of EPA limits. A number of individuals, who were members of the Friends of the Earth environmental organization, submitted affidavits and deposition evidence stating in what specific way the pollutants affected his or her specific recreational, aesthetic, and economic interests. The Supreme Court determined that the Friends of the Earth had standing to bring a Clean Water Act claim against the company because the affiant members had a reasonable fear arising out of and related to unlawful conduct that caused them “to curtail their recreational use of that waterway and . . . subject[ed] them to other economic and aesthetic harms,” and “that is enough for injury in fact.” 528 U.S. at 184-85. Doe maintains that, similarly, her “illegally-retained blood sample is an

¹⁰ By way of example, Does notes having “pervasive and reasonable fear” that the DBS samples, including hers, would be used by the State to “sidestep” warrant or informed consent requirements. *Appellant’s Br.* at 16.

injury-in-fact sufficient to confer standing under *Friends of the Earth*.” *Appellant’s Br.* at 12.

[35] We find, however, that the type of injury sustained by the individuals in *Friends of the Earth* is distinguishable. There, the Supreme Court’s determination that Friends of the Earth had standing was based on affidavits and deposition testimony that identified the affiant members’ reasonable concerns about the effects of the pollutants and how that directly affected their recreational, aesthetic, and economic interests – such as a member saying that he would no longer fish, camp, swim, and picnic near the river, another’s statement that she had planned to purchase a home near the river but did not do so because of defendant’s discharges into the river, and another’s attesting that her home located near defendant’s facility had a lower value than similar homes located farther from the facility. 528 U.S. at 183-85. ISDH contends that Doe’s claimed harm about her stored DBS sample is lacking this same type of direct effect on specific interests as was present in *Friends of the Earth*. We agree.

[36] The record before us reveals that ISDH presented evidence to the trial court to show that Doe’s blood – which was taken pre-June 2013, when ISDH’s policy on retention of DBS samples was changed – was not used for medical research, nor will it be without parental authorization. Indeed, the ISDH website, which Doe cited to in her Complaint, states that DBS samples of babies born before June 1, 2013, which includes Doe’s, have “not been made available for medical research.” See <http://www.in.gov/isdh/20215.htm> (last visited Mar. 23, 2016). ISDH also presented evidence, namely Bowman’s Affidavit, that there were

only two instances in which DBS samples had been released without authorization, and neither involved Doe’s DBS sample (Allen County Child Fatality Review Team¹¹ and a doctor request for parent-sought genetic testing). ISDH also presented evidence to demonstrate that Doe’s parents could at any time request that her DBS sample be destroyed. Under the facts of this case, Doe’s fear of potential misuse is, as the trial court found, “speculative,” and does not constitute the type of direct injury necessary to support a finding of standing. ISDH presented evidence to establish that, as a matter of law, Doe lacked standing, and Doe did not present evidence to create any genuine issue of material fact to preclude judgment in favor of ISDH.

[37] Affirmed.¹²

Crone, J., and Brown, J., concur.

¹¹ Doe argues that the release of information to the Allen County Coroner is an example of an unauthorized release of information “to law enforcement” – just as she alleged in her complaint – which puts millions of Hoosiers at risk. ISDH maintains that (1) the release to the Allen County Coroner was statutorily mandated under Indiana Code chapter 16-49-3, and (2) the purpose of the Child Fatality Review Team is to identify factors surrounding a child’s death and whether similar deaths could be prevented; it is not a criminal investigation. ISDH noted that Review Team determinations are privileged and not subject to subpoena or discovery or admissible in evidence in any judicial proceedings. Ind. Code § 16-49-3-13. We do not resolve whether the release to the Allen County Coroner was or was not an unauthorized release to law enforcement. That release had nothing to do with Doe, and the question before us is whether Doe suffered or was in immediate danger of suffering direct injury as a result of ISDH’s storage of her DBS sample.

¹² Because we resolve this case on the basis that Doe lacked standing, we do not reach the trial court’s determinations with regard to the availability of an administrative remedy or the application of the mootness doctrine.