

Code required physicians and others attending a newborn child to “subject the child to screening tests approved by the department for phenylketonuria, other heritable diseases, hypothyroidism, and other disorders for which screening is required by the department.” TEX. HEALTH & SAFETY CODE § 33.011. Until May 2009, Chapter 33 did not specify what would happen to the blood specimens obtained as part of the screening program after screening was completed. Apparently, the blood specimens were being kept and stored after the screening.

Parents concerned about this storage filed the *Beleno* lawsuit in March 2009. The Amended Complaint in *Beleno* complained that the Department collected the blood specimens and stored them indefinitely for the purpose of undisclosed research, and that the Department had not disclosed any transactions related to the specimens. During the pendency of the *Beleno* lawsuit, the Texas Legislature amended Chapter 33, effective May 27, 2009. *See* Act of May 27, 2009, 81st Leg., R.S., ch. 179. The amendments included the addition of sections 33.0111 (“Disclosure”), 33.0112 (“Statement Prohibiting Retention of Genetic Material”), and 33.017 (“Confidentiality”).

Section 33.0111 requires that the Department “develop a disclosure statement that discloses to the parent or guardian of a newborn child subjected to screening under § 33.011 that the department or a laboratory established or approved by the department under Section 33.016 may retain for use by the department or laboratory genetic material used to conduct the newborn screening tests and discloses how the material is managed and used; and (2) that the parent, managing conservator, or guardian may limit the use of the genetic material by providing to the department in accordance with Section 33.0112 a written statement prohibiting the department or laboratory from retaining the genetic material or using the genetic material for any purpose other than the conduct of newborn screening tests authorized under this chapter.” TEX. HEALTH & SAFETY

CODE § 33.0111(a). This disclosure must be presented to a parent or guardian at the time the newborn is subjected to the screening tests. *Id.* § 33.0111(c).

Section 33.0112 also provides that a parent or guardian “of a newborn child may file with the department a signed written statement prohibiting the department or a laboratory established or approved by the department from retaining any genetic material related to the newborn screening tests conducted under this chapter or using the genetic material for any purpose other than the conduct of the newborn screening tests.” *Id.* § 33.0112(a). Within 60 days of receiving such a statement, “the department or laboratory shall destroy the genetic material used in the screening tests.” *Id.* § 33.0112(b). Further, an adult individual may file a written statement instructing the department or a laboratory to destroy any genetic material of the individual that is retained and used under the chapter. *Id.* § 33.0112(c).

Section 33.017, entitled “Confidentiality,” makes confidential all reports, records, and information obtained or developed by the Department under Chapter 33, allowing their disclosure only (1) for purposes of diagnosis or follow-up authorized under Section 33.014, with the consent of each identified individual or someone authorized to consent on behalf of an identified individual; (2) as authorized by court order; (3) to a medical examiner authorized to conduct an autopsy on a child or an inquest on the death of a child; or (4) to public health programs of the department for public health research purposes provided that the disclosure is approved by an institutional review board or privacy board of the department as authorized by the federal privacy requirements adopted under HIPAA. *Id.* § 33.017(a),(b). However, “reports, records, and information that do not identify a child or the family of a child may be released without consent” if the disclosure is for: (1) statistical purposes; (2) purposes related to obtaining or maintaining certification, approval, or

quality assurance for the department's laboratory or a public or private laboratory to perform newborn screening tests; (3) purposes relating to review, quality assurance, or improvement of the department's newborn screening or newborn screening program services; (4) research purposes, provided that the disclosure is approved by an institutional review board or privacy board of the department; or (5) quality assurance.

The parties settled the *Beleno* case in November 2009. Pursuant to the settlement agreement, the Department agreed to destroy all blood specimens that were taken as part of the newborn screening program and received by the Department before May 27, 2009 in its or Texas A&M Health Science Center's possession (Texas A&M facilities were used to store the specimens) for which it did not have written consent for continued retention and use. The Department further agreed to post on the newborn screening program website a list of all research projects for which the defendants had provided blood specimens, and also agreed to post a comprehensive list of categories of quality assurance and quality control uses for which defendants provided the blood specimens. Last, the Department agreed to inform the named plaintiffs in writing of the uses to which their children's blood specimens had been put, as well as any financial transactions regarding those specimens.

Plaintiffs Higgins and McCall filed this lawsuit in December 2010, asserting violations of their rights based on the distribution of the newborn screening blood samples to private research companies, government agencies, and other third parties without knowledge or consent. Citing the information posted on the Department's website pursuant to the *Beleno* settlement, Plaintiffs note that "Defendants have distributed, sold, bartered, and traded at least 8,800 blood samples" and "[t]here is no compelling state justification for such secretive, deceptive, and non-consensual

activity.” Plaintiffs complain “that Defendants deceptively and unlawfully sold, traded, bartered, and distributed blood samples collected from their children . . . for fees, various lab equipment, and various other purposes” and that the blood samples “were made available to private companies for undisclosed purposes and to the Armed Forces Institute of Pathology, without Plaintiffs’ knowledge or consent.” Plaintiffs complain that “Defendants knowingly and deceptively withheld this information during settlement negotiations in *Beleno*.” Plaintiffs allege that Defendants were asked during the settlement negotiation process whether they ever distributed or sold blood samples to third parties, and Defendants consistently denied that they had.

Plaintiffs “object to Defendants expropriating an infant’s blood sample and any data obtained from it through research or other means, without their knowledge or consent, effectively making it Defendants’ property for undisclosed non-consensual purposes, unrelated to the purposes for which the infants’ blood was originally drawn, and deriving profit therefrom.” Plaintiffs assert that “[g]iven the sensitive and highly personal information contained in the blood samples, such as DNA, and the fact that such data has been indiscriminately disclosed to private companies and federal agencies, Plaintiffs are deeply and rightfully concerned about the potential misuse of that information.” “Plaintiffs fear the possibility of discrimination against their children and perhaps even relatives through the use of such blood samples and research activity thereon.”

Thus, Plaintiffs’ complaint is based on the possibility that their children’s blood samples, which were taken in 2007 and 2008, have been distributed to third parties without their knowledge or consent, and their fear that the blood and the information contained therein, such as DNA, may be misused. On behalf of themselves and a proposed class of similarly situated parents, Plaintiffs sue under 28 U.S.C. § 1983 for violations of the Fourth and Fourteenth Amendments, seeking

declaratory and injunctive relief.

With regard to themselves, Plaintiffs seek a declaration that Defendants violated their rights under the Fourth and Fourteenth Amendments, and seek an injunction: (1) commanding Defendants to account for and destroy all blood samples and spots of Plaintiffs' children, whether or not in Defendants' possession, that Defendants have distributed, sold, bartered, or traded without informed parental consent and guarantee that they have done so; and (2) commanding Defendants to advise Plaintiffs for what purposes Defendants used the blood samples and spots of Plaintiffs' children and disclose all financial transactions involved with the use of such samples and blood.

With regard to the proposed class, Plaintiffs ask the Court to certify a class action on behalf of all similarly situated parents whose infants' blood samples or spots were or will be sold, traded, or distributed by Defendants for purposes unrelated to the newborn screening without the knowledge or consent of the parents, and then: (1) enter the same declaratory relief as for the named Plaintiffs and determine the extent to which HB-1672, as codified in Chapter 33 of the Texas Health and Safety Code and implemented by the Defendants, satisfies the requirements of the Fourth and Fourteenth Amendments; (2) issue an injunction commanding Defendants to account for and destroy all blood samples and spots sold, traded, bartered, or distributed without informed parental consent and guarantee that they have done so; (3) issue an injunction commanding Defendants to advise each class member for what purposes Defendants used the blood samples and spots of the class members and disclose all financial transactions involved with the use of such samples and blood; and (4) issue an injunction commanding Defendants, their agents, successors in office, and all those acting in concert with them to cease and desist immediately from the actions complained of herein.

II. Standard of Review

Defendants move to dismiss for lack of jurisdiction pursuant to Rule 12(b)(1) based on Eleventh Amendment immunity, standing, and mootness. In the alternative, Defendants move to dismiss under Rule 12(b)(6) for failure to state a claim. “When a Rule 12(b)(1) motion is filed in conjunction with other Rule 12 motions, the court should consider the Rule 12(b)(1) jurisdictional attack before addressing any attack on the merits.” *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001). This requirement prevents a court without jurisdiction from prematurely dismissing a case with prejudice. *Id.*

The Court must dismiss a cause for lack of subject matter jurisdiction “when the court lacks the statutory or constitutional power to adjudicate the case.” *See Home Builders Assn of Mississippi, Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998). A motion to dismiss for lack of Article III standing is properly considered under Rule 12(b)(1). *Harold H. Huggins Realty, inc. v. FNC, Inc.*, 634 F.3d 787, 795 n.2 (5th Cir. 2011). A motion to dismiss for lack of jurisdiction under 12(b)(1) may be decided on: (1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts, plus the Court’s resolution of disputed facts. *Freeman v. United States*, 556 F.3d 326, 334 (5th Cir. 2009). Unlike a 12(b)(6) motion, the district court is empowered to consider matters outside the Complaint and matters of fact that may be in dispute. *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001).

III. Analysis

A. Rule 12(b)(1) Motion to Dismiss based on Eleventh Amendment Immunity

1. the § 1983 claims against the Department directly are barred by the Eleventh Amendment

The Department contends that Plaintiffs' claims made directly against it are barred by the Eleventh Amendment. The Department, as an arm of the State of Texas, retains its immunity from suit by individuals under § 1983. Plaintiffs apparently concede that the claims against the Department directly should be dismissed, stating that the Department "was named initially to provide notice to the agency of its official as a Defendant." Thus, the motion to dismiss the claims against the Department based on Eleventh Amendment immunity is granted.

2. claims against Lakey in his official capacity

Plaintiffs contend that they may assert their claims for prospective equitable relief against Lakey in his Official Capacity pursuant to *Ex parte Young*, 209 U.S. 123 (1908). *Ex parte Young* established a limit on the sovereign immunity principle. Therein, the Supreme Court explained that because an unconstitutional legislative enactment is "void," a state official who enforces that law "comes into conflict with the superior authority of [the] Constitution," and therefore is "stripped of his official or representative character and is subjected in his person to the consequences of his individual conduct. The State has no power to impart to him any immunity from responsibility to the supreme authority of the United States." *Virginia Office for Protection & Advocacy v. Stewart*, 131 S. Ct. 1632, 1638 (2011). *Ex parte Young* "rests on the premise . . . that when a federal court commands a state official to do nothing more than refrain from violating federal law, he is not the State for sovereign-immunity purposes." *Id.*

"In determining whether the doctrine of *Ex parte Young* avoids an Eleventh Amendment bar to suit, a court need only conduct a 'straightforward inquiry into whether [the] complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective.'" *Id.* (quoting *Verizon Md. Inc. v. Public Serv. Comm'n of Md.*, 535 U.S. 635, 645 (2002)). The Fifth

Circuit has held that, in order to use the *Ex Parte Young* exception, the plaintiff must demonstrate that the state actor has “some connection” with a disputed act’s enforcement. *K.P. v. LeBlanc*, 627 F.3d 115, 124 (5th Cir. 2010) (citing *Ex Parte Young*, 209 U.S. at 157). “Enforcement” typically involves compulsion or constraint. *Id.* Plaintiffs make no allegation or argument concerning Lakey’s connection to the disputed actions. Their only allegation in the Amended Complaint concerning Lakey specifically is that he is the Commissioner of the Department. All allegations in the complaint state that “Defendants” committed the alleged various actions.

Though Defendants’ motion makes assertions regarding Lakey’s role (or lack thereof) with regard to the release of newborn screening blood specimens, they do not appear to be contesting Plaintiffs’ claim that they may pursue their claims against Lakey under *Ex parte Young*. In a footnote, Defendants complain that Plaintiffs “ignored Defendants’ assertion of DSHS’s Eleventh Amendment sovereign immunity and focused instead only on the *Ex parte Young* exception for official-capacity suits against *state officials* for prospective injunctive relief, for which Defendants made no Eleventh Amendment challenge.” Thus, for purposes of deciding this motion, the Court will presume that Plaintiffs’ claim are appropriately brought against Lakey under *Ex parte Young*.

B. Rule 12(b)(1) Motion to Dismiss based on Lack of Standing and Mootness

1. what may be considered in resolving the motion

The parties dispute the extent to which consideration of matters outside the pleadings is permitted in deciding this motion. Without differentiating between a 12(b)(1) and a 12(b)(6) motion, Plaintiffs assert that “[t]he law is well-settled that a court may not ‘go outside the complaint’ when considering a motion to dismiss by considering any evidence.” Response at 4. Plaintiffs further assert that Defendants’ statement of undisputed facts “quite regularly contradict[s] Plaintiffs’

Complaint,” and the Court must assume all facts and inferences in Plaintiffs’ favor when deciding a Rule 12(b)(6) motion. *Id.* Plaintiffs then state that “Defendants’ motion attempts to prove their case prematurely by introducing nineteen separate documents, consisting primarily of affidavits and other evidence from Defendants themselves, none of which are permissible at this stage of the proceedings.” *Id.* at 5. Plaintiffs assert that Defendants “argue about facts which are far from undisputed, and cite extensively to external evidence which was not introduced in Plaintiffs’ pleading and cannot be considered by the Court on a Rule 12 motion.” *Id.* Plaintiffs then contend that Defendants’ motion should be denied in its entirety “because it is so heavily reliant on inappropriate evidence that the Court could not properly rule on their arguments at the motion to dismiss stage.” *Id.* at 6.

As noted, Plaintiffs’ arguments conflate the applicable standards under Rule 12(b)(1) and 12(b)(6). When evaluating jurisdiction, “a [federal] court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.” *MDPhysicians & Assoc., Inc. v. State Bd. of Ins.*, 957 F.2d 178, 181 (5th Cir. 1992). Thus, it is well established that a motion to dismiss for lack of jurisdiction under 12(b)(1) may be decided on: (1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts, plus the Court’s resolution of disputed facts. *Freeman v. United States*, 556 F.3d 326, 334 (5th Cir. 2009).

When a motion to dismiss is based on the lack of jurisdiction on the face of the complaint, the plaintiff is left with safeguards similar to those retained when a Rule 12(b)(6) motion to dismiss for failure to state a claim is raised – the court will consider the allegations in the plaintiff’s complaint as true and determine whether they sufficiently state a basis for jurisdiction. *Williamson*

v. Tucker, 645 F.2d 404, 412 (5th Cir. 1981). However, when the court considers disputed facts “[i]n evaluating jurisdiction, the district court must resolve [such] disputed facts without giving a presumption of truthfulness to the plaintiff’s allegations.” *Vantage Trailers, Inc. v. Beall Corp.*, 567 F.3d 745, 748 (5th Cir. 2009) (citing *Williamson*, 645 F.2d at 413). In other words, where the defendant supports the 12(b)(1) motion with evidence, then the attack is factual and “no presumptive truthfulness attaches to plaintiff’s allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims.” *Williamson*, 645 F.2d at 413.¹ Under either standard, the party asserting jurisdiction maintains the burden of proving that jurisdiction does exist. *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001) (per curiam).

Defendants contend that this case can be decided on the complaint supplemented by undisputed facts in the record, and has submitted a statement of assertedly undisputed facts. Plaintiffs appear to argue that some of the facts therein are disputed because they “quite regularly contradict Plaintiffs’ Complaint.” Response at 4. Plaintiffs provide no statement of supposedly disputed facts, however, and provide no evidence in support of their alleged facts, despite being put on notice by Defendants’ reply that matters outside the pleadings are appropriately considered in deciding a 12(b)(1) motion.

¹ “The distinction between factual Rule 12(b)(1) motions and factual Rule 12(b)(6) motions is rooted in the unique nature of the jurisdictional question. It is elementary that a district court has broader power to decide its own right to hear the case than it has when the merits of the case are reached. Jurisdictional issues are for the court-not a jury-to decide, whether they hinge on legal or factual determinations. The unique power of district courts to make factual findings which are decisive of jurisdiction is, therefore, not disputed. This means that the district court is not limited to an inquiry into undisputed facts. It may hear conflicting written and oral evidence and decide for itself the factual issues which determine jurisdiction.” *Id.* (citations omitted).

However, there is an exception to the Court's power to resolve disputed facts when the jurisdictional fact issues overlap with the merits. Neither party addresses this issue. Part of Defendants' "undisputed" evidence is that Plaintiffs' children's blood specimens were never distributed and have been destroyed. It is not clear whether the issue of whether Defendants in fact distributed Plaintiffs' children's blood specimens, which is related to the mootness argument, is a merits issue that cannot be decided at the 12(b)(1) stage. The Court does consider that evidence with regard to Defendants' mootness arguments because Plaintiffs have not disputed it or asked for discovery to be able to dispute it. However, the Court concludes that it need not consider that evidence to decide the standing issue, and that Plaintiffs' lack of standing can be determined based on the face of the Complaint. Thus, mootness is an alternative holding to the Court's conclusion that Plaintiffs lack standing based on the face of the Complaint.

2. factual allegations in the complaint

Plaintiffs' Complaint contains the following facts and allegations: Texas has a mandatory newborn screening program in which hospitals, birthing centers, and midwives draw blood from the infant's heel so that the state can test for a variety of birth defects. Am. Compl. ¶ 11. Since 2003, if not before, Defendants have sold, traded, bartered, and distributed blood samples obtained through the newborn screening program to private research companies, government agencies, and other third parties, without the knowledge or consent of the infants' parents. Am. Compl. ¶ 8. Defendants provided blood samples to private companies such as PerkinElmer in exchange for a fee or various lab and testing equipment. *Id.* Defendants also secretly distributed the blood samples to the United States Armed Forces Institute of Pathology. *Id.* Defendants have not as of yet accounted for and destroyed all of the outstanding blood samples that they unlawfully distributed, sold, or traded. *Id.*

¶ 17.

Plaintiff Jeffrey Higgins is the father of an infant born on September 26, 2007. *Id.* ¶ 4. Andromida McCall is the mother of an infant born March 7, 2008. *Id.* ¶ 5. Plaintiffs do not object to the screening program so long as safeguards are in place to prevent the unlawful distribution of blood samples. *Id.* ¶ 12. They do object to the Defendants' expropriating an infant's blood sample and any data obtained from it through research or other means without their knowledge or consent, effectively making it Defendants' property for undisclosed, non-consensual purposes, unrelated to the purposes for which it was originally drawn, and deriving profit therefrom. *Id.* Plaintiffs allege that, given the sensitive and highly personal information contained in the blood samples, such as DNA, and the fact that such data has been indiscriminately disclosed to private companies and federal agencies, Plaintiffs "are deeply and rightfully concerned about the potential misuse of that information" and "fear the possibility of discrimination against their children and perhaps even relatives through the use of such blood samples and research activity thereon." *Id.* ¶ 13.

3. relief sought by the named Plaintiffs Higgins and McCall

Plaintiffs seek declaratory relief for the Plaintiff individuals that "Defendants intentionally, and with complete and deliberate indifference to the rights of Plaintiffs' children, unlawfully deprived them of their right to be free from unlawful search and seizure, as guaranteed by the Fourth Amendment" and that "Defendants intentionally, and with complete and deliberate indifference to the rights of Plaintiffs' children, unlawfully deprived them of their liberty and privacy interests, as guaranteed by the Fourteenth Amendment."

Plaintiffs seek injunctions commanding Defendants (1) to forthwith account for and destroy all blood samples and spots of Plaintiffs' children, whether or not in Defendants' possession, which

Defendants have distributed, sold, bartered, or traded without informed parental consent and guarantee to the Court within ten days of the order that they have done so; and (2) to advise Plaintiffs for what purposes Defendants used the blood samples and spots of Plaintiffs' children and disclose all financial transactions involved with the use of such samples and blood, within ten days of the order.

4. standing analysis

“[T]he irreducible constitutional minimum of standing contains three elements.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). These elements are (1) an injury in fact that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) a causal connection between the injury and the conduct complained of – the injury has to be fairly traceable to the challenged action of the defendant and not the result of independent action of some third party not before the court; and (3) the likelihood that a favorable decision will redress the injury. *Id.*; *Croft v. Governor of Texas*, 562 F.3d 735, 745 (5th Cir. 2009). Particularized means “that the injury must affect the plaintiff in a personal and individual way.” *Lujan*, 504 U.S. at 560 n.1. “The party invoking federal jurisdiction bears the burden of establishing these elements.” *Lujan*, 504 U.S. at 561.

Defendants argue that Plaintiffs lack standing because Plaintiffs have suffered no injury in fact and Plaintiffs' injuries are not redressable by the injunctive relief they seek. Defendants argue that Plaintiffs' claim of injury is only conjectural and hypothetical because the only arguable assertion of future injury in their complaint is that they are “deeply and rightfully concerned about the potential misuse” of information contained in the blood spots, and that they fear the possibility of discrimination against their children and perhaps their relatives through research done on the

spots.” Defendants argue that this is merely abstract injury, and that Plaintiffs do not allege that any misuse has occurred or is even likely, much less that it is threatened or imminent.

Plaintiffs state that Judge Biery “recently held that similar plaintiffs complaining of DSHS’s unlawful uses of infant blood samples had standing to pursue their claims.” In *Beleno*, Judge Biery concluded that the plaintiffs had suffered an injury in fact because the storage of the blood was an injury that had occurred and continued to occur, and there was reasonable fear of the potential for misuse because of the continued storage by the Department. However, a number of circumstances have changed since *Beleno*, including the fact that the Department may no longer store newborn blood specimens after testing if the parents request destruction of the specimens. Thus, Defendants contend that, to the extent Plaintiffs argue that Defendants released the blood spots to outside entities, there is no reasonable fear of future misuse by the Defendants because Defendants no longer have them. Further, Defendants argue, to the extent Plaintiffs’ fears are directed at future alleged wrongful releases, rather than the past releases they address in their pleading, they have not established any real and immediate threat of future injury because all previously stored specimens in Defendants’ possession were destroyed pursuant to the *Beleno* settlement and thus cannot be released or misused by Defendants. Defendants contend that any releases after May 2009 are governed by the additional protections afforded by amendments made to Chapter 33, which were not yet in effect at the time of the releases complained of by Plaintiffs, and Plaintiffs have pled no facts to support any alleged injury or likelihood of injury under the new law.

Plaintiffs may have suffered a past injury in fact if their children’s blood samples were retained after the newborn screening was completed. In *Beleno*, the plaintiffs alleged that all the blood samples had been retained, and thus were subject to potential misuse. However, Defendants

were required to destroy all blood samples in the Department's possession for which no consent was had to retain them, pursuant to the terms of the *Beleno* settlement. Thus, that injury – the Department's indefinite retention of specimens – is not ongoing, and Plaintiffs' complaint in this case is not based on that alleged injury.

Regardless of whether they suffered a past injury by such retention, in order to have standing to seek injunctive relief, they must demonstrate that they are “likely to suffer future injury by the defendant.” *K.P.*, 627 F.3d at 123 (quoting *James v. City of Dallas*, 254 F.3d 551, 563 (5th Cir. 2001)). Because a federal plaintiff must demonstrate standing for each type of relief sought, and the only relief available to Plaintiffs is prospective equitable relief, Plaintiffs must satisfy the Article III standing requirements for injunctive and declaratory relief. *Grant ex rel. Family Eldercare v. Gilbert*, 324 F.3d 383, 387-88 (5th Cir. 2003) (noting that plaintiff had suffered past injury in fact, but “[b]ut because he [sought] only declaratory and injunctive relief, he must ‘demonstrate either continuing harm or a real and immediate threat of repeated injury in the future’”). As the Fifth Circuit recently noted, “This principle is rote. To obtain forward-looking equitable remedies, a plaintiff must show she faces imminent threat of future injury.” *Fisher v. Univ. of Tex. at Austin*, 631 F.3d 213, 217 (5th Cir. 2011). The Court distinguished this aspect of standing from standing to seek money damages for past injury. *Id.*

Because all blood specimens in the Department's possession were destroyed in 2009 (or would be destroyed upon the Plaintiffs' written request under section 33.0112), the only potential continuing injury that existed at the time Plaintiffs filed this lawsuit was the possibility that Plaintiffs' children's blood spots were among the blood spots that had been distributed to third parties and used for purposes other than newborn screening before the *Beleno* settlement. The

Amended Complaint makes clear that this is the named Plaintiffs' concern. Plaintiffs allege that "Defendants have not as of yet accounted for and destroyed all of the outstanding blood samples that they unlawfully distributed, sold, or traded" and state that "injunctive relief is necessary to account for the blood samples not currently in Defendants' possession which they distributed wrongfully and illegally and without the consent of the Plaintiffs and the class, and will continue to do." Thus, the relief sought by Plaintiffs (as opposed to the proposed class) is three-fold: (1) for Defendants to account for all blood samples and spots of Plaintiffs' children, whether or not in Defendants' possession, which Defendants have distributed, sold, bartered, or traded without informed parental consent; (2) for Defendants to advise Plaintiffs for what purposes Defendants used the blood samples and spots of Plaintiffs' children and disclose all financial transactions involved with the use of such samples and blood; and (3) for Defendants to destroy all such blood samples.

Plaintiffs' alleged ongoing harm is the *possible* expropriation of their children's previously taken blood by its release to third parties and those third parties' retention and use of the blood specimens. Two of the three forms of relief requested by Plaintiffs are informational, and the third (destruction) is relevant only if the informational relief discloses that Plaintiffs' children's blood has in fact been released. An inability to obtain information may be an injury in fact in some circumstances. *See Fed. Election Comm'n v. Akins*, 524 U.S. 11, 21 (1998) (a plaintiff suffers an injury in fact when the plaintiff fails to obtain information that must be publicly disclosed pursuant to a statute). But there is no allegation that, at the time Plaintiffs filed this suit, they had even requested information about the fate of their children's blood specimens, much less that they had done so and were refused. Nor had they requested that the blood specimens be destroyed and been informed that this was not possible due to their release to third parties. Thus, their informational

claims were not ripe at the time they filed suit and/or they lacked standing because they had suffered no injury in fact with regard to the denial of information or the denial of a request for destruction.

Further, at the time they filed suit, Plaintiffs lacked standing to assert their claim for injunctive relief requiring destruction of released blood specimens because whether they had suffered the injury in fact of blood specimen release and thus would suffer possible future injury from that release was entirely speculative. Plaintiffs assert that “the unlawful distribution and sale of the infants’ blood samples is an injury that has occurred” and “with thousands of samples remaining in circulation which may be redistributed or re-identified, there is a reasonable fear of the potential for misuse because of Defendants’ actions.” However, Plaintiffs conflate their claims with the potential class claims. Whether *Plaintiffs’* children’s blood was distributed and could be potentially misused in the future was speculative at the time they filed their complaint, and it was speculative because Plaintiffs had not requested destruction or requested information about their children’s blood specimens. While it may be true that *some* blood specimens were distributed to third parties before the *Beleno* settlement, Plaintiffs simply did not know at the time they filed their complaint whether their children’s blood had been distributed or destroyed (nor, as noted, had they asked for this information or requested destruction). Thus, this alleged ongoing injury was speculative at the time the Complaint (and Amended Complaint) was filed. Such speculation is insufficient to demonstrate a real and immediate threat of future injury.² Thus, Plaintiffs lack

² Plaintiffs assert that, if a police officer takes someone’s diary or personal financial information without a warrant and proceeds to hold it indefinitely for undisclosed purposes without consent, that is an injury *per se*. But in their hypothetical, the plaintiff knew that their diary or personal financial information was taken, whereas in this case Plaintiffs did not know if their blood specimens were ever distributed, nor do they allege that Defendants had refused to disclose whether the specimens were distributed.

standing.

5. mootness

Even if Plaintiffs had standing, their claims are now moot. The harm alleged by Plaintiffs was the distribution of the blood spots and the potential misuse resulting therefrom. But Defendants have offered (undisputed) evidence that Plaintiffs' children's blood spots were never released to any other entity and have been destroyed. The affidavit of Dr. Adolfo Valadez, the Assistant Commissioner for the Division of Prevention and Preparedness Services "affirm[s] that as of April 12, 2010 DSHS has destroyed all blood specimens in its or Texas A&M University Health Science Center's possession which were taken from infants born in Texas as part of the Newborn Screening Program and received by DSHS prior to May 27, 2009, for which DSHS does not have written consent from the parent/guardian/managing conservator to retain and use those specimens." Ex. 1B.

Defendants also provide the affidavit of Susan M. Tanksley, the Biochemistry and Genetics Branch Manager for the Department. Ex. 3 (Feb. 15, 2011 Affidavit). She states that, using the name and birthday information provided in the Complaint, the Department was able to determine from its records the status of Plaintiffs' children's samples. She states that, with regard to the Higgins infant: (1) newborn screening was conducted under Chapter 33 on blood spots from an infant Higgins born on September 26, 2007; (2) the Higgins blood spots were never used for any purpose other than newborn screening conducted at the DSHS newborn screening laboratory; (3) other than for storage at Texas A&M University, the spots were not distributed to any individual or entity at any time for any purpose, including research; and (4) the Higgins blood spots were destroyed on or before April 12, 2010, in compliance with the *Beleno* settlement.

Similarly, with regard to the McCall infant, Tanksley attests that the records indicate that:

(1) newborn screening was conducted pursuant to Chapter 33 on blood spots from an infant McCall born on March 7, 2008, whose mother was listed as Andromida McCall; (2) the blood spots were never used for any purpose other than newborn screening conducted at the DSHS Laboratory; (3) the blood spots were never distributed to any individual or entity at any time, for research or any other purpose; and (4) DSHS records indicate that the McCall blood spots were destroyed on or before April 12, 2010 in compliance with the *Beleno* settlement.

Plaintiffs never refute Defendants' evidence that Plaintiffs' children's blood samples were not distributed and have in fact been destroyed. Accordingly, even if Plaintiffs had standing, their claims are now moot.

6. class claims

The Court finds that Plaintiffs' claims must be dismissed for lack of jurisdiction. Plaintiffs may not rely on the claims of class members to establish their own standing. As the Fifth Circuit has explained,

Standing is a jurisdictional requirement that focuses on the party seeking to get his or her complaint before a federal court and not on the issues he or she wishes to have adjudicated. "A litigant must be a member of the class which he or she seeks to represent at the time the class action is certified by the district court." If the litigant fails to establish standing, he or she may not seek relief on behalf of himself or herself or any other member of the class.

James v. City of Dallas, Tex., 254 F.3d 551, 562-63 (5th Cir. 2001). Accordingly, dismissal of Plaintiffs' claims requires dismissal of the proposed class claims as well.

Conclusion

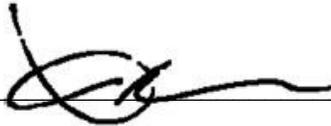
Defendants' Motion to Dismiss (docket no. 4) is GRANTED IN PART and DISMISSED AS MOOT IN PART. Specifically, the motion to dismiss under Rule 12(b)(1) for lack of jurisdiction is granted, and the 12(b)(6) motion is dismissed as moot. Plaintiffs' claims are therefore

DISMISSED WITHOUT PREJUDICE for lack of jurisdiction. Further, Plaintiffs' Opposed Motion for Leave to File Motion to Certify the Class (docket no. 19) is DISMISSED AS MOOT.

This Order disposes of all claims and parties. The Clerk's office is directed to enter a final judgment pursuant to Rule 58 dismissing all claims without prejudice, and to close this case.

It is so ORDERED.

SIGNED this 7th day of July, 2011.

A handwritten signature in black ink, appearing to read 'Xavier Rodriguez', is written over a horizontal line.

XAVIER RODRIGUEZ
UNITED STATES DISTRICT JUDGE