UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

SHARP HEALTHCARE; INTERNIST LABORATORY; SCRIPPS HEALTH,

Plaintiff,

vs.

MICHAEL LEAVITT, Secretary of the Department of Health and Human Services,

Defendant.

CASE NO. 08-CV-0170 W POR

ORDER:

1) GRANTS-IN PART AND DENIES-IN PART DEFENDANT'S MOTION [DOC. NO. 30.]

2) DENYING PLAINTIFFS' MOTION FOR LEAVE TO FILE SURREPLY [DOC.NO.33.]

On January 29, 2008, Plaintiffs Sharp Healthcare, Internist Laboratory, and Scripps Health (jointly, "Plaintiffs") filed a complaint against Defendant Michael Leavitt, Secretary of the Department of Health and Human Services ("Defendant") for violations of the Administrative Procedure Act, takings, and violations of the statute creating the project at issue, 42 U.S.C.§ 1395(w-3). On April 8, 2008, the Court granted Plaintiffs' motion for a preliminary injunction enjoining Defendant. (Doc. No. 25.)

Defendant has now filed a motion to: (1) dismiss the complaint on mootness grounds, (2) dissolve the preliminary injunction, and (3) vacate the Court's interlocutory opinions. (Doc. No. 30.) The Court decides the matter on the papers

submitted and without oral argument. See S.D. Cal. Civ. R. 7.1(d)(1). After a thorough review of the parties' submissions, the Court **GRANTS** the motion to dismiss and **DENIES** the motion to dissolve the preliminary injunction and vacate the Court's interlocutory opinions.

I. BACKGROUND

This litigation involves Part B of the Medicare program. Medicare Part B is a voluntary insurance program that covers a portion of the costs for, among other things, clinical diagnostic laboratory services for Medicare beneficiaries. Typically, Medicare pays for clinical laboratory services on a fee-for-service basis according to the Medicare Part B Clinical Laboratory Fee Schedule established in 1984.

In 2003, Congress passed the Medicare Prescription Drug Improvement and Modernization Act of 2003, 42 U.S.C. § 1395w–3. The statute requires the Secretary, through the Center for Medicare and Medicaid Services ("CMS"), to conduct a demonstration project on the application of competitive acquisition for payment of clinical diagnostic laboratory tests that would otherwise be covered by the Medicare Part B Fee Schedule. 42 U.S.C. § 1395w–3(e). The statute also requires Defendant to designate competitive acquisition areas where the project will be implemented. Id.

On October 17, 2007, Defendant announced the San Diego-Carlsbad-San Marcos area as the first competitive acquisition demonstration site. See 72 Fed.Reg. 58856-01. Under the bidding process, laboratories must submit bids for 303 laboratory tests, and for the collection and handling of laboratory specimens. Laboratories are required to bid for each of the 303 tests, even if the laboratory does not provide the specific test. Bids will be evaluated based on CMS's determination of the "best value for the Medicare program," using price and non-price criteria. The deadline for submitting bids was February 15, 2008. The winning bidders would have been announced on April 11, 2008.

On January 29, 2008, Plaintiffs filed this lawsuit seeking to enjoin Defendant from implementing the demonstration project. The Complaint includes four counts. Count I alleges Defendant violated notice and comment requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(b), in developing certain demonstration project rules. In Count II, Plaintiffs allege that three of Defendant's rules (including the limitation on the face-to-face exception) violate sections 701–706 of the APA because the rules are arbitrary, capricious, an abuse of discretion or not otherwise in accordance with the law. Count III alleges that Defendant's rules will cause a taking in violation of the Fifth Amendment to the United States Constitution. In Count IV, Plaintiffs contend that Defendant violated 42 U.S.C. § 1395w–3(e) by increasing the scope of the demonstration project to include collecting and handling laboratory specimens.

On February 4, 2008, Plaintiffs filed a motion for a Temporary Restraining Order ("TRO") to enjoin the demonstration project before the February 15, 2008, application deadline. On February 14, 2008, the Court denied the motion because Defendant had raised serious issues regarding the Court's jurisdiction–thereby preventing a finding that Plaintiffs had a likelihood of success on the merits– and because Plaintiffs had failed to establish that they would suffer irreparable harm by having to comply with the application deadline. In light of the serious jurisdictional issues raised by Defendant, the Court also issued an order to show cause ("OSC") requiring the parties to provide briefing regarding whether jurisdiction existed, and whether Plaintiffs had standing.

On March 10, 2008, Plaintiffs filed a preliminary injunction motion seeking to enjoin the demonstration project before April 11, 2008, the date Defendant would have announced the winning bidders. After Plaintiffs' motion was filed, the parties filed their briefs on the OSC. On April 4, 2008, the Court issued an Order Finding The Court Has Jurisdiction And Plaintiffs' Claims Are Ripe For Review ("OSC Order"). (Doc. No. 23.) On April 8, 2008, the Court granted Plaintiffs' motion for a preliminary injunction enjoining Defendant from (1) announcing winners in the laboratory services

demonstration project at issue; (2) implementing the laboratory services demonstration project; and (3) disclosing any information included in the bid applications submitted in connection with the laboratory services demonstration project. (Doc. No. 25.)

On July 15, 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"). Pub.L. 110-275, § 145, 122 Stat. 2494 (2008). Both parties agree that this law repealed the original statutory authority for the demonstration project. (*See Pl.'s Opp* at 1:5–7.)

On August 8, 2008, Defendant filed a motion to: (1) dismiss on mootness grounds, (2) dissolve the preliminary injunction, and (3) vacate the Court's interlocutory opinions. (Doc. No. 30.) Defendant contends that the complaint is moot because the statute authorizing the laboratory services demonstration project has been overturned by Congress.[1] The Court now decides Defendant's motion to dismiss.

II. LEGAL STANDARD

A mootness challenge may be brought as a lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure. Bland v. Fessler, 88 F.3d 729, 732 n. 4 (9th Cir. 1996). Rule 12(b)(1) provides that a court may dismiss a claim for "lack of jurisdiction over the subject matter[.]" Fed. R. Civ. P. 12(b)(1). Although the defendant is the moving party in a motion to dismiss, the plaintiff is the party invoking the court's jurisdiction. Therefore, the plaintiff bears the burden of proof on the necessary jurisdictional facts. McCauley v. Ford Motor Co., 264 F.3d 952, 957 (9th Cir. 2001).

"Unlike a Rule 12(b)(6) motion, a Rule 12(b)(1) motion can attack the substance of a complaint's jurisdictional allegations despite their formal sufficiency, and in so doing rely on affidavits or any other evidence properly before the court." St. Clair

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[1]Plaintiffs have also filed an *ex parte* application for leave to file a surreply. Defendant filed an opposition to that motion. (Doc. No. 34) The Court finds the previously submitted briefing is sufficient to resolve the issues presented, and as such, **DENIES** the motion. (Doc.No. 33.)

v. City of Chico, 880 F.2d 199, 201 (9th Cir. 1989) (citing Thornhill Publishing Co. v. General Tel. & Elec. Corp., 594 F.2d 730, 733 (9th Cir. 1979)); see also Marriot Int'l, Inc. v. Mitsui Trust & Banking Co., Ltd., 13 F. Supp. 2d 1059, 1061 (9th. Cir. 1998).

"The jurisdiction of federal courts depends on the existence of a 'case or controversy' under Article III of the Constitution." GTE California, Inc. v. Federal Communications Comm'n, 39 F.3d 940, 945 (9th Cir. 1994). Generally, a case is moot "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." Murphy v. Hunt, 455 U.S. 478, 481 (1982) (quoting U.S. Parole Comm'n v. Geraghty, 445 U.S. 388, 396 (1980)). The court must be able to grant effective relief, otherwise itlacks jurisdiction. GTE California, Inc., 39 F.3d at 945.

III. DISCUSSION

Defendant contends that Plaintiffs' entire case is moot because Congress has repealed the underlying statute authorizing the laboratory services demonstration project, 42 U.S.C.§ 1395(w-3). (*See Def.'s Mot.* at 1:3–4.) In response, Plaintiffs concede that the majority of this dispute has been mooted. However, they claim that a single issue remains "very much in dispute between the parties." (*Pltf.'s Opp.* at 1:5–10.) The Court agrees with the Plaintiffs.

A. The Complaint is Moot as Currently Pled

Defendant contends that Plaintiffs' case is moot because Congress has repealed the underlying statute authorizing the laboratory services demonstration project. Plaintiffs argue that the controversy is still live because they could still be harmed should Defendant decide to use information obtained prior to the date on which the Court's preliminary injunction was issued.

If it is determined that the court may not provide relief of a prospective nature because the claim has been mooted by extra-judicial events, the court must dismiss the complaint. Smith v. University of Washington, Law School, 233 F.3d 1188, 1193 (9th Cir. 2000). However, the party moving for dismissal based on mootness grounds bears

a heavy burden of demonstrating that there is no longer a live controversy. See, e.g., West v. Secretary of Dept. of Transp., 206 F.3d 920, 924 (9th Cir. 2000).

When the complaint requests only declaratory or injunctive relief and intervening legislation settles or alters the controversy, the case is moot and must be dismissed. Chemical Producers and Distributors Association v. Helliker, 463 F.3d 871, 875 (9th Cir. 2006). If the law has been sufficiently altered from the original statute challenged in the complaint, there is no basis for claiming that the challenged conduct is being continued. Id. However, intervening changes to the law do not always render a case moot. See Ne. Fla. Chapter of Associated Gen. Contractors of Am. V. City of Jacksonville, 508 U.S. 656, 662 (1993). There are rare cases where the law at issue is repealed or expires and the case does not become moot, but these generally involve situations where it is virtually certain that the repealed law will be reenacted. Native Vill. of Noatak v. Blatchford, 38 F.3d 1505, 1510 (9th Cir. 1994).

Here, the statute giving rise to Plaintiffs' claims has been repealed by act of Congress. As such, it is undisputed that Defendant has been forced to abandon the laboratory services demonstration project entirely, and will no longer be implementing the program. Significantly, all four counts alleged in the Complaint address the implementation of, or actions in relation to, the program. And the Complaint only seeks injunctive relief to prevent the program's continuance. None of the counts currently alleged challenge the Secretary's retention of bid information.

Plaintiffs disagree with this conclusion and believe that the Complaint was written broadly enough that it can be read to include a cause of action for the wrongful retention of the bid information. (*Pltf.'s Opp.* at 10: n. 1) This Court has examined the Complaint, under the appropriate standard of review, and can not award such specific effect to Plaintiffs' request for "any other relief the Court deems necessary and appropriate." (*Id.*) Thus, the legal causes of action currently pled are moot and the Complaint must be dismissed.

However, in light of dismissing the Complaint, the Court is persuaded that a controversy may still exist between these parties. During the course of this litigation

Defendant came to possess the bidding information that Plaintiffs deem confidential. This Court previously protected that data in the preliminary injunction. Specifically, this Court enjoined Defendant from:

> 3. Further disclosing any information included in the bid applications submitted in connection with the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project for the San Diego-Carlsbad-San Marcos Metropolitan Area.

(Doc. No. 25 at 19:12–15.) Despite the fact that the program which gave the authority to collect the information has been repealed by Congress, Defendant has maintained possession of the bidding applications. In their opposition brief, Plaintiffs persuasively contend that they will be harmed if Defendant decides to use the confidential information obtained during the bidding process prior to the statute's repeal. In fact, Plaintiffs have offered to amend the Complaint "to add a specific claim related to the Secretary's wrongful and unauthorized retention of the bid information." (*Pltf.'s Opp.* at 11: n. 1.) Defendant objects to this request and asserts that he is "not aware of any other cause of action that plaintiffs might assert" that would provide the protection they seek. (*Def. Mot.* at 6:14–16.) Defendants may be correct in their research. However, this Court will not speculate as to what Plaintiffs could or could not assert as a cause of action and then provide preemptive relief.

As such, the Court finds the situation merits the requested relief. Therefore, the Court will **GRANT** the motion to dismiss **WITH LEAVE TO AMEND** in order to enable Plaintiffs to plead new facts that they believe entitle them to relief.

B. It Would Be Inappropriate for the Court to Vacate the Prior Orders and the Preliminary Injunction at this Time

Additionally, Defendant contends that the Court should dissolve the preliminary injunction and vacate the prior orders because the case is moot and therefore no further harm can befall Plaintiffs. The Court disagrees.

A district court has wide discretion to modify or dissolve a preliminary injunction if circumstances should so require. Mariscal-Sandoval v. Ashcroft, 370 F.3d 851, 859 (9th Cir. 2004) (holding that if factual or legal circumstances change, "sound judicial discretion may call for the modification of the terms of an injunction decree"). There are two tests that are generally considered when a court decides whether to grant a preliminary injunction. Reconsideration of these tests at this time is appropriate given the change in circumstances in this case.

To obtain a preliminary injunction under the "traditional" test, a plaintiff must show "'(1) a strong likelihood of success on the merits, (2) the possibility of irreparable injury to plaintiff if preliminary relief is not granted, (3) a balance of hardships favoring the plaintiff, and (4) advancement of the public interest (in certain cases).'" Save Our Sonoran, Inc. v. Flowers, 408 F.3d 1113, 1120 (9th Cir. 2005) (quoting Johnson v. Cal. State Bd. of Accountancy, 72 F.3d 1427, 1430 (9th Cir. 1995)).

To obtain a preliminary injunction under the "alternative" test, a plaintiff must demonstrate *either* (1) a combination of probable success on the merits and the possibility of irreparable injury *or* (2) serious questions are raised and the balance of hardships tips sharply in his favor. Save Our Sonoran, 408 F.3d at 1120 (citing Johnson, 72 F.3d 1430); Immigrant Assistance Project of the L.A. County of Fed'n of Labor v. INS, 306 F.3d 842, 873 (9th Cir. 2002). "These two formulations represent two points on a sliding scale in which the required degree of irreparable harm increases as the probability of success decreases. They are not separate tests but rather outer reaches of a single continuum." Baby Tam & Co. v. City of Las Vegas, 154 F.3d 1097, 1100 (9th Cir. 1998). Thus, "the greater the relative hardship to the moving party, the less probability of success must be shown." Immigrant Assistant Project, 306 F.3d at 873.

As mentioned above, Defendant has not denied retention of the bidding applications and the information therein. Currently, Defendants are enjoined from disclosing that information. Vacating the preliminary injunction would suddenly give Defendants the discretion to attempt another use for the information. Plaintiffs claim that the bid applications contain highly confidential and proprietary data that is of

value to Plaintiffs and other laboratories that submitted bids. (*Pltf.'s Opp.* at 1.) Plaintiffs further contend that they will be harmed considerably if Defendant is permitted to use the information obtained under the now-dissolved project, and that without the preliminary injunction Plaintiffs will be deprived of the relief to which they believe they are entitled. (*Pltf.'s Opp.* at 1–2.) Specifically, Plaintiffs believe that Defendant will use the bid prices obtained during the submission process to set Medicare reimbursement rates for laboratory services. (*Pltf.'s Opp.* at 9–10.) Plaintiffs argue that if Defendant were allowed to set Medicare rates based on this information, he would essentially be able to achieve the goals of the demonstration project without going through with the actual project itself. (*Pltf.'s Opp.* at 10.)

In contrast, Defendants describe this possibility as having "no basis in reality." (*Def.'s Reply* at 7:21.) In support, they claim the Trade Secrets Act already prohibits the government's unauthorized disclosure of confidential information. 18 U.S.C. § 1905. Additionally, they claim federal law dictates that the Secretary would have to cite the basis for any proposed Medicare rate changes and accept public comment thereon. 42 U.S.C. § 1395*l*(h)(8) Thus, the Secretary can not "unilaterally" set rates in the manner being alleged by Plaintiffs. (*Def.'s Reply* at 8:4.) The Court finds these arguments persuasive. However—and in especially in light of this information—the Court does not understand why Defendant vehemently insists on maintaining possession of the information.[2]

Defendants also contend that the Plaintiffs cannot maintain the "likelihood of success" element of the preliminary injunction test, and therefore are no longer entitled

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[2] In Reply, Defendant makes a passing comment about using the "data submitted in bid applications in order to evaluate and report to Congress what this information reveals about the design of the competitive bidding process and other such matters...." (*Def.'s Reply* at 8:5–7.) In support, they claim Plaintiffs were informed of this possibility in the "Final Bidder's Package." Ultimately, this argument may have effect. However, this fleeting comment could also be construed as an admission that the Secretary has a not-previously-mentioned design for the enjoined information. In any event, the Court is concerned that the authority sustaining this argument has been repealed and that Plaintiffs have not been afforded the opportunity to plead or brief this issue.

to the preliminary injunction. However, in situations where the possible harm to plaintiffs is very great, less probability of success needs to be shown. Furthermore, because the Court is granting Defendant's motion to dismiss with leave to amend, the dismissal is not final. See WMX Technologies, Inc. v. Miller, 104 F.3d 1133, 1135 (9th Cir. 1997) (holding that a dismissal with leave to amend is not a final order). Plaintiffs are entitled to amend their complaint and have expressed their desire to do so, and therefore it is still possible that they will succeed on the merits. (*Pl.'s Opp.* at 10-11 n.1.) Thus, the Court need not dissolve the preliminary injunction at this time.

In sum, the Court **DENIES** Defendant's motion requesting vacatur of the Court's prior orders and dissolution of the preliminary injunction. However, should Plaintiffs fail to file an amended complaint within the required time period, the preliminary injunction will be dissolved and the prior orders will be vacated.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendant's motion to dismiss on mootness grounds **WITH LEAVE TO AMEND**. The Court **DENIES** Defendant's motion for vacatur of the Court's prior orders and dissolution of the preliminary injunction. If the parties can not resolve this matter informally, and should Plaintiffs desire to amend the complaint, they must do so on or before **April 27, 2009**. As mentioned above, if Plaintiffs do not timely file an amended complaint, the Court will dismiss the action with prejudice, dissolve the preliminary injunction, and vacate the prior orders.

IT IS SO ORDERED.

DATE: March 25, 2009

HON. THOMAS J. WHELAN
United States District Court
Southern District of California