

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
FT. LAUDERDALE DIVISION

CASE NO.: 18-61047-CIV-UNGARO/O'SULLIVAN

UNITED STATES OF AMERICA,  
Plaintiff,  
v.

US STEM CELL CLINIC, LLC, a Florida  
limited liability company,  
US STEM CELL, INC., a Florida profit  
corporation, and  
KRISTIN C. COMELLA, individual,  
Defendants.

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**AMENDED EXPEDITED MOTION TO INTERVENE AND FOR STAY  
OF DESTRUCTION OF APPLICANTS FOR INTERVENTION'S PROPERTY  
AND CLARIFICATION OF ORDER OF PERMANENT INJUNCTION**

**With incorporated  
MEMORANDUM OF LAW**

**And attached  
PLEADING OF APPLICANTS FOR INTERVENTION**

Applicants in intervention Jan Aitken, Carol Barrows, David H. Buckles, Barbara Burns, Stephanie Ciaramitaro, Evelyn L. Clough, Samuel Colacurio, Eric C. Congiardo, Enrique Corral, Lawrence Coughlin, Lydia Cronin, Allison L. Cronin, Paul Decker, Robert Demane, Gay D'Surney, Sada Fenton, Camilla J. Foreman, Jan Gimian, Darcy Goette Darro Grieco, Gail Grill, Naota Hashimoto, Luz C. Hernandez, Laurel L. Hodory, Gregory O. Hudgins, Alan D. Hudson, Karen J. Jeffries, James L. Jeffries, Maureen Jones, Michael L. Kelby, Mary Klucarich, Deanna M. Lawrence, Suzanne M. Lawrence, Fay Magennis, Jeffery Masters, Margarita Mattingly, Elaine Murin, Bernadette Newlon, Olivia Newsome-Grieco, Edwin Noble, Kathryn L. O'Harrow, Robert I. Orenstein, Michael K. Pool, Frank Poucher, Kathleen Rogers, Reid Runzheimer, Mary Sczepaniak, Shannon E. Seth, Deborah Simmons, Charmie Smith, Judith Smith, Christen

Streufert, Linda T. Taylor, John M. Temple, Thomas Thibodeau, Anthony J. Thynne, Dawn Washkewicz, Pam Washkewicz, Steven Waterman, Nancy Weaver, Kurt Wuellner, Renate Wilson, Dawn Winslow, Joyce Yeargan, Charles Yeargan, each an individual whose stem cells (the “Stem Cells”) are banked at an FDA-registered tissue bank (hereinafter “Applicants” or “Applicants for Intervention”, each, an “Applicant”) operated by Defendant US Stem Cell, Inc. (“US Stem”), move to intervene as of right in this action, pursuant to Rule 24(a)(2), Federal Rules of Civil Procedure, or alternatively, move for permissive intervention, pursuant to Rule 24(b)(2), and Local Rule 7.1(d)(2) to protect those Stem Cells from destruction, and seek an emergency stay of paragraph 10 of the Order of Permanent Injunction issued June 25, 2019 (the “Injunction Order”) [D.E. 85] ordering the destruction of the Stem Cells on or before July 25, 2019.<sup>1</sup> An expedited ruling on this matter is required by July 24, 2019, prior to the scheduled destruction date. Pursuant to Rule 24(c), Applicants attach their proposed Complaint in Intervention. In support of their motions Applicants state:

1. Applicants have an urgent, direct and substantial interest in this matter, as Applicants’ Stem Cells, which are the irreplaceable property of the Applicants, are slated for destruction by Thursday, July 25, 2019 pursuant to Paragraph 10 of the Court’s Order of Permanent Injunction (the “Injunction Order”). [D.E. 85]

2. Applicants for Intervention are individuals who have banked their stem cells for storage at the tissue bank operated by US Stem (the “Tissue Bank”), pursuant to a Stem Cell Processing and Storage Agreement (the “Storage Agreement”).

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<sup>1</sup> Applicants file this amended motion to advise the Court and the parties that for some of the Applicants the first correspondence from US Stem to Applicants advising Applicants of the existence of this lawsuit was on June 6, 2019, to correct the spelling of the name of two of the Applicants and to add Applicants.

3. Each Applicant's Storage Agreement expressly provides that the Stem Cells stored pursuant to the agreement remain the sole property of the individual entering the Storage Agreement.

4. For example, in the Storage Agreement of Applicant Dr. Linda Taylor, the Storage Agreement states:

(d) Notwithstanding Bank's possession of the Tissue and the stem cells derived therefrom, **Patient is and shall remain the owner of the Tissue and the stem cells derived therefrom**, until the release or disposition of same by Bank.

*E.g.*, Storage Agreement between Linda Taylor and US Stem Cell, Inc., attached to the Amended Declaration of Linda Taylor, M.D., along with the Declarations and Storage Agreements of multiple Applicants, which are attached hereto as Composite Exhibit A (Storage Agreement p.3 at Part II ¶ 3(d)) (emphasis added).<sup>2</sup>

5. The Stem Cells constitute valuable property of each Applicant. Each Applicant has paid thousands of dollars in fees to first obtain the Stem Cells and then to cryopreserve and store the Stem Cells for future use by such Applicant. Many Applicants suffer from disease and illness that has been until recently successfully treated with the Stem Cells. In some cases, the Stem Cells offer the Applicants their only viable means of treatment.

6. The Tissue Bank where Applicants currently store their Stem Cells is registered with the United States Food and Drug Administration (the "FDA") as a human cells, tissues, and cellular and tissue-based product establishment", [D.E. 1 ¶ 17], pursuant to 21 CFR Part 1271,

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<sup>2</sup> Due to the urgency of the need for relief from the Injunction Order before July 25, 2019, and the limited time Intervenor has had to attempt to intervene in this matter, not every Intervenor has been able to successfully locate his or her Storage Agreement by the time of filing of this motion. Upon information and belief, each Intervenor's Storage Agreement contains substantially equivalent language retaining property rights in the Stem Cells for such Intervenor.

with an FDA Establishment Identifier of 3005825762. A printout of the public query establishment details from the FDA website for the Tissue Bank is attached hereto as Exhibit B.

7. On June 25, 2019, the Court issued the Injunction Order requiring that “Defendants,” including US Stem, “destroy any and all SVF Product that is in Defendants’ possession, custody, or control.” [D.E. 83 ¶ 10] The Injunction Order, therefore, orders the destruction of Applicants’ Stem Cells.

8. Applicants were not named parties to this action prior to the issuance of the Injunction Order.

9. Applicants received no notice that Plaintiff sought the destruction of their Stem Cells in this action.

10. The Complaint in this action does not provide any notice, in any way, that the United States sought, or that this Court would order, the destruction of the irreplaceable property of any of the Applicants. The Complaint does not identify any of the Applicants as a Defendant or otherwise connected to the litigation. As this Court has already found, the “SVF product created from Intervenor’s stem cells and stored at Defendant’s facility was not the subject of the action; the action was not an in rem proceeding and the SVF Product is not the *res* before the Court.” *See* Order dated July 12, 2019 [D.E. 208, p. 4]. The Complaint does not contain any prayer for relief seeking the destruction of any SVF Product, let alone Applicants’ Stem Cells.

11. Applicants have been afforded no opportunity to be heard before the issuance of the Injunction Order requiring the destruction of their property.

12. The Injunction Order provides Applicants with no compensation for the Court-ordered destruction of their property.



13. Applicants cannot replace the Stem Cells currently ordered destroyed with Stem Cells of equal quality. Scientific evidence indicates that stem cells that are cryopreserved and banked, like Applicants' Stem Cells, maintain the quality and age of the individual they were extracted from at time when such stem cells were extracted and stored.<sup>3</sup> Because human stem cells within a person's body degrade as a person ages,<sup>4</sup> Applicants have no way of replicating their stored Stem Cells, which have been extracted and cryopreserved when each Applicant was younger. Because the Stem Cells are of a higher quality than any stem cells which could be extracted from the Applicants currently or in the future, the Stem Cells are irreplaceable.

14. On June 6, 2019, some Applicants were notified for the first time by US Stem of this litigation (but were not advised that the Stem Cells may be subject to destruction). Some Applicants never received this June 6, 2019 notice. On June 28, 2019, the Applicants were notified *for the first time* by US Stem that their Stem Cells were slated for destruction by US Stem

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<sup>3</sup> See, e.g., Geeta Shroff & Damini Vatsa, *Cell Viability of Human Embryonic Stem Cells Stored for a Period of 9 Years*, 15 Experimental and Clinical Transplantation 344, 344-349 (2017). A copy of this article is attached hereto as Exhibit E.

<sup>4</sup> See, e.g., Meichen Liu et al., *Adipose-Derived Mesenchymal Stem Cells from Elderly Exhibit Decreased Migration and Differentiation Abilities with Senescent Properties*, 26(9) Cell Transplantation 1501, 1505 (2017) ("[T]he increased age of the donors was found to have a significant negative effect on [human adipose-derived mesenchymal stem cells ("hASCs")] frequency base on colony-forming unit fibroblasts assay... When considering potential applications of hASCs in cell-based therapeutic strategies, the negative influence of age on hASC differentiation potential and migration abilities should be taken seriously."); Monika Maređziak et al., *The Influence of Aging on the Regenerative Potential of Human Adipose Derived Mesenchymal Stem Cells*, Stem Cells International, Vol. 2016, at 9 ("Our results found that age significantly affected the growth kinetic and the PDT of the investigated groups, with evident differences between young and elderly patients ... in clinical practice, due to the lower proliferative rates of cells isolated from older patients, it may be necessary to culture and expand MSCs in vitro for a longer period before clinical use"); Anastasios Tsekouras, et al., *Comparison of the Viability and Yield of Adipose-Derived Stem Cells (ASCs) from Different Donor Areas*, 31 In Vivo 1229, 1233 (2017) ("Literature suggests that except for donor areas, age is another strong determinant of the quality of the ASCs. It has been shown that ASCs from younger patients hold a greater proliferative capacity and are more efficient in differentiating into mature adipocytes than those from older patients"). Copies of the cited articles are attached hereto as Composite Exhibit F.

pursuant to the Injunction Order. Attached as composite Exhibit C is exemplar correspondence dated June 6, 2019 and June 28, 2019 (“US Stem Correspondence”) from US Stem informing Applicants of this action and of the Injunction Order.

15. In its “Order” and dated June 25, 2019 [D.E. 82], the Court explained that “[w]hile the Court largely agrees with the terms of the United States’ proposed injunction, it does not agree that the scope of injunctive relief should include all drugs manufactured by Defendants. Injunctive relief must be limited in scope to remedy the specific harm that results from the conduct found to be unlawful.” [D.E. 82 p. 1] The Court recognized that the “only ‘drug’ at issue in this action was the SVF product manufactured by Defendants,” and was “cognizant of the fact that stem cell treatments and products are rapidly evolving, but every such treatment and product is unique and whether they constitute ‘drugs,’ or ‘biological products’ subject to DFA regulation... requires independent consideration.” [D.E. 82 p. 2]

16. For the above reasons, and those explained in the incorporated Memorandum of Law, the Applicants submit this motion respectfully requesting to (i) intervene in this lawsuit to protect their property rights in their valuable and irreplaceable Stem Cells and (ii) to stay the destruction of Applicants’ Stem Cells.

17. Attached hereto as Exhibit D is Applicants for Intervention’s proposed pleading.

### **MEMORANDUM OF LAW**

#### **I. Applicants for Intervention Have Standing to Intervene**

A party seeking to intervene must have standing under Article III of the United States Constitution to intervene in the case. *Salvors, Inc. v. Unidentified Wrecked & Abandoned Vessel*, 861 F.3d 1278, 1290 (11th Cir. 2017). The well-settled test for establishing Article III standing includes three basic requirements. “First, the plaintiff must have suffered an injury in fact -- an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or

imminent, not conjectural or hypothetical.” *Id.*, quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992). “Second, the plaintiff must establish a causal connection between its injury and the defendant’s conduct. Third, the plaintiff must show that it is likely -- and not merely speculative -- that a favorable decision by the court will redress the injury.” *Salvors, Inc.*, 861 F.3d at 1290 (citing *Duty Free Americas, Inc. v. Estée Lauder Cos.*, 797 F.3d 1248, 1271 (11th Cir. 2015)).

Applicants satisfy all three standing requirements. Applicants have a Fifth Amendment right to not be deprived of their property without due process of law or have their property taken without just compensation.

No person shall be . . . be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

U.S. Const. Amend. V. This includes property destroyed by virtue of a judicial decree. *See e.g. Stop the Beach Renourishment, Inc. v. Florida Dept. of Environmental Protection*, 560 U.S. 702, 715 (2010) (“the Takings Clause bars the State from taking private property without paying for it, no matter which branch is the instrument of the taking.”). Applicants’ property interests are being invaded by the imminent destruction of Applicants’ Stem Cells pursuant to the Injunction Order which resulted, solely and exclusively, from Defendants’ failure to meet FDA standards at Defendants’ clinic, which is separate and distinct from the Tissue Bank. Finally, this Court has the power to redress the potential irreparable harm to Applicants by granting the relief sought in the Complaint and preventing destruction of Applicants’ Stem Cells pursuant to the Injunction Order.

## **II. Intervention as a Matter of Right**

Applicants are entitled to intervene in this action as a matter of right. Rule 24, Federal Rules of Civil Procedure, in relevant part, provides that:



(a) Intervention of Right. Upon timely application anyone shall be permitted to intervene in an action: . . . (2) when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.

A party seeking to intervene as a matter of right must show that “(1) his application to intervene is timely; (2) he has an interest relating to the property or transaction which is the subject of the action; (3) he is so situated that disposition of the action, as a practical matter, may impede or impair his ability to protect that interest; and (4) his interest is represented inadequately by the existing parties to the suit.” *Fox v. Tyson Foods, Inc.*, 519 F.3d 1298, 1302 (11th Cir. 2008) (citing *Chiles v. Thornburgh*, 865 F.2d 1197, 1213 (11th Cir. 1989)). When the applicant makes the required showing, intervention must be permitted. *Stone v. First Union Corp.*, 371 F.3d 1305 (11th Cir. 2004); *U.S. v. State of Ga.*, 19 F.3d 1388 (11th Cir. 1994). The Applicants’ motion for intervention meets each of these criteria identified in *Fox*.

#### **A. The Motion to Intervene is Timely.**

The Applicants’ motion for intervention is timely because, although the United States filed suit in May 2018, neither the United States nor US Stem gave the Applicants any notice of this lawsuit until June 6, 2019, when US Stem first notified some of the Applicants of this lawsuit. None of the Applicants received any notice that their Stem Cells were at risk of destruction until June 28, 2019 when they were notified by US Stem that the Stem Cells were slated for destruction pursuant to the Injunction Order. Ex. C. Even if Applicants *had* been given prior notice of the suit, there is nothing in the Complaint that could have reasonably put them on notice that this lawsuit endangered their interests in their Stem Cells, which were stored in the US Stem-operated Tissue Bank (which the FDA had not cited for any wrongdoing), not Defendant US Stem Cell Clinic, LLC’s (“USSCC”) treatment clinic (the “Clinic”). The Complaint alleged unapproved



action by USSCC in the Clinic, and made no allegations with respect to actions taken by US Stem with respect to Stem Cells Stored at the Tissue Bank. *See Generally* [D.E. 1], *and paragraphs 9-12 therein*. As this Court has already found, the “SVF product created from Intervenor’s stem cells and stored at Defendant’s facility was not the subject of the action; the action was not an in rem proceeding and the SVF Product is not the *res* before the Court.” *See* Order dated July 12, 2019 [D.E. 208, p. 4]. The Complaint does not contain any prayer for relief seeking the destruction of any SVF Product, let alone Applicants’ Stem Cells.

“Timeliness is not limited to chronological considerations but ‘is to be determined from all the circumstances’.” *Stallworth v. Monsanto Co.*, 558 F.2d 257, 263 (5th Cir. 1977). In *Georgia v. U.S. Army Corps of Engineers*, 302 F.3d 1242 (11th Cir. 2002), the Eleventh Circuit emphasized that: “Timeliness is not a word of exactitude or of precisely measurable dimensions. The requirement of timeliness must have accommodating flexibility toward both the court and the litigants if it is to be successfully employed to regulate intervention in the interest of justice.” *Id.* at 1259. Intervention may be timely filed even if it occurs after a case has concluded; timeliness depends on the circumstances of each case. *Comm’r, Ala. Dep’t of Corr. v. Advance Loc. Media, LLC*, 918 F.3d 1161, 1171 (11th Cir. 2019); *Acree v. Republic of Iraq*, 370 F.3d 41, 50 (2004) (“Post-judgment intervention is often permitted ... where the prospective intervenor’s interest did not arise until the appellate stage or where intervention would not unduly prejudice the existing parties.”), abrogated on other grounds by *Republic of Iraq v. Beaty*, 556 U.S. 848 (2009); *Cf. Salvors, Inc.*, 861 F.3d at 1294 (11th Cir. 2017) (finding intervention timely even though the contested order was entered 33 years earlier).

A district court must consider four factors in assessing timeliness, namely “(1) the length of time during which the would-be intervenor knew or reasonably should have known of his

interest in the case before he petitioned for leave to intervene; (2) the extent of prejudice to the existing parties as a result of the would-be intervenor's failure to apply as soon as he knew or reasonably should have known of his interest; (3) the extent of prejudice to the would-be intervenor if his petition is denied; and (4) the existence of unusual circumstances militating either for or against a determination that the application is timely.” *United States v. Jefferson Cty.*, 720 F.2d 1511, 1516 (11th Cir. 1983) (citing *Stallworth*, 558 F.2d at 264-66). Each of these factors weighs in favor of intervention.

First, Applicants immediately took action upon learning that their property was threatened. Some Applicants for Intervention had no notice of this litigation or the underlying FDA investigation into the US Stem parties until June 6, 2019, when some (not all) of the Applicants were sent notice for the first time from US Stem that Defendants were Defendants in this action. None of the Applicants had notice that their Stem Cells were at risk of destruction until June 28, 2019, when they were sent notice of the Injunction Order requiring destruction of Applicants’ Stem Cells. In the 18 days since receiving notice of the Injunction Order, Applicants investigated their options, retained the undersigned and filed this Motion.

In the Court’s Order dated July 12, 2019 [D.E. 208], the Court finds that this action has been pending for over a year and has received substantial national press coverage. The Court does not identify the specific press coverage nor find that any of the Applicants actually saw the press coverage. The Declarations of Applicants filed contemporaneously with this motion indicate that they did not have any knowledge of such press coverage. Perhaps more fundamental, even if the Applicants had seen such unidentified press coverage, this still would not have put the Applicants on notice that their property (the Stem Cells) were are risk of being ordered destroyed because the Complaint never sought that relief. *Sierra Club v. Espy*, 18 F.3d 1202, 1206 (5th Cir. 1994).

Rather, as the Court has already held, the “SVF product created from Intervenor’s stem cells and stored at Defendant’s facility was not the subject of the action; the action was not an *in rem* proceeding and the SVF Product is not the *res* before the Court.” *See* Order dated July 12, 2019 [D.E. 208, p. 4]. Thus, the press coverage could not, as a matter of law, have provided Applicants notice that they risked destruction of their Stem Cells unless they intervened earlier in this action.

In *Sierra Club*, 18 F.3d at 1206, the Fifth Circuit faced a similar procedural posture. Environmentalist groups initiated a lawsuit to challenge certain United States Forest Service practices for managing four national forests in Texas. After the District Court entered an injunction order granting broader relief than requested in the original complaint, and at odds with the magistrate judge’s recommendations with respect to a subsequent iteration of the complaint, the district denied a motion to intervene by certain trade associations who purchased timber from the forests at issue. The Fifth Circuit reversed the denial of intervention, despite the fact that one of the intervenors had previously participated as *amicus curiae* in the case because “the status of the ... claims changed dramatically over the course of the lawsuit” and the injunction granted broader relief than requested in the complaint. Specifically, the injunction was applied in a way that applied to *all* timber sales, not just the sales challenged by the plaintiffs, and the intervenors could not have anticipated this until entry of the injunction. Because the intervenors moved to intervene within two months of the issuance of the preliminary injunction, when it first became clear that the types of timber sales that involved their interests would be affected, the Fifth Circuit held that their motion was timely, and reversed the denial of intervention. *Sierra Club*, 18 F.3d at 1206. Compare *Staley v. Harris Cty. Tex.*, 160 F. App’x 410, 412 (5th Cir. 2005) (holding motion to intervene untimely where substantial media coverage existed in a case regarding *the specific relief sought by the plaintiff* – removal of a monument owned by the proposed intervenor from in front



of a courthouse – and the proposed-intervenor’s Director of Operations actually testified concerning the monument at trial).

Second, permitting intervention in the instant case will not delay or prejudice the adjudication of the rights of the original parties. The Parties to this suit have already had the opportunity to argue their positions before this Court, which has resulted in entry of a final judgment. Applicants for Intervention do not seek to alter the Court’s findings of facts or conclusions of law with respect to the USSCC Clinic; rather Applicants seek to intervene only for the limited purpose of staying the destruction of their property without due process of law, namely their own Stem Cells which are currently slated for destruction. “The requirement of timeliness is not a tool of retribution to punish the tardy would-be intervenor, but rather a guard against prejudicing the original parties by the failure to apply sooner . . . Federal courts should allow intervention ‘where no one would be hurt and greater justice could be attained.’” *Sierra Club*, 18 F.3d at 1205 (internal citations omitted).

Staying the destruction of Applicants’ Stem Cells would harm no one – it would not interfere with the requested relief that the Defendants “be permanently restrained and enjoined from directly or indirectly doing any act with respect to a drug... that results in the drug being adulterated or misbranded ... if such act is done while such drug ... is held for sale,” [D.E. 1 at 16], because the Storage Agreements make clear that Applicants’ Stem Cells are Applicants’ property, so there is no risk that Defendants could market or sell the Stem Cells as a drug to the general public. *See* Ex. A (Storage Agreement p.3 at Part II ¶ 3(d)). On the other hand, destruction of Applicants’ Stem Cells would cause severe harm to Plaintiffs. *Compare United States v. United States Steel Corp.*, 548 F.2d 1232, 1235 (5th Cir. 1977) (Steelworkers’ union’s motion to intervene was untimely where the Environmental Protection Agency had negotiated a settlement dispensing



defendant Steel company from compliance with an air quality plan for 13 months in return for the company's agreement to not seek judicial review of the consent decree, the union's intervention would allow such further judicial review, and the union was aware of (and had been given the opportunity to comment on) the proposed consent decree, but did not seek to intervene until nearly a year after the order enforcing the decree was entered by the court.)

As the Court has acknowledged, "a post-judgment motion to intervene is not untimely if the putative intervenor acts as soon as it is clear that the parties will not represent its interests." [D.E. 208 p. 3] (quoting *Amarin Pharm. Ireland Ltd. v. Food & Drug Admin.*, 139 F. Supp. 3d 437, 444 (D.D.C. 2015) (citing *United Airlines, Inc. v. McDonald*, 432 U.S. 385 (1977))). As discussed in further detail in Section D below, it was not until entry of the Injunction Order that it became clear to the Applicants that US Stem would not adequately represent their interests.

Third, Applicants face severe prejudice if their irreplaceable property is to be destroyed without due process of law. Not only will Applicants lose their significant monetary investment unless they are permitted to be heard, they will lose the potentially life-saving and irreplaceable Stem Cells.

Fourth, Applicants face Court-ordered destruction of their Stem Cells in unusual circumstances. Applicants were entirely denied notice and an opportunity to be heard in this action before issuance of the Injunction Order and, even if they had been given notice, the pleadings fail to put anyone on notice that the Plaintiff sought destruction of Applicants Stem Cells being stored at the FDA registered Tissue Bank.

**B. Applicants Have an Interest Relating to the Transaction Which is the Subject of the Action.**

This element requires intervenors to demonstrate that they have a legally protectable interest. *United States v. South Fla. Water Mgmt. Dist.*, 922 F.2d 704, 707 (11th Cir. 1991). Under

Rule 24(a)(2), Fed. R. Civ. P., intervention must be supported by a “direct, substantial, legally protectible interest in the proceeding.” *Chiles v. Thornburgh*, 865 F.2d 1197, 1213-14 (11th Cir. 1989), but “need not, however, be of a legal nature identical to that of the claims asserted in the main action.” *Id.* (citation and quotation marks omitted). The inquiry on this issue is a flexible one, which focuses “on the particular facts and circumstances surrounding” each motion for intervention. *Id.*

In this case, the Applicants have a clear legal interest in protecting their ownership rights to the Stem Cells and protecting that property from destruction. Numerous cases support the rule that an individual claiming title to property has a legal interest in litigating when such property is threatened. *See, e.g., Atlantis Dev. Corp. v. United States*, 379 F.2d 818 (5th Cir. 1967) (Claim of ownership by development corporation to certain property was interest adequate for intervention as of right in an action by the United States for injunctive relief against two other companies to prohibit certain activities in connection with that property); *Deauville Associates, Inc. v. Eristavi-Tchitcherine*, 173 F.2d 745 (5th Cir. 1949) (Corporation which was formed after commencement of lawsuit, and which was assignee of alleged interest in subject matter of litigation of parties to lawsuit, was entitled to intervene as of right in action by virtue of Rule 24(a)(2).); *Treasure Salvors, Inc. v. Unidentified Wrecked and Abandoned Sailing Vessel*, 459 F. Supp. 507, 513 (S.D. Fla. 1978) *aff'd in part and rev'd in part on other grounds* 458 U.S. 670, 102 S. Ct. 3304, 73 L. Ed. 2d 1057 (1982) (Florida state agency had a right to intervene in an in rem action brought by treasure-salvage company to confirm its title to a sunken and abandoned vessel); *U.S. Commodity Futures Trading Comm'n v. Giddens*, 2012 U.S. Dist. LEXIS 23728, 2012 WL 603592 at \*7 (N.D. Ga. Feb. 24, 2012) (investor was entitled to intervene in suit by United States Commodity Futures Trading Commission against managers of commodity investment pools alleged to have

misappropriated multiple investor funds where investor sought return of \$80,000.00 he had transferred to managers prior to freezing of assets held by managers and none of the parties objected to intervention). An individual may properly retain their property interests in human tissue by contract. *York v. Jones*, 717 F. Supp. 421, 427 (E.D. Va. 1989) (plaintiffs retained property rights in their frozen embryos pursuant to a written contract); *compare Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F.Supp.2d 1064 (S.D. Fla. 2003) (individuals did not retain a property right in their tissue after it was *donated for medical research*). Here, Applicants maintained their property interest in the subject Stem Cells by contract. Because the Injunction Order requires destruction of Applicants' property, Applicants have a direct, clear, legally protectable interest supporting intervention as a matter of right.

**C. Disposition Of The Action, As A Practical Matter, Will Impede And Impair The Applicants' Ability To Protect Their Interests.**

Under circuit precedent, "[a]ll that is required under Rule 24(a)(2) is that the would-be intervener be practically disadvantaged by his exclusion from the proceedings." *Salvors, Inc.*, 861 F.3d at 1295 (quoting *Huff v. Comm'r of IRS*, 743 F.3d 790, 800 (11th Cir. 2014)); *see also Tech. Training Assocs. v. Buccaneers Ltd. P'ship*, 874 F.3d 692, 696 (11th Cir. 2017) (Individuals may intervene as a matter of right where a judgment in a case will definitively determine individuals' substantive rights). Here, Applicants own the Stem Cells. Any disposition of this action through enforcement of the Injunction Order (in its current broad form) without allowing Applicants' intervention would permanently deprive Applicants of their opportunity to be heard in connection with the deprivation of their property. The fundamental requirements of due process provide that a party must be given an opportunity to be heard before being deprived of their property rights. *See Mullane v. Cent. Hanover Bank & Tr. Co.*, 339 U.S. 306, 313 (1950) ("[A]t a minimum [the Due Process Clause] require[s] that deprivation of life, liberty or property by adjudication be



preceded by notice and opportunity for hearing appropriate to the nature of the case.”). If the Injunction Order is enforced as is, the Stem Cells will be destroyed, Applicants will have been denied their rights to due process under the United States Constitution and the Applicants will be irrevocably denied potentially life-saving medical treatment.

**D. The Applicants For Intervention's Interests Are Represented Inadequately By The Existing Parties To The Suit.**

With respect to the fourth factor, the “requirement of the Rule is satisfied if the applicant shows that representation of his interest ‘may be’ inadequate; and the burden of making that showing should be treated as minimal.” *Clark v. Putnam Cty.*, 168 F.3d 458, 461 (11th Cir. 1999) (quoting *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n. 10, 92 S. Ct. 630, 636 n. 10, 30 L. Ed. 2d 686 (1972)); *Salvors, Inc.*, 861 F.3d at 1295; *Chiles*, 865 F.2d at 1214. The Applicants have carried this minimal burden. Plainly, neither the United States nor US Stem adequately represent Applicants’ interests. The United States is adverse to Applicants having belatedly sought wholesale destruction of the Stem Cells (even though this was never included in the prayer for relief in the Complaint). Meanwhile US Stem has focused its defense on arguments that its Clinic and the procedures practiced therein should not be regulated by the FDA at all. As this Court found, the “subject of this FDA enforcement action is whether Defendant’s SVF product is a ‘drug’ within the meaning of the FDCA, such that the FDA has the authority to regulate its manufacture and sale.” Order dated July 12, 2019 [D.E. 208, p. 5]. In making its defenses, US Stem essentially ignored the status of Applicants’ Stem Cells in storage at the Tissue Bank since this was never an issue in the litigation.

Inadequate representation will most commonly be found when the interests of the existing parties are adverse to, or different from, those of the applicant for intervention. *Thurman v. FDIC*, 889 F.2d 1441 (5th Cir. 1989). *See Stone v. First Union Corp.*, 371 F.3d 1305, 1312 (11th Cir.



2004) (“Although all of the plaintiffs allege to have been subject to the same plan of age discrimination, the manner in which they were discriminated against may not be identical.”); *Karsner v. Lothian*, 532 F.3d 876, 886 (D.C. Cir. 2008) (holding that the Maryland Securities Commissioner had a right to intervene in an action that would have resulted in expunging a customer’s complaint against a securities broker from the Central Registration Depository (“CRD”) because “neither party to the action represents the Commissioner’s interest in protecting the integrity of the CRD”). However, “[a]ny doubt concerning the propriety of allowing intervention should be resolved in favor of the proposed intervenors because it allows the court to resolve all related disputes in a single action.” *Federal Sav. & Loan v. Falls Chase Sp. Taxing Dist.*, 983 F.2d 211, 216 (11th Cir. 1993). Here, interests of Defendant US Stem and Applicants are neither the same nor are they aligned. US Stem cannot assert ownership interests over the Applicants’ Stem Cells, and Applicants have the ability to take their Stem Cells to other companies and/or other jurisdictions where their use is lawful and proper.<sup>5</sup> This, of course, would be contrary to the commercial interests of US Stem as it would lose the business associated with storing the Stem Cells should Applicants exercise this option.

Clearly, the rights of the Applicant owners of the Stem Cells ordered to be destroyed have not been adequately represented by either party to this case as is best evidenced by Paragraph 10 of the Injunction Order which requires the destruction of those Stem Cells. Further, US Stem has taken no concrete steps indicating that it intends to vigorously defend Applicants’ property rights in the Stem Cells on appeal; to date there has been no notice of appeal filed by US Stem, the

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<sup>5</sup> Intervenors are in the process of researching their options with respect to the potential permitted uses of their Stem Cells in jurisdictions where such therapies have been conducted legally. *See, e.g.,* <https://www.cnn.com/2018/04/27/health/jack-nicklaus-stem-cell-therapy/index.html>, reporting on adipose-derived stem cell therapy conducted in Germany.

Injunction Order requires destruction of the Stem Cells *prior to* expiration of the sixty-day appeal period, and the filing of an appeal may not necessarily stay the destruction of Applicants' Stem Cells. Applicants have no control over or say in the decisions that the US Stem Defendants may make with respect to any appeal or the arguments made therein. Applicants, therefore, do not have their interests adequately represented by any party in these proceedings.

Because the Applicants meet all of Rule 24(a)'s criteria for intervention as a matter of right, the Court should grant this Motion and stay destruction of Applicants' Stem Cells.

## **II. Permissive Intervention**

Alternatively, Applicants seek to intervene at the discretion of the Court through Rule 24(b), allowing for permissive intervention. An applicant for permissive intervention must show "(1) his application to intervene is timely; and (2) his claim or defense and the main action have a question of law or fact in common." *Chiles*, 865 at 1213. The Applicants' application meets these criteria. This application is timely for the reasons advanced in support of intervention as a matter of right. Some Applicants first received notice of this litigation on June 6, 2019 and the danger it posed to their Stem Cells became apparent only *after* entry of the Injunction Order on June 25, 2019; otherwise, this Motion would have been filed much earlier in the litigation.

Applicants' efforts to preserve their Stem Cells banked at US Stem unquestionably shares common questions of fact and law with the claims being pursued by the United States against the US Stem Defendants, because Applicants' Stem Cells have been included, by virtue of the broad language in the current form of the Injunction Order, among the SVF Product that is slated for destruction.

WHEREFORE, Applicants respectfully request permission to intervene as intervenors as of right, or alternatively, to intervene through permissive intervention. Applicants further

respectfully request an immediate stay of Paragraph 10 of the Injunction Order requiring destruction of the Stem Cells stored at the Tissue Bank pending adjudication on the merits of Applicants' Complaint in Intervention.

**CERTIFICATE OF GOOD FAITH CONFERENCE**

Pursuant to S.D. Fla. L.R. 7.1(A)(3), undersigned counsel for Applicants hereby certifies that it has conferred with counsel for the United States and the US Stem Defendants in a good faith effort to resolve by agreement the issues raised in this Motion, and Plaintiff United States of America has declined to take any position on the intervention of the Applicants prior to the filing of this motion. Defendants do not oppose the granting of this Motion to Intervene.

Dated this 16th day of July, 2019.

Respectfully submitted,

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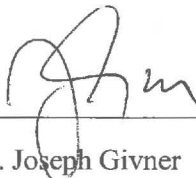
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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on July 16, 2019, a true and correct copy of the foregoing Applicants' Amended Expedited Motion to Intervene and for Stay of Destruction of Applicants for Intervention's Property and Clarification of Order of Permanent Injunction with Incorporated Memorandum of Law and Attached Pleading of Applicants for Intervention was filed with the Clerk of the Court via CM/ECF and the CM/ECF system will send a notice of electronic filing to all counsel and parties of record listed on the Service List Below.



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J. Joseph Givner



**SERVICE LIST**

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