

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION

CARETOLIVE, etc.	:	
	:	
Plaintiff,	:	Case No. C2-07-729
	:	
v.	:	JUDGE FROST
	:	
ANDREW VON ESCHENBACH, etc.	:	Magistrate Judge King
et al.	:	
	:	
Defendants.	:	

MOTION TO DISMISS OF DEFENDANTS  
RICHARD PAZDUR, M.D. AND HOWARD SCHER, M.D.

Defendants Richard Pazdur, M.D. and Howard Scher, M.D. move the Court, pursuant to Rules 12(b)(1), (2), and (6) of the Federal Rules of Civil Procedure, for an Order dismissing Plaintiff’s<sup>1</sup> First Amended Complaint as to them. In addition, Defendants move, pursuant to Rule 21, Federal Rules of Civil Procedure, for an Order dismissing the “Joe Doe” Plaintiff. The Court’s attention is directed to the accompanying memorandum of law.<sup>2</sup>

Respectfully submitted,  
Gregory G. Lockhart  
United States Attorney

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<sup>1</sup> On September 5, 2007, Plaintiff CareToLive as ordered by the Court, filed an Amended Complaint. The Amended Complaint purports to add a “John Doe” as an additional plaintiff. Because the Amended Complaint does not comply with Federal Rule of Civil Procedure 10(a), and Plaintiff did not seek leave of Court to add an anonymous party, Defendants will refer to Plaintiff only.

<sup>2</sup> Drs. Pazdur and Scher, as sued in their individual capacities, incorporate by reference all applicable arguments made in the Motion to Dismiss filed by Defendants in their official capacities including, but not limited to, ripeness, finality, exhaustion, and standing.

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**SUMMARY OF POINTS RAISED  
AND AUTHORITIES CITED**

**INTRODUCTION** ..... 9

42 U.S.C. §§1985 & 1986 ..... 10

**STANDARD OF REVIEW** ..... 11

Rogers v. Stratton Industries, Inc., 798 F.2d 913, 916 (6th Cir. 1986) ..... 11

Estate of Mikinah Smith v. Hamilton County Department of Job and Family  
Services, 2007 WL 2572184 (S.D. Ohio, August 31, 2007) ..... 11

Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) ..... 11

Blackburn v. Fisk University, 443 F.2d 121, 124 (6th Cir. 1974) ..... 11

Lewis v. ACB Business Services, 135 F.3d 389, 405 (6th Cir. 1998) ..... 11

Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955 (2007) ..... 11

Conley v. Gibson, 355 U.S. 41, 45-46 (1957) ..... 11

International Technology Consultants, Inc. v. Euroglas S.A., 107 F.3d 386, 391  
(6th Cir. 1997) ..... 12

Rothschild Berry Farm v. Serendipity Group, LLC, 84 F. Supp. 2d 904, 905 (S.D.  
Ohio 1999) ..... 12

**ARGUMENT** ..... 12

**I. DRS. PAZDUR AND SCHER IN THEIR OFFICIAL CAPACITY ARE NOT PROPER  
PARTIES.** ..... 12

Scott v. Lacy, 811 F.2d 1153 (7th Cir. 1987)(per curiam) ..... 12

Howe v. Bank for Intern. Settlements, 194 F.Supp.2d 6, 19 (D. Mass 2002) ..... 13

Del Raine v. Carson, 826 F.2d 698, 703 (7th Cir. 1987) ..... 13

**II. DRS. PAZDUR AND SCHER MUST BE GRANTED QUALIFIED IMMUNITY IN  
THEIR INDIVIDUAL CAPACITIES AT THIS STAGE OF THE LITIGATION ON  
PLAINTIFF’S CLAIMS THAT THEY VIOLATED THE UNITED STATES  
CONSTITUTION.** ..... 13

Joyner v. Reno, 466 F.Supp.2d 31, 40 (D.D.C. 2006) ..... 13

Mahmud v. Oberman, 2007 WL 1799643 (N.D. Ga., June 19, 2007) ..... 13

Harlow v. Fitzgerald, 457 U.S. 800, 814-16 (1982) ..... 13

Cameron v. Thornburgh, 983 F.2d 253, 258 (C.A.D.C. 1993) ..... 13

Saucier v. Katz, 533 U.S. 194, 200-01 (2001) ..... 14

Hunter v. Bryant, 502 U.S. 224, 227 (1991) ..... 14

Behrens v. Pelletier, 516 U.S. 299, 306 (1996) ..... 14

Mitchell v. Forsyth, 472 U.S. 511, 526 (1985) ..... 14

Hope v. Peltzer, 536 U.S. 730, 739, 742 (2002) ..... 14

Siegert v. Gilley, 500 U.S. 226, 232 (1991) ..... 14

Ciminillo v. Streicher, 434 F.3d 461, 466 (6th Cir. 2006) ..... 14

Radvansky v. City of Olmstead Falls, 395 F.3d 291, 302 (6th Cir. 2005) ..... 14

Brosseau v. Haugen, 543 U.S. 194, 198 (2004) ..... 15

Anderson v. Creighton, 483 U.S. 635, 640 (1987) ..... 15

Spagnola v. Mathis, 809 F.2d 16, 30 (D.C. Cir. 1986) ..... 15

Silberstein v. City of Dayton, 440 F.3d 306, 311 (6th Cir. 2006) ..... 15

A. Plaintiff’s Allegations Fail to Show Any Constitutional Violation ..... 15

Abigail Alliance v. von Eschenbach, 495 F.3d 695 (C.A.D.C. 2007) ..... 16

Abigail Alliance v. McClellan, 2004 WL 3777340 (D.D.C., Aug. 30, 2004) ..... 17

Washington v. Glucksberg, 521 U.S. 702, 720-21 (1997) ..... 17

Collins v. Harker Heights, 503 U.S. 115, 125 (1992) ..... 17-18

Gonzales v. Raich, 545 U.S. 1, 28 (2005) ..... 18

United States v. Rutherford, 442 U.S. 544, 552 (1979) ..... 18

United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483, 490  
(2001) ..... 18

Rutherford v. United States, 616 F.2d 455,457 (10<sup>th</sup> Cir.) ..... 19

Mitchell v. Clayton, 995 F.2d 772, 775 (7<sup>th</sup> Cir. 1993) ..... 19

United States v. Burzynski Cancer Research Inst., 819 F.2d 1301, 1313-14  
(5<sup>th</sup> Cir. 1987) ..... 19

Carnohan v. United State, 616 F.2d 1120, 1122 (9<sup>th</sup> Cir. 1980) ..... 19

Trihealth, Inc. v. Bd. of Comm’rs, 430 F.3d 783, 788 (6<sup>th</sup> Cir. 2005) ..... 20

Jackson v. Jamrog, 411 F.3d 615, 618 (6<sup>th</sup> Cir. 2005) ..... 20

Bray v. Alexandria Women’s Health Clinic, 506 U.S. 263, 271-72 (1993) ..... 20

Mass. Bd. of Retirement v. Murgia, 427 U.S. 307, 314 (1976) ..... 20

B. Even if Plaintiff’s Allegations Showed a Violation of Any Constitutional Rights, Such Rights  
Were Not “Clearly Established.” ..... 20

Sallier v. Brooks, 343 F.3d 868, 878 (6th Cir. 2003) ..... 20

Scott v. Clay Cty., 205 F.3d 867, 873-74 n. 9 (6th Cir. 2000) ..... 21

Malley v. Briggs, 475 U.S. 335, 341 (1986) ..... 21

Gragg v. Kentucky Cabinet for Workforce Development, 289 F.3d 958, 964 (6th  
Cir. 2002) ..... 21

Saylor v. Bd. of Educ. of Harlan County, 118 F.3d 507, 515 (6th Cir.1997) ..... 21

Akers v. McGinnis, 352 F.3d 1030, 1042 (6th Cir. 2003) ..... 21

Dominique v. Telb, 831 F. 2d 673, 676 (6<sup>th</sup> Cir. 1987) ..... 22

Davis v. Scherer, 468 U.S. 183, 192-96 & n.12 (1984) ..... 21

**III. THE COURT LACKS PERSONAL JURISDICTION OVER THESE DEFENDANTS. .... 22**

Ins. Corp. of Ireland v. Compagnie des Bauxites de Guinee, 456 U.S. 694, 701 (1982) ..... 22

Ruhgras AG v. Marathon Oil Co., 526 U.S. 574, 584 (1999) ..... 22

Bird v. Parsons, 289 F.3d 865, 871 (6th Cir. 2002) ..... 22

Ecclesiastical Order of the Ism of Am, Inc. v. Chasin, 845 F.2d 113, 116 (6th Cir. 1988) ..... 22

42 U.S.C. §§1985 & 1986 ..... 23

Caphalon Corp. v. Rowlette, 228 F.3d 718, 721 (6th Cir. 2000) ..... 23

Nationwide Mutual Ins. Co. v. Tryg Int’l Ins. Co., 91 F.3d 790, 793 (6<sup>th</sup> Circ. 1993) ..... 23

International Shoe Co. v. Washington, 326 U.S. 310, 316 (1945) ..... 23

Burger King Corp. v. Rudzewicz, 471 U.S. 462, 471-72 (1985) ..... 24

Helicopteros Nacionales de Columbia v. Hall, 466 U.S. 408, 414 and n.8 (1984) ..... 24

Southern Machine Co. v. Mohasco Indus., Inc., 401 F.2d 374, 381 (6<sup>th</sup> Cir. 1968) ..... 24

World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980) ..... 25

Third Nat’l Bank in Nashville v. WEDGE Group, In., 882 F.2d 1087, 1089 (6<sup>th</sup> Cir. 1989) ..... 25

**IV. PLAINTIFF FAILS TO STATE A CLAIM UNDER 42 U.S.C. §1985 & §1986 ..... 26**

42 U.S.C. §1985(3) ..... 27

42 U.S.C. §1986 ..... 27

Bass v. Robinson, 167 F.3d 1041, 1050-51 n.5 (6<sup>th</sup> Cir. 1999) ..... 27

Estate of Bing v. City of Whitehall, 373 F. Supp. 2d 770 (S.D. Ohio 2005) ..... 27

Vakilian v. Shaw, 335 F.3d 509, 518 (6th Cir. 2003) ..... 28

United Bhd. of Carpenters & Joiners of Am. v. Scott, 463 U.S. 825, 828-29 (1983) ..... 28

Griffin v. Breckenridge, 403 U.S. 88, 102 (1971) ..... 28

Bray v. Alexandria Women's Health Clinic, 506 U.S. 263, 267-68 (1993) ..... 28

Newell v. Brown, 981 F.2d 880, 886 (6<sup>th</sup> Cir. 1992) ..... 28

Bartell v. Lohiser, 215 F.3d 550 (6<sup>th</sup> Cir. 2000) ..... 29

Browder v. Tipton, 630 F.2d 1149, 1150 (6<sup>th</sup> Cir. 1980) ..... 29

Lucas v. City of Ludlow, Kentucky, Civ. No. 05-52, 2005 U.S. Dist. LEXIS 33271 7 (E.D. Ky. Dec. 15, 2005) ..... 29

Center for Bio-ethical Reform, Inc. v. City of Springboro, 477 F.3d 807, 831 (6th

Cir. 2007) ..... 29  
 Gutierrez v. Lynch, 826 F.2d 1534, 1538-39 (6th Cir. 1987) ..... 29  
 Lanier v. Bryant, 332 F.3d 999, 1007 (6th Cir. 2003) ..... 29  
 Majeske v. Fraternal Order of Police, 94 F.3d 307, 311 (7<sup>th</sup> Cir. 1996) ..... 30  
 Federer v. Gephardt, 363 F.3d 754, 758 (8th Cir. 2004) ..... 31

**V. PLAINTIFF FAILS TO STATE A CLAIM FOR “INTERFERENCE WITH AID”** ..... 31

Paul v. Davis, 424 U.S. 692, 713 (1976) ..... 32  
 Correctional Services Corp. V. Malesko, 534 U.S. 61, 74 (2001) ..... 32

**VI. PLAINTIFF’S STATE LAW TORT CLAIMS MUST BE DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION** ..... 33

28 U.S.C. §§2671-2680 ..... 33  
 28 U.S.C. §2679(b)(1) ..... 33  
 28 U.S.C. §2679(d)(1) ..... 33  
 Osborn v. Haley, U.S. \_\_\_, 127 S. Ct. 881, 887 (2007) ..... 33  
 Celestine v. Mount Vernon Neighborhood Health Center,  
 403 F.3d 76, 80 (2d Cir. 2005) ..... 33  
 28 C.F.R. § 15.4 ..... 34  
 28 U.S.C. § 2679(d)(1) ..... 34  
 28 U.S.C. § 2679(a), (d)(1) & (4) ..... 34  
 United States v. Smith, 499 U.S. 160,166 (1991) ..... 34  
 28 U.S.C. § 2675(a) ..... 34  
 McNeil v. United States, 508 U.S. 106, 107, 113 (1993) ..... 34  
 Singleton v. United States, 277 F.3d 864, 872-73 (6<sup>th</sup> Cir. 2001) ..... 34

**VII. PLAINTIFF FAILS TO STATE A CLAIM FOR “WRONGFUL DEATH.”** ..... 35

Ohio Rev. Code Ann. § 2125.02 ..... 35  
 Citizens for a Strong Ohio v. Marsh, 123 Fed.Appx. 630, 636, 2005  
 WL 14986 (6<sup>th</sup> Cir. 2005) ..... 35-36  
 Doe v. Porter, 370 F.3d 558, 560 (6<sup>th</sup> Cir. 2004) ..... 36  
 Nat’l Commodity & Barter Ass’n, Nat’l Commodity Exch. v. Gibbs, 886  
 F.2d 1240, 1245 (10<sup>th</sup> Cir.1989) ..... 36

**VIII. PLAINTIFF FAILS TO STATE A CLAIM FOR TORT RELIEF AGAINST DR. SCHER.** ..... 37

Wentwood Woodside I LP v. GMAC Commer. Mortg. Corp., 419 F.3d  
 310, 319 (5<sup>th</sup> Cir. 2005) ..... 37

**CONCLUSION** ..... 38

MEMORANDUM IN SUPPORT OF MOTION

INTRODUCTION

On September 5, 2007, Plaintiff, allegedly an association of prostate cancer patients, cancer patients, patient families, doctors, investors, and advocates, filed its Amended Complaint. Plaintiff objects to the United States Food and Drug Administration's ("FDA") failure to approve the biologics license application ("BLA") for Provenge, a biological product intended to treat a particular type of metastatic prostate cancer. Like its predecessor, the Amended Complaint names as Defendants Richard Pazdur, M.D. ("Dr. Pazdur") and Howard Scher, M.D. ("Dr. Scher") (or collectively, "Drs. Pazdur and Scher"), in both their official and individual capacities.<sup>3</sup> Dr. Pazdur is the Director of the Office of Oncologic Drug Products in FDA's Center for Drug Evaluation and Research ("CDER"). Dr. Scher was a special government employee who served on the FDA Advisory Committee that considered the Provenge BLA.

Although the allegations in the Amended Complaint are not entirely clear, Plaintiff claims that Dr. Pazdur: intentionally violated "Federal Regulations and US Law by improperly controlling the makeup of the FDA [Cellular, Tissue and Gene Therapies] Advisory Committee, and applying improper pressure on Committee members" in an effort to deny due process for the BLA for Provenge; purposely placed on the Advisory Committee two oncologists who had

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<sup>3</sup> As will be shown *infra*, neither Dr. Pazdur nor Dr. Scher, as named in their official capacities, are necessary parties for the injunctive relief Plaintiff seeks, since it is the federal agency that would have to act if the requested relief were granted. Plaintiff appears to have neglected the instruction of the Court, offered during the Rule 65.1 informal conference held on August 29, 2007, that in preparing its Amended Complaint Plaintiff should carefully look at who it wants to name as defendants and in what capacities. Given the established law concerning injunctive relief against the government, the naming of Drs. Pazdur and Scher in their official capacities merely forces the Court and the government to unnecessarily address issues that Plaintiff, without any prejudice to its case, could have easily avoided.

conflicts of interest and who Dr. Pazdur was sure would be opposed to the approval of Provenge; prior to the vote, changed the question posed to the Advisory Committee members to get them to recommend against approval of Provenge; and “recruited and illegally used FDA employees” at and after the Advisory Committee meeting to assist Dr. Pazdur in wrecking the Provenge BLA by requesting anti-Provenge letters and “design[ing] a method for ‘leaking’ them to the press.” Dr. Scher is alleged to have “fail[ed] to disclose Conflicts of Interest that would have placed FDA on notice that his own personal interests provided him additional reasons” to be opposed to the immediate approval of the Provenge BLA; written a letter attacking Provenge that contained false information and that was later “leaked to the press”; and failed to exercise care in the responsibility he undertook to aid patients.

Based on these allegations, Plaintiff asserts claims against Drs. Pazdur and Scher in their individual capacities based on Due Process and Equal Protection, 42 U.S.C. §§1985 & 1986, the Ohio wrongful death statute (by a “John Doe” Plaintiff), interference with rescue efforts of third parties, and (Dr. Scher only) the Restatement of Torts (Second) §323 (Good Samaritan).

Plaintiff has failed to state a claim upon which relief can be granted for any of these claims. Moreover, the Court is without subject matter jurisdiction to hear Plaintiff’s state law tort claims. In addition, Plaintiff has failed to allege any basis for asserting personal jurisdiction over the individual defendants in this court. All claims against Drs. Pazdur and Scher should therefore be dismissed.

### STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(1) provides that a defense asserting lack of subject matter jurisdiction may be made by motion, and plaintiff has the burden of proving jurisdiction to survive the motion. See Rogers v. Stratton Industries, Inc., 798 F. 2d 913, 916 (6th Cir. 1986).

A motion to dismiss pursuant to Rule 12(b)(6) operates to test the sufficiency of the complaint. Estate of Mikinah Smith v. Hamilton County Department of Job and Family Services, 2007 WL 2572184 at \*3 (S.D. Ohio, August 31, 2007). When ruling on a Rule 12(b)(6) motion, a court is required to construe the pleading in the light most favorable to the plaintiff, and accept as true plaintiff's well-pleaded facts. Id. (citing Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). "A court, however, will not accept conclusions of law or unwarranted inferences which are presented as factual allegations." Id. (citing Blackburn v. Fisk University, 443 F.2d 121, 124 (6th Cir. 1974)). "A complaint must contain either direct or reasonable inferential allegations that support all material elements necessary to sustain a recovery under some viable legal theory." Id. citing Lewis v. ACB Business Services, 135 F.3d 389, 405 (6th Cir. 1998). As the Supreme Court recently held in Bell Atlantic Corp. v. Twombly, 550 U.S. \_\_\_, 127 S.Ct. 1955 (2007), a complaint must be dismissed for failure to state a claim upon which relief can be granted if it does not plead "enough facts to state a claim to relief that is plausible on its face." Id. at 1974 (rejecting the traditional 12(b)(6) standard set forth in Conley v. Gibson, 355 U.S. 41, 45-46...(1957)). To survive a motion to dismiss, the factual allegations in the complaint "must be enough to raise a right to relief above the speculative level..." Id. at 1965. Plaintiff's Amended Complaint is replete with conclusory allegations and unwarranted

inferences presented as factual allegations, and cannot survive a Motion to Dismiss under Rule 12(b)(6).

A plaintiff has the burden of showing personal jurisdiction when there is a motion to dismiss for a lack of personal jurisdiction under Fed.R.Civ.P. 12(b)(2). Int'l Tech. Consultants, Inc. v. Euroglas S.A., 107 F.3d 386, 391 (6th Cir. 1997). When there is a motion to dismiss for lack of personal jurisdiction and no hearing is conducted, “the court must consider the pleadings and affidavits in a light most favorable to the plaintiff. To defeat such a motion, the plaintiff need only make a prima facie showing of jurisdiction.” Rothschild Berry Farm v. Serendipity Group, LLC, 84 F.Supp.2d 904, 905 (S.D. Ohio 1999).

#### ARGUMENT

##### I. DRS. PAZDUR AND SCHER IN THEIR OFFICIAL CAPACITY ARE NOT PROPER PARTIES.

Drs. Pazdur and Scher are named both in their official and individual capacities. As a matter of law, equitable relief for violations of federal rights is not available from government officials, current or former, in their individual capacities. “As a practical matter, a public official who is a defendant in a suit seeking an injunction is not ‘on trial’ at all. The suit seeks relief against him in his official capacity...” Scott v. Lacy, 811 F.2d 1153 (7<sup>th</sup> Cir. 1987) (per curiam).

Courts consistently look past language in pleadings naming employees where the government’s own interests are at stake. “Regardless of the manner by which the plaintiff designates the action, a suit should be regarded as an official capacity suit, subject to the defense of sovereign immunity, when a ‘judgment sought would expend itself on the public treasury or domain, or interfere with the public administration, or if the effect of the judgment would be to

restrain the Government from acting, or compel it to act.” Howe v. Bank for Intern. Settlements, 194 F.Supp.2d 6, 19 (D. Mass 2002).

A suit that seeks equitable relief “that only officials and not private individuals...can provide is a suit against the United States.” Del Raine v. Carson, 826 F.2d 698, 703 (7<sup>th</sup> Cir. 1987). Only by acting as a government official (i.e., not as an individual), can a defendant officer comply with a court decree by altering government policy or practice.

Neither Dr. Pazdur, an employee of CDER, nor Dr. Scher, a member of the Advisory Committee, would be the individuals ordered to act on behalf of the FDA if this Court were to order injunctive relief, since neither have authority to approve the Provenge BLA. As such, their presence in this suit in their official capacities is unnecessary, and all claims against them in their official capacity should be dismissed.

II. DRS. PAZDUR AND SCHER MUST BE GRANTED QUALIFIED IMMUNITY IN THEIR INDIVIDUAL CAPACITIES AT THIS STAGE OF THE LITIGATION ON PLAINTIFF’S CLAIMS THAT THEY VIOLATED THE UNITED STATES CONSTITUTION.<sup>4</sup>

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<sup>4</sup> Courts often hold that they cannot reach the issue of qualified immunity where personal jurisdiction is lacking. See, e.g. Joyner v. Reno, 466 F.Supp.2d 31, 40 (D.D.C. 2006). There is support, however, for the notion that qualified immunity may be addressed first. See Mahmud v. Oberman, 2007 WL 1799643 (N.D. Ga., June 19, 2007). In the context of the claims raised by Plaintiff in the instant case, the direction of the Supreme Court in Harlow v. Fitzgerald, 457 U.S. 800, 814-16 (1982), that insubstantial claims should not proceed to trial should be followed. In Cameron v. Thornburgh, 983 F. 2d 253, 258 (C.A.D.C. 1993), the court (weighing transfer as opposed to personal jurisdiction) held that “we would frustrate the Supreme Court’s intentions in developing the whole doctrine of qualified immunity (which is intended to enable lower courts ‘expeditiously to weed out’ insubstantial Bivens actions)...were we to transfer these frivolous claims...We think it plainly not in the interests of justice to further prolong the exposure of (defendants) to personal liability in this litigation.” Accordingly, the personal capacity claims raised by Plaintiff in this case should not proceed beyond this motion.

Qualified immunity protects government officials performing discretionary functions from suit for damages as long as their conduct “does not violate clearly established statutory or constitutional rights of which a reasonable person would have known.” Harlow, 457 U.S. at 18–19. Qualified immunity “is an immunity from suit rather than a mere defense to liability.” Saucier v. Katz, 533 U.S. 194, 200–01 (2001). Thus, the Supreme Court “repeatedly ha[s] stressed the importance of resolving immunity questions at the earliest possible stage in litigation.” Hunter v. Bryant, 502 U.S. 224, 227 (1991) (citing Harlow, 457 U.S. at 818). It is well settled that “[u]nless the plaintiff’s allegations state a claim of violation of clearly established law, a defendant pleading qualified immunity is entitled to dismissal before the commencement of discovery.” Behrens v. Pelletier, 516 U.S. 299, 306 (1996) (quoting Mitchell v. Forsyth, 472 U.S. 511, 526 (1985)).

The Supreme Court has instructed courts to use a two part test to assess qualified immunity. Saucier, 533 U.S. at 201. The “initial inquiry” must be whether the officer’s alleged conduct violated a constitutional right. Id. If no constitutional right was violated, then “there is no necessity for further inquiries concerning qualified immunity.” Id. “The next, sequential step is to ask whether the right was clearly established.” Id. The “salient question” is whether the officer had “fair warning” or “fair notice” that his alleged actions would violate the law. Hope v. Peltzer, 536 U.S. 730, 739, 742 (2002). The Supreme Court has warned against skipping ahead to the second step and instead insisted that whether a plaintiff has alleged a violation of a constitutional right should be resolved first. Siegert v. Gilley, 500 U.S. 226, 232 (1991).<sup>5</sup> The

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<sup>5</sup> The Sixth Circuit has used both the two-step test and a three-step test in assessing qualified immunity. See Ciminillo v. Streicher, 434 F.3d 461, 466 (6th Cir. 2006) (two-step test); Radvansky v. City of Olmstead Falls, 395 F.3d 291, 302 (6th Cir. 2005) (three-step test).

qualified immunity “inquiry must be undertaken in light of the specific context of the case, not as a broad general proposition.” Brosseau v. Haugen, 543 U.S. 194, 198 (2004). Further, “[t]he contours of the right” must be sufficiently clear so that a reasonable official would understand that his conduct violated an individual’s rights. Anderson v. Creighton, 483 U.S. 635, 640 (1987). Where a plaintiff fails to demonstrate a clear violation of a constitutional or statutory right, or where the individual official was not on notice that his conduct was unlawful, the qualified immunity defense will be sustained. See Spagnola v. Mathis, 809 F.2d 16, 30 (D.C. Cir. 1986).

The plaintiff bears the burden of rebutting qualified immunity once a defendant has raised the defense. See Silberstein v. City of Dayton, 440 F.3d 306, 311 (6th Cir. 2006) (“Once the qualified immunity defense is raised, the burden is on the plaintiff to demonstrate that the officials are not entitled to qualified immunity.”). Because Plaintiff has failed to identify a cognizable liberty or property interest or otherwise properly plead a constitutional violation, Plaintiff cannot meet the standard for overcoming qualified immunity.

A. Plaintiff’s Allegations Fail to Show Any Constitutional Violation

As discussed in more detail in the Motion to Dismiss filed by all of the official capacity Defendants, Plaintiff has failed to allege a cognizable due process or equal protection claim. In

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The three-step version asks “(I) ‘whether, based upon the applicable law, the facts viewed in the light most favorable to the plaintiffs show that a constitutional violation has occurred;’ (ii) ‘whether the violation involved a clearly established constitutional right of which a reasonable person would have known;’ and (iii) ‘whether the plaintiff has offered sufficient evidence to indicate that what the official allegedly did was objectively unreasonable in light of the clearly established constitutional rights.’” Radvansky, 395 F.3d at 302.

an attempt to state a substantive due process claim Plaintiff, in conclusory fashion, references the following “rights” in its Amended Complaint:

¶ 3 - “[T]he right to life of prostate cancer patients;” “[the] absolute right to fight for their lives”

Count 1, ¶ E - “[the right] ...to protect their own life, to live...”

Count 1, ¶ F - “The Right to Preserve...Life (The Right of Self Preservation)”

“The Right to Privacy.”

“The Right to Personal Dignity and Autonomy.”

“The Right to Self Defense.”

“The Right not to have interference with the attempted aid by others.”

“A Right of control over one’s body.”

“Rights implicit in the concept of ordered liberty.”

“Life, Liberty and the Pursuit of Happiness.”

Many of the same or similar claims were raised by plaintiffs and rejected by the United States Court of Appeals for the District of Columbia, sitting en banc, in Abigail Alliance v. von Eschenbach, 495 F. 3d 695 (D.C. Cir. 2007). In that case, a group of terminally ill cancer patients sought unfettered access to unapproved drugs and alleged that FDA regulations and policy barring such access violated their substantive due process rights. On August 7, 2007, the en banc court ruled, in an 8-2 decision, that the claims were properly dismissed. Both the history of that case and the D.C. Circuit en banc opinion are significant to this Court’s consideration of the issues presented by Plaintiff because they demonstrate that, at all times relative to the instant

suit, Plaintiff has not—and cannot—allege the violation of any constitutional right, let alone allege the violation of a constitutional right that was “clearly established.”<sup>6</sup>

On August 30, 2004, the United States District Court for the District of Columbia dismissed the Abigail Alliance suit, denying plaintiff’s claimed violations of privacy and liberty rights and holding that there is no constitutional right of access to unapproved drugs. Abigail Alliance v. McClellan, 2004 WL 3777340 (D.D.C., Aug. 30, 2004). On May 2, 2006, a divided three judge panel reversed. However, on November 21, 2006, the Court of Appeals for the District of Columbia vacated the decision, and granted rehearing en banc. See 445 F.3d 470 (D.C. Cir. 2006). Thus, during the operative period for the matters raised in this case, i.e., between March 29, 2007 (the Advisory Committee meeting) and May 9, 2007 (the Complete Response letter from the FDA to Dendreon), the only Abigail Alliance decision was the District Court’s 2004 dismissal.

On August 7, 2007, in its 8-2 en banc decision, the Court of Appeals affirmed the district court. Abigail Alliance, 495 F. 3d 695. The Court concluded that “there is no fundamental right ‘deeply rooted in this Nation’s history and tradition’ of access to experimental drugs for the terminally ill,” Id. at 697, citing Washington v. Glucksberg, 521 U.S. 702, 720-21 (1997). The Court of Appeals noted that “the Supreme Court has cautioned against expanding the substantive rights protected by the Due Process Clause ‘because guideposts for responsible decisionmaking in this uncharted area are scarce and open-ended,’” Id. at 702, citing Collins v. Harker Heights,

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<sup>6</sup> Indeed, Plaintiff cites no case which supports the notion that Defendants violated a clearly established constitutional right, of which a reasonable person should have known, in its discussion of the requirement to show likelihood of success on the merits in its Motion for Preliminary Injunction. This speaks volumes in the context of qualified immunity.

503 U.S. 115, 125 (1992). The Court also expressed the concern that “[b]y extending constitutional protection to the asserted right or liberty interest, we, to a great extent, place the matter outside the arena of public debate and legislative action,” *Id.*, citing *Glucksberg*, 521 U.S. at 720. Thus, the Court of Appeals in *Abigail Alliance* was mindful to “exercise the utmost care whenever we are asked to break new ground in this field, lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the [court’s members].” *Id.*

The *Abigail Alliance* en banc Court rejected plaintiff’s arguments of “necessity,” “intentional interference with rescue,” and “self defense.” Further, the Court noted that the Supreme Court has rejected several similar challenges to the [Federal Food, Drug, and Cosmetic Act] and related laws brought on statutory grounds, citing *Gonzales v. Raich*, 545 U.S. 1, 28 (2005) (“the dispensing of new drugs, even when doctors approve their use, must await federal approval”), *United States v. Rutherford*, 442 U.S. 544, 552 (1979) (“we are persuaded by the legislative history and consistent administrative interpretation of the [FDCA] that no implicit exemption for drugs used by the terminally ill is necessary to obtain congressional objectives”), and *United States v. Oakland Cannabis Buyers’ Cooperative*, 532 U.S. 483, 490 (2001) (“with respect to whether there is an implied ‘medical necessity’ exemption to prosecution for marijuana use under the Controlled Substances Act... ‘[w]hether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial interference.’”).<sup>7</sup>

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<sup>7</sup> Indeed, the *Abigail Alliance* en banc Court acknowledged that the plaintiff group “can, of course, advocate its position vigorously before Congress and the FDA, and convince our Nation’s democratic branches that the values the Alliance favors should be protected.” *Id.* at n 17. In the instant case, Plaintiff is, of course, similarly free to advocate its positions in an effort to convince Congress and the FDA, and in fact members participated in a rally at the FDA on

The court also noted that “[n]o circuit court has acceded to an affirmative access claim.” *Id.* at 710, n. 18.<sup>8</sup> See also Rutherford v. United States, 616 F.2d 455, 457 (10th Cir.) (rejecting terminally ill cancer patients’ asserted constitutional right of access to unapproved drugs, and holding that “the patient[’s]...selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health”), cert. denied, 449 U.S. 937 (1980); Mitchell v. Clayton, 995 F.2d 772, 775 (7th Cir. 1993) (“a patient does not have a constitutional right to obtain a particular type of treatment or to obtain treatment from a particular provider”); United States v. Burzynski Cancer Research Inst., 819 F.2d 1301, 1313-14 (5th Cir. 1987) (patients had no “constitutional right to obtain medical treatment that is encompassed by their right to privacy”); Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980) (“Constitutional rights of privacy and personal liberty do not give individuals the right to obtain [an unapproved drug] free of the lawful exercise of government police power.”).

Also as discussed in more detail in the Motion to Dismiss filed by all of the official capacity Defendants, Plaintiff has failed to establish any basis for its claim that FDA’s handling of the Provenge application violated the Equal Protection Clause of the United States Constitution. Under equal protection analysis, government action need bear only a rational relationship to a legitimate state interest unless it “burdens a fundamental right, targets a suspect class, or intentionally treats one differently than others similarly situated without any rational

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September 18, 2007. See [www.caretolive.com](http://www.caretolive.com).

<sup>8</sup> Even if the Abigail Alliance en banc decision of August 7, 2007 had been resolved in favor of the plaintiff, the only decision in effect at the time the Defendants in the instant case are alleged to have acted was the district court decision of 2004.

basis for the difference.” Trihealth, Inc. v. Bd. of Comm’rs, 430 F.3d 783, 788 (6th Cir. 2005); see also Jackson v. Jamrog, 411 F.3d 615, 618 (6th Cir. 2005). Further, to demonstrate discrimination against either a suspect class or an individual in violation of the Constitution, a plaintiff must show discriminatory purpose. Bray v. Alexandria Women’s Health Clinic, 506 U.S. 263, 271-72 (1993). Here, however, Plaintiff has failed to allege either a fundamental right (as shown above) or a discriminatory purpose.

Because CareToLive has failed to allege facts that would subject its equal protection claims to heightened scrutiny, any alleged government classification is reviewed under a rational basis standard, which is “a relatively relaxed standard,” under which the government classification is “presumed to be valid.” Mass. Bd. of Retirement v. Murgia, 427 U.S. 307, 314 (1976). The only supposed “classification” even involved here is that FDA evaluates each drug and biologic application individually. Certainly, it is rational for FDA to treat each biologic and drug approval application on its own merits, evaluate the data in each application, and approve the application only when the approval standards are satisfied. See Abigail Alliance, 495 F.3d at 713 (“...prior to distribution of a drug outside of controlled studies, the government has a rational basis for ensuring that there is a scientifically and medically acceptable level of knowledge about the risks and benefits of such a drug.”)

Abigail Alliance clearly stands for the proposition that no substantive due process rights as alleged by Plaintiff were recognized at the time of the alleged violation (and indeed do not exist today). Likewise, Plaintiff has not stated an equal protection claim under well established Supreme Court and Sixth Circuit precedent.

- B. Even if Plaintiff’s Allegations Showed A Violation of Any Constitutional Rights, Such Rights Were Not “Clearly Established.”

Even assuming arguendo that Plaintiff has made allegations sufficient to meet its burden of alleging a Constitutional violation, it fails to meet its additional burden of showing that the contours of the claimed rights were sufficiently clear to put Drs. Pazdur and Scher on notice that their alleged actions crossed a constitutional bright line. Sallier v. Brooks, 343 F.3d 868, 878 (6th Cir. 2003) (“Qualified immunity is a purely legal question . . . and a plaintiff bears the burden of proving that a clearly established right existed at the time a defendant’s actions took place.”). The defense of qualified immunity “sweeps broadly” and gives “ample room for mistaken judgments.” Scott v. Clay Cty., 205 F.3d 867, 873-74 n. 9 (6th Cir.2000) (quoting Malley v. Briggs, 475 U.S. 335, 341 (1986)).

To determine whether rights were clearly established, binding precedent from the Supreme Court or the Sixth Circuit must “dictate, that is, truly compel (not just suggest or allow or raise a question about) the conclusion for every like-situated, reasonable government agent that what the defendant is doing violates federal law *in the circumstances*.” Gragg v. Kentucky Cabinet for Workforce Development, 289 F.3d 958, 964 (6th Cir. 2002) (quoting Saylor v. Bd. of Educ. of Harlan County, 118 F.3d 507, 515 (6th Cir.1997)).<sup>9</sup> If a reasonable official would not have understood his conduct to violate a clearly established constitutional right, qualified immunity must be granted. Akers v. McGinnis, 352 F.3d 1030, 1042 (6th Cir. 2003) (holding that the relevant question is “whether any officer in the defendant’s position, measured

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<sup>9</sup> It is well settled that violations of some authoritative source other than the Constitution, such as statutes that do not supply the cause of action for damages, regulations, or manual provisions, cannot be used to deny qualified immunity, even if they advance important interests or are designed to protect constitutional rights. See Davis v. Scherer, 468 U.S. 183, 192-96 & n.12 (1984).

objectively...would have clearly understood that he was under an affirmative duty to have refrained from such conduct.” (quoting Dominique v. Telb, 831 F. 2d 673, 676 (6th Cir. 1987)).

Plaintiff can point to no binding precedent from the United States Supreme Court or the Sixth Circuit Court of Appeals—or any court for that matter—that clearly established either a due process right or an equal protection right such that the law would put Drs. Pazdur and Scher on fair notice that their alleged conduct violated the United States Constitution.<sup>10</sup> Accordingly, they must be granted qualified immunity.

### III. THE COURT LACKS PERSONAL JURISDICTION OVER THE INDIVIDUAL DEFENDANTS.

Where, as here, a plaintiff seeks money damages from the personal financial assets of a federal employee, the court must obtain personal jurisdiction over the defendant before it can issue a binding judgment. “The validity of an order of a federal court depends upon that court’s having jurisdiction over both the subject matter and the parties.” Ins. Corp. of Ireland v. Compagnie des Bauxites de Guinee, 456 U.S. 694, 701 (1982). Without personal jurisdiction, the Court is “powerless to proceed to an adjudication.” Ruhgras AG v. Marathon Oil Co., 526 U.S. 574, 584 (1999). Plaintiff bears the burden of proving that there is personal jurisdiction over the Defendants in their individual capacity. Bird v. Parsons, 289 F.3d 865, 871 (6<sup>th</sup> Cir. 2002); see also Ecclesiastical Order of the Ism of Am, Inc. v. Chasin, 845 F.2d 113, 116 (6th Cir. 1988) (when damage claims are asserted individually against federal employees seeking

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<sup>10</sup> Drs. Pazdur and Scher raise the defense of qualified immunity for each and every claim alleged in the Amended Complaint to the extent it is construed as a constitutional claim or to allege a violation of federal statutory rights. See Part II. *infra*.

recovery against their personal resources, a plaintiff is required to plead facts establishing that the court has personal jurisdiction over the employees). Because the Amended Complaint's allegations fail to make even a prima facie showing of personal jurisdiction over Drs. Pazdur and Scher in their individual capacities, all claims against them in their individual capacities should be dismissed.<sup>11</sup>

The exercise of personal jurisdiction is valid only if it meets both the Ohio long-arm statute and constitutional due process requirements. Calphalon Corp. V. Rowlette, 228 F.3d 718, 721 (6<sup>th</sup> Cir. 2000) (citing Nationwide Mutual Ins. Co. v. Tryg Int'l Ins. Co., 91 F.3d 790, 793 (6<sup>th</sup> Cir. 1993)). The Ohio long-arm statute "does not extend to the constitutional limits of the Due Process Clause." Id. Nonetheless, "in evaluating whether personal jurisdiction is proper under Ohio's long-arm statute," the Sixth Circuit has "consistently focused on whether there are sufficient minimum contacts between the nonresident defendant and the forum state so as not to offend 'traditional notions of fair play and substantial justice.'" Bird, 289 F.3d at 871 (quoting International Shoe Co. v. Washington, 326 U.S. 310, 316 (1945)).

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<sup>11</sup> The same analysis applies to Plaintiff's constitutional claims and 42 U.S.C. §§1985 & 1986 claims. It would apply to Plaintiff's state law tort claims against Drs. Pazdur and Scher only if the Court determined that Drs. Pazdur and Scher were not in fact within the scope of their employment. With respect to Plaintiff's state law tort claims, the United States Attorney has certified that Drs. Pazdur and Scher were within the scope of their employment, the United States has been substituted for these individuals by operation of law and the United States is the only proper party to any state law tort claim alleged in this Court. See 28 U.S.C. § 2679(a)-(d); Doc. 34 and 35. If the Court were to determine that Drs. Pazdur and Scher were in fact not in the scope of employment, then personal jurisdiction would be lacking with respect to these claims as well.

Plaintiff has not pled sufficient minimum, or indeed, any, contacts by Drs. Pazdur and Scher to satisfy the constitutional prerequisites of personal jurisdiction. “The Due Process Clause protects an individual's liberty interest in not being subject to the binding judgments of a forum with which he has established no meaningful contacts, ties, or relations.” Burger King Corp. v. Rudzewicz, 471 U.S. 462, 471-72 (1985) (internal citation and quotation omitted). The constitutional standard can be met in either of two ways. First, “specific jurisdiction” may be exercised over a defendant when a relationship exists between the forum, the litigation, and the defendant's conduct. Helicopteros Nacionales de Columbia v. Hall, 466 U.S. 408, 414 and n.8 (1984); Bird, 289 F.3d at 873. Under this analysis, a forum may exercise specific jurisdiction over a non-resident defendant if the defendant has “purposefully directed” his activities to forum residents and the resulting litigation derives from alleged injuries that “arise out of or relate to” those activities. Burger King, 471 U.S. at 472. The Sixth Circuit has framed the specific jurisdiction analysis as a three-part test:

First, the defendant must purposefully avail himself of the privilege of acting in the forum state or causing a consequence in the forum state. Second, the cause of action must arise from the defendant's activities there. Finally, the acts of the defendant or consequences caused by the defendant must have a substantial enough connection with the forum state to make the exercise of jurisdiction over the defendant reasonable.

Calphalon, 228 F.3d at 721 (quoting Southern Machine Co. v. Mohasco Indus., Inc., 401 F.2d 374, 381 (6th Cir. 1968)); see Bird, 289 F.3d at 874.

Second, even if a suit does not “arise out of or relate to” the defendant's contacts with the forum, “general jurisdiction” may nevertheless be permissible when sufficient independent contacts exist between the forum and the defendants. Helicopteros Nacionales, 466 U.S. at 414, 419 n.9. General jurisdiction may be exercised when the non-resident's “conduct and connection

with the forum State are such that he should reasonably anticipate being hauled into court there.” World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980); see also Bird, 289 F.3d at 873 (general jurisdiction is “proper only where a defendant's contacts with the forum state are of such a continuous and systematic nature that the state may exercise personal jurisdiction over the defendant even if the action is unrelated to the defendant's contacts with the state.”) (quoting Third Nat'l Bank in Nashville v. WEDGE Group, Inc., 882 F.2d 1087, 1089 (6th Cir. 1989)). Unless these requirements are satisfied, personal jurisdiction may not be exercised over a defendant “[e]ven if the defendant would suffer minimal or no inconvenience from being forced to litigate . . . [in the forum State]; even if the forum state has a strong interest in applying its law to the controversy; [and] even if the forum State is the most convenient location for litigation . . . .” World-Wide Volkswagen, 444 U.S. at 294.

Plaintiff fails to allege facts that would support the exercise of specific jurisdiction over the individual defendants. The Amended Complaint alleges that Drs. Pazdur and Scher reside in Maryland and New Jersey, respectively. Amended Complaint ¶ 33 and at 1-2. Dr. Pazdur works for FDA’s Center for Drug Evaluation and Research, which is located in Maryland. See <http://ds1.psc.dhhs.gov/hhsdir/eeKey.asp?Key=23294>. Dr. Scher works in New York. Moreover, the Advisory Committee meeting that Drs. Pazdur and Scher are alleged to have improperly influenced took place in Maryland. See Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting, 72 Fed. Reg. 9766 (March 5, 2007) (giving notice that the meeting will occur in Gaithersburg, Maryland). Plaintiff does not claim that any of Dr. Pazdur or Dr. Scher's conduct – or, for that matter, any of FDA’s regulatory activities with respect to Provenge – occurred in or were directed to Ohio. Specific jurisdiction is thus not

present here because the controversy described in the Amended Complaint is not alleged to arise out of a “relationship among defendants, the forum, and the litigation” that is the essential foundation for personal jurisdiction.

The Amended Complaint likewise fails to allege any facts that would supply an independent basis upon which the fairness of an exercise of general jurisdiction over Drs. Pazdur and Scher in this forum could be defended. See Int'l Shoe v. Washington, 326 U.S. 310, 361-20 (1945). Nothing in the Amended Complaint suggests that Drs. Pazdur and Scher's “conduct and connection with [Ohio] are such that [they] should reasonably anticipate being haled into court there.” See Burger King, 471 U.S. at 474.

Therefore, the Court should dismiss the Amended Complaint as against both of the individual defendants in their individual capacities, pursuant to Fed. R. Civ. P. 12(b)(2).

IV. PLAINTIFF FAILS TO STATE A CLAIM UNDER 42 U.S.C. §1985 & §1986.

In Count II, Plaintiff newly alleges that Drs. Pazdur and Scher “conspired to cause injury and deny equal protection of the law to this discriminated against group of people” (Amended Complaint at ¶N), said group being “all men, they are mostly elderly men, and African Americans are disproportionately affected by AIPC [androgen-independent prostate cancer].” Amended Complaint at ¶M. Plaintiff further claims that the “co-conspirators” shared the “common objective to obtain a denial or non approval of the BLA for Provenge even though they knew that the decision would hurt all prostate cancer sufferers.” Id. at ¶T (emphasis added). Based on these allegations, Plaintiff claims that Drs. Pazdur and Scher have violated 42 U.S.C. §§1985 and 1986. Count II should be dismissed because it fails to state a claim under either of those sections.

Section 1985(3) provides:

If two or more persons in any State or Territory conspire..., for the purpose of depriving, either directly or indirectly, any person or class of persons of the equal protection of the laws, or of equal privileges and immunities under the laws, . . .; in any case of conspiracy set forth in this section, if one or more persons engaged therein do, or cause to be done, any act in furtherance of the object of such conspiracy, whereby another is injured in his person or property, or deprived of having and exercising any right or privilege of a citizen of the United States, the party so injured or deprived may have an action for the recovery of damages, occasioned by such injury or deprivation, against any one or more of the conspirators.

42 U.S.C. §1985(3).<sup>12</sup> Section 1986, in turn, addresses actions for failure to prevent such conspiracies:

Every person who, having knowledge that any of the wrongs conspired to be done, and mentioned in the preceding section [42 U.S.C. §1985], are about to be committed, and having power to prevent or aid in preventing the commission of the same, neglects or refuses so to do, if such wrongful act be committed, shall be liable to the party injured, or his legal representatives, for all damages caused by such wrongful act, which such person by reasonable diligence could have prevented...

42 U.S.C. §1986. Thus, to effectuate a cause of action under 42 U.S.C. §1986, a plaintiff must also state a cause of action under 42 U.S.C. §1985. See Bass v. Robinson, 167 F.3d 1041, 1050-51 n.5 (6th Cir. 1999); Estate of Bing v. City of Whitehall, 373 F. Supp. 2d 770 (S.D. Ohio 2005), rev'd in part on other grounds, 456 F.3d 555 (6<sup>th</sup> Cir. 2006). In the absence of a viable §1985 claim, there can be no violation of §1986.

To state a claim under 42 U.S.C. §1985(3), a plaintiff must allege: “(1) a conspiracy; (2) for the purpose of depriving, either directly or indirectly, any person or class of persons of the

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<sup>12</sup>Plaintiff did not identify the subsection of 42 U.S.C. §1985 on which it relies; however, subsections (1) “Preventing an officer from performing duties” and (2) “Obstructing justice; intimidating party, witness, or juror” are plainly inapplicable.

equal protection of the laws, or of equal privileges or immunities of the laws; (3) an act in furtherance of the conspiracy; (4) whereby a person is either injured in his person or property or deprived of any right or privilege of a citizen of the United States.” Vakilian v. Shaw, 335 F.3d 509, 518 (6<sup>th</sup> Cir. 2003) (citing United Bhd. Of Carpenters & Joiners of Am. v. Scott, 463 U.S. 825, 828-29 (1983)). To avoid the “constitutional shoals that would lie in the path of interpreting §1985(3) as a general federal tort law,” the Supreme Court has confined the reach of §1985(3) to conspiracies motivated by animus against certain types of classes. United Bhd., 463 U.S. at 834-35 (conspiracy to harm nonunionized employees is not the kind of class-based animus covered by 42 U.S.C. §1985(3)) (quoting Griffin v. Breckenridge, 403 U.S. 88, 102 (1971)). Thus, in addition to the foregoing, a plaintiff also must show that “some racial, or perhaps otherwise class-based, invidiously discriminatory animus [lay] behind the conspirators’ action...” Bray v. Alexandria Women’s Health Clinic, 506 U.S. 263, 267-68 (1993) (internal citations and quotations omitted). As interpreted by the Supreme Court, the term “class”:

unquestionably connotes something more than a group of individuals who share a desire to engage in conduct that the §1985(3) defendant disfavors. Otherwise, innumerable tort plaintiffs would be able to assert causes of action under §1985(3) by simply defining the aggrieved class as those seeking to engage in the activity the defendant has interfered with. This definitional ploy would convert the statute into the “general federal tort law” it was the very purpose of the animus requirement to avoid...[T]he class cannot be defined simply as the group of victims of the tortious action.

Id. at 269 (internal citations and quotations omitted) (women seeking an abortion is not a qualifying class); see Vakilian, 335 F.3d at 518-19 (“the acts which are alleged to have deprived the plaintiff of equal protection must be the result of class-based discrimination.”) (citing Newell v. Brown, 981 F.2d 880, 886 (6<sup>th</sup> Cir. 1992)).

Plaintiff's §1985(3) claim must be dismissed because Plaintiff has not alleged the type of class-based discriminatory animus that is required for such a claim. Accepting the allegations in the Amended Complaint as true for purpose of this motion, Drs. Pazdur and Scher are claimed to have engaged in conduct that injures all prostate cancer sufferers. See Amended Complaint ¶T. However, "prostate cancer sufferers" is not the type of class that is protected by 42 U.S.C. § 1985(3), which "covers conspiracies against: (1) classes who receive heightened protection under the Equal Protection Clause; and (2) 'those individuals who join together as a class for the purpose of asserting certain fundamental rights.'" Bartell v. Lohiser, 215 F.3d 550 (6th Cir. 2000) (quoting Browder v. Tipton, 630 F.2d 1149, 1150 (6th Cir. 1980)); see also Lucas v. City of Ludlow, Kentucky, Civ. No. 05-52, 2005 U.S. Dist. LEXIS 33271 7 (E.D. Ky. Dec. 15, 2005) (HIV positive status is not "within the § 1985(3) classes recognized by the Supreme Court or the Sixth Circuit").

Apparently anticipating this defect in its claim, Plaintiff baldly asserts that the Defendants' actions will disproportionately hurt African Americans. See Amended Complaint ¶P. However, Plaintiff alleges no facts in the Amended Complaint to support this assertion.<sup>13</sup> Moreover, even if Plaintiff had offered some basis for this assertion, a showing of unintentional disproportionate impact on a racial class is insufficient to state a claim under § 1985(3). See

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<sup>13</sup>Conspiracy claims "must be pled with some degree of specificity and . . . vague and conclusory allegations unsupported by material facts will not be sufficient to state such a claim." Center for Bio-ethical Reform, Inc. v. City of Springboro, 477 F.3d 807, 831 (6th Cir. 2007), citing Gutierrez v. Lynch, 826 F.2d 1534, 1538-39 (6th Cir. 1987). Damage claims against government officials alleged to arise from constitutional violations cannot be founded on conclusory, vague, or general allegations. Lanier v. Bryant, 332 F.3d 999, 1007 (6th Cir. 2003). In particular, in the instant case the Court should enforce the rule that a conspiracy be pleaded with particularity.

Majeske v. Fraternal Order of Police, 94 F.3d 307, 311 (7th Cir. 1996) (“Disparate impact alone does not satisfy the pleading requirements for...§ 1985(3).”).

Assuming arguendo that Plaintiff has identified a protected class, the facts alleged in the Amended Complaint do not support the conclusion that Drs. Pazdur and Scher were motivated by animus against a protected class. Indeed, the Amended Complaint claims that Dr. Pazdur sabotaged the Provenge BLA because he believed the product should have been regulated by his Division in FDA's Center for Drug Evaluation and Research rather than by FDA's Center for Biologics Evaluation and Research. See Amended Complaint ¶30 (describing Pazdur as driven by anger of the “assignment of the Provenge BLA to” CBER's CTGT Advisory Committee “which set off a chain of events that can only be described by calling it ‘political infighting’ or ‘human nature’...”) (emphasis added); id. ¶31 (Dr. Pazdur “want[ed] to assert his/[his division's] power within the agency”); id. ¶71 (Pazdur was “upset by a perceived usurpation of his carefully cultivated power, and wanting to regain control...”); id. ¶73 (Pazdur was on “a private quest to become a one man wrecking crew to the Provenge BLA, in part to fulfill his promise that he had stated that no new cancer treatment would ever be approved if it did not go through his CDER division”). Dr. Scher allegedly was driven by financial and/or political motives. See id. ¶36 (claiming Scher was motivated by his “own future political and monetary benefit”); id. ¶37 (Scher “decided for his own political and monetary reasons”); id. ¶78 (claiming Scher sent a letter containing false information “for his own political and financial gain”); see also id. ¶¶52, 58, & 67. Because Plaintiff has failed to allege that the individual defendants were motivated by the sort of class-based animus necessary for a claim under §1985(3), Count II must be dismissed. See Bray, 506 U.S. at 271-72 (“‘Discriminatory purpose’...implies more than intent as volition or

intent as awareness of consequences. It implies that the decisionmaker...selected or reaffirmed a particular course of action at least in part ‘because of,’ not merely ‘in spite of,’ its adverse effects upon an identifiable group. The same principle applies to the ‘class-based, invidiously discriminatory animus’ requirement of § 1985(3).” (emphasis added) (internal citations omitted).

Plaintiff’s §1985 claim fails for a second, independent reason. To state a claim for a private conspiracy, the conspiracy “requires an intent to deprive persons of a right guaranteed against private impairment.” Bray, 506 U.S. at 274.<sup>14</sup> Plaintiff claims that Drs. Pazdur and Scher deprived prostate cancer patients of their right to substantive due process. See Amended Complaint ¶¶Q. Plaintiff has failed to allege a substantive due process violation for the reasons set forth above and in the Motion to Dismiss being filed by all Defendants in their official capacities. Further, because Plaintiff has demonstrated no infringement of any clearly established constitutional right, Drs. Pazdur and Scher are entitled to qualified immunity from the claims brought under §1985(3) to the same extent as any other constitutional claims alleged by Plaintiff.

For all of these reasons, Count II should be dismissed.

V. PLAINTIFF FAILS TO STATE A CLAIM FOR “INTERFERENCE WITH AID”.

Count III of the Amended Complaint is titled “Violation of Constitutional Torts/Interference With Aid - Intentional Constitutional Torts As To The Individual

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<sup>14</sup> The equal protection provision of §1985(3) “grants no substantive stand-alone rights.” Federer v. Gephardt, 363 F.3d 754, 758 (8<sup>th</sup> Cir. 2004). Rather, a plaintiff “must allege that an independent federal right has been infringed,” and “[t]he source of the rights or laws violated must be found elsewhere.” Id. at 757-58.

Defendants.” This count alleges that Drs Pazdur and Scher “did intentionally interfere with the rescue efforts of third parties that could save a terminally ill patient’s life.” Amended Complaint, ¶U. Plaintiff cites Restatement of Torts (First), Sec. 326 in support of its allegation, and claims that such interference in this case “was...sufficient to raise an ordinary tort to the stature of a constitutional violation.” Id., ¶W.

The Abigail Alliance en banc Court dismissed a similar allegation:

In essence, the Alliance insists on a constitutional right to assume any level of risk. It is difficult to see how a tort addressing interference with providing “necessary” aid would guarantee a constitutional right to override the collective judgment of the scientific and medical communities expressed through the FDA’s clinical testing process. Thus, we cannot agree that the tort of intentional interference with rescue evidences a right of access to experimental drugs.

495 F.3d at 709.

Plaintiff’s attempt to “constitutionalize” a common law tort theory should be rejected.

The Supreme Court has instructed lower courts not to allow common law torts to be constitutionalized, and has uniformly rejected efforts to elevate common law tort claims to constitutional dimensions by artful pleading. Paul v. Davis, 424 U.S. 692, 713 (1976) (government official’s defamatory statement did not deprive plaintiff of liberty without due process). Indeed, the Supreme Court has emphasized its “caution toward extending Bivens remedies into any new context, a caution consistently and repeatedly recognized for three decades.” Correctional Services Corp. v. Malesko, 534 U.S. 61, 74 (2001). The Court refused to endorse a “marked extension of Bivens, to contexts that would not advance Bivens’ core purpose

of deterring individual officers from engaging in *unconstitutional* wrongdoing.” Id.<sup>15</sup> (emphasis added).

VI. PLAINTIFF’S STATE LAW TORT CLAIMS MUST BE DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION.

Plaintiff’s state law tort claims against Drs. Pazdur or Scher must be dismissed because the United States Attorney has certified that Drs. Pazdur and Scher were acting within the scope of their employment pursuant to the Federal Tort Claims Act (“FTCA”), 28 U.S.C. §§ 2671–2680. See Doc. 34 and 35.

The FTCA is a limited waiver of sovereign immunity, and it is the sole source of subject-matter jurisdiction over tort claims arising from negligent or wrongful acts of federal employees acting within the scope of their employment. 28 U.S.C. § 2679(b)(1) (“The remedy against the United States provided by sections 1346(b) and 2672 of this title for injury or loss of property... arising or resulting from the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment is exclusive of any other civil action or proceeding for money damages by reason of the same subject matter against the employee...”).

Federal employees have absolute immunity for state common law torts they commit while acting within the scope of their employment. See 28 U.S.C. § 2679(d)(1); Osborn v. Haley, 549 U.S. \_\_\_, 127 S. Ct. 881, 887 (2007); see also Celestine v. Mount Vernon Neighborhood Health Center, 403 F.3d 76, 80 (2d Cir. 2005). The FTCA provides that when a federal employee is sued in tort, the United States Attorney for that district must certify whether

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<sup>15</sup> To the extent that this claim can be construed to allege a common law tort, see Part VI *infra*.

the employee was acting within the scope of his office or employment at the time of the allegedly tortious act. 28 U.S.C. § 2679(d)(1); 28 C.F.R. § 15.4. If the United States Attorney certifies that the employee acted within the scope of his office or employment, then (1) the United States is substituted as the party defendant, and (2) the plaintiff may sue the United States only in accordance with the FTCA. 28 U.S.C. § 2679(d)(1); Osborn, 127 S. Ct. at 887. Any state law tort claims “shall be deemed an action against the United States,” and this is Plaintiff’s exclusive remedy. See 28 U.S.C. § 2679(a), (d)(1) & (4). Absolute immunity applies even where the FTCA bars the plaintiff’s recovery. United States v. Smith, 499 U.S. 160, 166 (1991).

The FTCA requires that tort claims be submitted to the appropriate federal agency for administrative consideration before an action upon those claims is instituted. 28 U.S.C. § 2675(a) (“An action shall not be instituted upon a claim...unless the claimant shall have first presented the claim to the appropriate Federal agency...”); see id. § 2401(b); McNeil v. United States, 508 U.S. 106, 107, 113 (1993); Singleton v. United States, 277 F.3d 864, 872-73 (6th Cir. 2001) (“failure to file a timely administrative claim under the FTCA bars federal jurisdiction”). This requirement of exhaustion of administrative tort remedies is an absolute prerequisite to federal district court jurisdiction, and it is neither capable of being waived nor subject to estoppel. McNeil, 508 U.S. at 107, 113 (applying rule of “strict adherence” to pro se prisoner who instituted his complaint prior to exhausting administrative tort remedies under the FTCA); see also Celestine, 403 F.3d at 84. This Court lacks subject matter jurisdiction on any state law claims against the United States because plaintiff does not allege—and cannot allege—that it has

presented an administrative tort claim and had that claim finally denied by the appropriate federal agency.

VII. PLAINTIFF FAILS TO STATE A CLAIM FOR “WRONGFUL DEATH”.

Even if subject matter jurisdiction were present over Plaintiff’s state law tort claims, they should be dismissed for failure to state a claim upon which relief can be granted. A new count in the Amended Complaint, Count IV, alleges an “anticipatory wrongful death.”<sup>16</sup> In this case, a living, hypothetical<sup>17</sup> “John Doe” Plaintiff seeks damages for “Ohio wrongful death action (intentional),” on the grounds that he “may soon die due to the intentional torts of” Drs. Pazdur and Scher. Am. Complaint ¶AA (emphasis added). However, since no such cause of action is recognized under Ohio law, Plaintiff fails to state a claim against Drs. Pazdur and Scher in their individual capacities. See Ohio Rev. Code Ann. § 2125.02.

The wrongful death claim is brought on behalf of a “John Doe” (who may or may not reside in the Southern District of Ohio).<sup>18</sup> “John Doe” has not alleged sufficient facts to be permitted to proceed in this case. “It is a general rule that a complaint must state the names of the parties. Fed.R.Civ.P. 10(a).” Citizens for a Strong Ohio v. Marsh, 123 Fed.Appx. 630, 636,

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<sup>16</sup> Since this allegation is brought on behalf of a John Doe Plaintiff, the Amended Complaint does not comply with Federal Rule of Civil Procedure 10(a). Plaintiff did not seek leave of Court to add an anonymous party. Thus, the John Doe Plaintiff should be stricken, and Count IV of the Amended Complaint should be dismissed.

<sup>17</sup> Plaintiff claims the action “will be more fully identified upon the death of the first Ohio prostate cancer patient who is a member of CareToLive and whose death could have been avoided and still could be avoided if the FDA did the right thing to correct this incredible injustice.” Am. Complaint, ¶AA (emphasis in original). Thus, it appears the “John Doe” Plaintiff is both alive and presently undetermined.

<sup>18</sup> The Amended Complaint merely identifies Doe as an “Ohio...patient.” ¶Z, p. 32.

2005 WL 14986 (6<sup>th</sup> Cir. 2005). Plaintiffs can only proceed anonymously if their circumstances justify an exception. Doe v. Porter, 370 F. 3d 558, 560 (6<sup>th</sup> Cir. 2004):

When determining whether such an exception is justified, a court may consider, among others, the following factors: (1) whether the plaintiffs seeking anonymity are suing to challenge government activity; (2) whether prosecution of the suit will compel the plaintiffs to disclose information of the utmost intimacy; (3) whether the litigation compels plaintiffs to disclose the intention to violate the law, thereby risking criminal prosecution; and (4) whether the plaintiffs are children.

Marsh 123 Fed.Appx. at 636, citing Porter, Id.

The “John Doe” to be determined meets none of these requirements. He is claiming a state law tort, he has already acknowledged in the Amended Complaint that he is a “late stage prostate cancer patient,” there is no risk of criminal prosecution to “John Doe,” and he is clearly not a child. There is no valid reason to permit this person to proceed under a pseudonym.<sup>19</sup>

In addition, Plaintiff has filed no motion to add this anonymous party. “Failure to seek permission to proceed under a pseudonym is fatal to an anonymous plaintiff’s case, because ‘the federal courts lack jurisdiction over the unnamed parties, as a case has not been commenced with respect to them’” Marsh 123 Fed.Appx. at 637, citing Nat’l Commodity & Barter Ass’n, Nat’l Commodity Exch. v. Gibbs, 886 F.2d 1240, 1245 (10th Cir. 1989).<sup>20</sup>

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<sup>19</sup> It is also unclear if the named “John Doe” is one person or a class of persons. Compare ¶Z, ¶AA (“which will be more fully identified upon the death of the first Ohio...patient...”), and ¶DD (“Plaintiffs” is referenced three times) of the Amended Complaint, pp. 32-33.

<sup>20</sup> Even if “John Doe” could proceed in this case, the Court has no personal jurisdiction over Drs. Pazdur and Scher, as argued in Part III, supra.

VIII. PLAINTIFF FAILS TO STATE A CLAIM FOR TORT RELIEF AGAINST DR. SCHER

In Count V, Plaintiff seeks relief from Dr. Scher based on a strained interpretation of the “Good Samaritan” doctrine, as embodied in Restatement (Second) of Torts §323. This claim again focuses inexplicably on Dr. Scher, who, Plaintiff claims, was merely one “no” vote on an Advisory Committee for which the majority voted in favor of approval of the Provenge BLA, and who is alleged to have written a letter to FDA setting forth objections to the approval of Provenge. These allegations do not support liability under §323.

The cited provision of the Restatement of Torts, Negligent Performance of Undertaking to Render Services, provides:

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other's person or things, is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if  
(a) his failure to exercise such care increases the risk of such harm, or  
(b) the harm is suffered because of the other's reliance upon the undertaking.

Restatement (Second) of Torts §323 (emphasis added).

Plaintiff has failed to allege facts that would support a cause of action under §323. First, Dr. Scher served as a special government employee on an FDA Advisory Committee, thereby rendering a service to FDA. He did not “undertake...to render services to” Plaintiff (or hypothetical “John Doe” plaintiffs). See, e.g., Wentwood Woodside I LP v. GMAC Commer. Mortg. Corp., 419 F.3d 310, 319 (5th Cir. 2005) (construing § 323, "Plainly, the only potential liability addressed is liability to the party the defendant undertook to render services to."). Second, §323 imposes liability for “physical harm” that results from the defendant's “failure to exercise reasonable care to perform his undertaking.” Plaintiff CareToLive has not alleged that

it has suffered any physical harm.<sup>21</sup> In addition, although Plaintiff offers the conclusory assertion that “patients, families, doctors, and advocates relied upon [Dr. Scher] ... to their detriment,” Amended Complaint ¶¶FF, the Amended Complaint alleges no facts that would support the claim that Plaintiff acted in any way in reliance on Dr. Scher's conduct.

In sum, even if this Court were to have personal jurisdiction over Dr. Scher and even if this claim were not barred by sovereign immunity for Plaintiff's failure to comply with the administrative claim requirement of the FTCA, Count V should be dismissed because Plaintiff has not plead a cause of action under §323 of the Restatement (Second) of Torts.

#### CONCLUSION

For the reasons set forth above, all of Plaintiff's claims against Drs. Pazdur and Scher should be dismissed.

Respectfully submitted,  
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<sup>21</sup>For the reasons discussed supra, “John Doe” is not a proper party to his proceeding.

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Motion to Dismiss was filed on the 5th day of October, 2007, using the Court's CM/ECF system, which will serve all counsel of record electronically.

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