
IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

CareToLive,
Plaintiff-Appellant,

v.

ANDREW von ESCHENBACH, Commissioner, Food and Drug Administration, *et al.*
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

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TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iv
STATEMENT OF JURISDICTION.	1
STATEMENT OF THE ISSUE.	2
STATEMENT OF THE CASE.	2
A. Nature of the Case and Course of Proceedings Below	2
B. Statutory and Regulatory Framework.	3
1. Drug and Biological Product Approval Process.	3
2. Advisory Committees.	6
3. FDA Responses to a BLA.	7
C. Statement of Facts.	8
1. Background.	8
2. Procedural History.	13
SUMMARY OF ARGUMENT.	16
ARGUMENT.	20
I. Standard of Review.	20
II. The District Court Properly Dismissed CTL’s Claims for Lack of Subject Matter Jurisdiction.	20

A.	The District Court Correctly Concluded That CTL’s Challenge Was Not Ripe for Adjudication and There Had Been No Final Agency Action.	21
1.	CTL’s Challenge is Not Fit for Judicial Decision Because It Does Not Raise Purely Legal Questions and There Has Been No Final Agency Action.	23
a.	Purely Legal Questions.	23
b.	Final Agency Action.	24
2.	Withholding Court Consideration Will Not Cause Hardship.	29
3.	CTL’s Ripeness and Finality Arguments Are Meritless	30
B.	The District Court Correctly Held That CTL’s Claims Were Barred by Sovereign Immunity.	40
C.	The District Court Applied the Correct Standard of Decision; Properly Decided Defendants’ Motion to Dismiss Without Discovery; and Did Not Commit Clear Error in Its Jurisdictional Fact Finding	42
1.	The District Court Applied the Correct Standard to Defendants’ Challenge to the Factual Basis of CTL’s Jurisdictional Claim	42
2.	The District Court Did Not Abuse Its Discretion in Deciding Defendants’ 12(b)(1) Motion Without Jurisdictional Discovery	44
3.	The District Court’s Jurisdictional Fact Finding Was Not Clearly Erroneous.	45

D. The District Court Did Not Abuse its Discretion When it Continued its Consideration of CTL’s Preliminary Injunction Until Briefing Was Complete on Defendants’ Motions to Dismiss; or When It Did Not Hold an Immediate Hearing on CTL’s Preliminary Injunction Motion 46

E. CTL’s Due Process Argument Is Not Properly Before the Court and Fails to State a Valid Claim for Relief in Any Event. . . . 50

CONCLUSION. 57

TABLE OF AUTHORITIES

CASES

	<u>Page(s)</u>
<i>Abbott Laboratories v. Gardner</i> , 387 U.S. 136 (1967).....	22, 23, 25
<i>Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach</i> , 495 F.3d 695 (D.C. Cir. 2007), <i>cert. denied</i> , 2008 U.S. LEXIS 836 (January 14, 2008).....	53, 55
<i>Air Brake System, Inc. v. Mineta</i> , 357 F.3d 632 (6th Cir. 2004).	25, 28, 37
<i>Airline Prof'ls Association Local Union No. 1224 v. Airborne, Inc.</i> , 332 F.3d 983 (6th Cir. 2003).	22, 29, 39
<i>Ayuda, Inc. v. Thornburgh</i> , 948 F.2d 742 (D.C. Cir. 1991), <i>vacated on other grounds</i> , 509 U.S. 916 (1993).....	21
<i>Beamon v. Brown</i> , 125 F.3d 965 (6th Cir. 1997).	41
<i>Bennett v. Spear</i> , 520 U.S. 154 (1997)	24, 26, 31, 32
<i>Carnohan v. United States</i> , 616 F.2d 1120 (9th Cir. 1980).	55
<i>Certified Restoration Dry Cleaning Network, LLC v. Tenke Corp.</i> , 511 F.3d 535 (6th Cir. 2007).	50
<i>Chrysler Corp. v. Fedders Corp.</i> , 643 F.2d 1229 (6th Cir. 1981).	44

<i>Clinton v. Jones</i> , 520 U. S. 681 (1997).....	20, 48
<i>Dalton v. Specter</i> , 511 U.S. 462 (1994).....	24
<i>Devia v. NRC</i> , 492 F.3d 421 (D.C. Cir. 2007).....	36
<i>Dixie Fuel Co. v. Commissioner of Social Sec.</i> , 171 F.3d 1052 (6th Cir. 1999), <i>overruled on other grounds by</i> <i>Barnhart v. Peabody Coal Co.</i> , 537 U.S. 149, 157 (2003).	22
<i>DLX, Inc. v. Kentucky</i> , 381 F.3d 511 (6th Cir. 2004).	20, 43
<i>FDIC v. Meyer</i> , 510 U.S. 471 (1994)	40
<i>Florida Power & Light Co. v. Lorion</i> , 470 U.S. 729 (1985).....	38, 39
<i>Franklin v. Massachusetts</i> , 505 U.S. 788 (1992).....	25, 28
<i>Hayes v. Equitable Energy Resources Co.</i> , 266 F.3d 560 (6th Cir. 2001).	20, 44
<i>Jean v. Nelson</i> , 472 U.S. 846 (1985).....	52
<i>McDonald’s Corp. v. Robertson</i> , 147 F.3d 1301 (11th Cir. 1998)	50
<i>McLaurin v. Fischer</i> , 768 F.2d 98 (6th Cir. 1985)	51

<i>Mitchell v. Clayton</i> , 995 F.2d 772 (7th Cir. 1993).	55
<i>National Park Hospitality Association v. Department of Interior</i> , 538 U.S. 803 (2003).	22
<i>Nat’l Treasury Employees Union v. United States</i> , 101 F.3d 1423 (D.C. Cir. 1996)	36
<i>Nationwide Mutual Insurance Co. v. Cisneros</i> , 52 F.3d 1351 (6th Cir. 1995).	22
<i>Nebraska HHS v. HHS</i> , 435 F.3d 326 (D.C. Cir. 2006).	23, 39
<i>Ohio National Life Insurance Co. v. United States</i> , 922 F.2d 320 (6th Cir. 1990).	20, 45
<i>Pfizer v. Shalala</i> , 182 F.3d 975 (D.C. Cir. 1999).	22
<i>Reed v. Reno</i> , 146 F.3d 392 (6th Cir. 1998).	40
<i>RMI Titanium Co. v. Westinghouse Electric Corp.</i> , 78 F.3d 1125 (6th Cir. 1996).	20
<i>Rutherford v. United States</i> , 616 F.2d 455 (10th Cir. 1980), <i>on remand from</i> 442 U.S. 544 (1979), <i>cert. denied</i> , 449 U.S. 937 (1980)	55-56
<i>SEC v. G. Weeks Securities, Inc.</i> , 678 F.2d 649 (6th Cir. 1982).	49
<i>Spector Motor Co. v. McLaughlin</i> , 323 U.S. 101 (1944)	52

<i>Telespectrum, Inc. v. Public Serv. Commission of Kentucky</i> , 227 F.3d 414 (6th Cir. 2000).	27
<i>Texas v. United States</i> , 523 U.S. 296 (1998).	22
<i>Toilet Goods Association v. Gardner</i> , 387 U.S. 158 (1967).	22, 23
<i>Torres v. Oakland Scavenger Co.</i> , 487 U.S. 312 (1988)	52
<i>United States v. Burzynski Cancer Research Institute</i> , 819 F.2d 1301 (5th Cir. 1987)	55
<i>United States v. King</i> , 395 U.S. 1 (1969).	40
<i>United States v. Mitchell</i> , 445 U.S. 535 (1980).	40
<i>United States v. Mitchell</i> , 463 U.S. 206 (1983).	40, 41
<i>United States v. Pro-Ag., Inc.</i> , 796 F. Supp. 1219 (D. Minn. 1991), <i>aff'd</i> , 968 F.2d 681, 683 (8th Cir. 1992).	4
<i>United States v. Rutherford</i> , 442 U.S. 544 (1979).	30
<i>United States v. Universal Management Services, Inc.</i> , 191 F.3d 750 (6th Cir. 1999).	48, 51, 52
<i>United States v. White Mountain Apache Tribe</i> , 537 U.S. 465 (2003).	40

<i>W.R. Grace & Co. v. EPA</i> , 959 F.2d 360 (1st Cir. 1992).....	36
<i>Washington v. Glucksberg</i> , 521 U.S. 702 (1997).....	53, 55
<i>Weinberger v. Hynson, Westcott & Dunning, Inc.</i> , 412 U.S. 609 (1973).....	24

STATUTES

5 U.S.C. § 702	41
5 U.S.C. § 704	24
21 U.S.C. § 321(p).....	4
21 U.S.C. § 331(d).....	4
21 U.S.C. § 355(b).....	5
21 U.S.C. § 355(d).....	5
21 U.S.C. § 355(d)(4).....	5
21 U.S.C. § 355(d)(5).....	5
21 U.S.C. § 355(i)(1).....	6
21 U.S.C. § 355(n)(7).....	47, 48
21 U.S.C. § 355(n)(8).....	47
28 U.S.C. § 1291.....	2
28 U.S.C. § 1331.....	1

28 U.S.C. §1346(b)	16
28 U.S.C. §§ 2671-2680	16
42 U.S.C. § 1985.....	13
42 U.S.C. § 1986.....	13
42 U.S.C. § 262(a).....	4, 30, 31
42 U.S.C. § 262(a)(2)(C)(i)(I).....	4
42 U.S.C. § 262(a)(2)(C)(i)(II).....	4
42 U.S.C. § 262(i).....	4, 8
42 U.S.C. § 262(j).....	4

REGULATIONS

21 C.F.R. § 10.25.....	12
21 C.F.R. § 10.30.....	12
21 C.F.R. § 10.30(e)(2).....	12
21 C.F.R. § 10.45.....	12
21 C.F.R. Pt. 14.....	6
21 C.F.R. § 14.5.....	6
21 C.F.R. § 20.61.....	11, 32, 47
21 C.F.R. § 312.2(a).....	6
21 C.F.R. § 312.20(a).....	6

21 C.F.R. § 312.21.....	6
21 C.F.R. § 600.3(s).....	4
21 C.F.R. § 601.2.....	7
21 C.F.R. § 601.2(a).....	6
21 C.F.R. § 601.4(a).....	7
21 C.F.R. § 601.4(b)	7
21 C.F.R. § 601.51(d).	11, 32, 47
68 Fed. Reg. 38067 (June 26, 2003)	8
FDA, <i>Applications for Approval to Market a New Drug</i> , 69 Fed. Reg. 43351 (July 20, 2004)	7, 25, 32

RULES

Fed. R. App. P. 3	51
Fed. R. App. P. 3(c)(1)(B).	52
Fed. R. Civ. P. 12(b)(1).	<i>passim</i>
Fed. R. Civ. P. 12(b)(6)	<i>passim</i>
Fed. R. Civ. P. 12(c).	44
Fed. R. Civ. P. 12(d)	44
Fed. R. Civ. P. 54(b).	2
Fed. R. Civ. P. 56	42

S.D. Ohio Civ. R. 65.1(a) (2007)..... 46

MISCELLANEOUS

Biologics Control Act of 1902, Pub. L. No. 57-244, 32 Stat. 728 (1902) 54

1962 Drug Amendments to the FDCA, Pub. L. No. 87-781, § 102,
76 Stat. 780, 781 (1962). 54

Food and Drug Administration Modernization Act of 1997 ("FDAMA"), Pub. L.
No.105-115, § 123(f), 111 Stat. 2296, 2324 (1997) 5

Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906)
(codified at 21 U.S.C. §§ 1-15 (1934) (repealed 1938). 55

U.S. Constitution Article III 24, 36

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
The Honorable Gregory L. Frost

PROOF BRIEF FOR THE APPELLEES

STATEMENT OF JURISDICTION

Plaintiff-Appellant CareToLive (“CTL”) brought this action against various officials of the U.S. Food and Drug Administration (“FDA”), invoking the district court’s jurisdiction under 28 U.S.C. § 1331. The district court (Frost, J.) dismissed CTL’s claims in decisions entered on November 21, 2007, JA____ (R. 64) (official capacity claims), and December 4, 2007, JA____ (R. 69) (individual capacity claims).

On December 3, 2007, CTL filed its notice of appeal, JA____ (R. 68), from the court’s November 21, 2007, decision, JA____ (R. 64). Final judgment was entered on December 4, 2007, JA____ (R. 70), and clarified on December 24, 2007, JA____ (R.71). Once the district court entered judgment, JA____ (R. 70), its earlier November 21, 2007 decision, JA____ (R. 64), became a final order under Fed. R. Civ. P. 54(b). This is thus an appeal from a final order, and this Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Whether the district court properly dismissed plaintiff’s action for lack of subject matter jurisdiction where plaintiff, an association of patients and investors, sought to challenge FDA’s decision to request additional information from the sponsor of a pending application for a biological product.

STATEMENT OF THE CASE

A. Nature of the Case and Course of Proceedings Below

Plaintiff-Appellant CTL, which characterizes itself as an association of cancer patients, patient families, doctors, investors and advocates, brought suit in district court challenging FDA’s failure to grant immediate approval to a biologics license application (“BLA”) for Provenge, a biological product intended to treat a particular type of metastatic prostate cancer. CTL sought review of FDA’s decision to issue a

complete response (“CR”) letter to Dendreon Corporation (“Dendreon”), the sponsor of the Provenge BLA, which, rather than approving Provenge for immediate distribution, identified various deficiencies in the BLA and requested that Dendreon submit additional data to demonstrate the drug’s safety and effectiveness. JA__ (R. 2, 22).

Because administrative proceedings on Dendreon’s pending BLA remain ongoing, the government moved to dismiss CTL’s complaint for lack of subject matter jurisdiction and failure to state a claim, citing *inter alia* the grounds of ripeness, finality, exhaustion of administrative remedies, standing, and sovereign immunity. The district court granted defendants’ motion on November 21, 2007, dismissing CTL’s official capacity claims for lack of subject matter jurisdiction based on the doctrines of ripeness, finality, and sovereign immunity. JA____ (R. 64). CTL appealed from that decision on December 3, 2007. JA__ (R. 68). The court entered final judgment in favor of the defendants on December 4, 2007. JA____ (R. 70, 71).

B. Statutory and Regulatory Framework

1. Drug and Biological Product Approval Process

Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), a new drug cannot be distributed in interstate commerce until the drug’s sponsor receives FDA’s

approval. 21 U.S.C. § 331(d).¹ If the new drug sought to be marketed is a biological product,² the sponsor seeks FDA’s approval by submitting a BLA pursuant to the Public Health Service Act (“PHSA”). 42 U.S.C. § 262(a).³

FDA will approve a BLA for an unapproved biological product if the BLA demonstrates that the product is safe, pure, and potent, 42 U.S.C. § 262(a)(2)(C)(i)(I), and that the facility in which the product is manufactured “meets standards designed to assure that the biological product continues to be safe, pure, and potent,” *id.* § 262(a)(2)(C)(i)(II).

As further defined in FDA regulations, the “potency” requirement for biological products requires evidence of effectiveness. *See* 21 C.F.R. § 600.3(s). This mirrors the requirement that a new drug application (“NDA”) for a new drug

¹ The FDCA defines “new drug” as, among other things (1) a drug that is “not generally recognized, among experts qualified by scientific training and experience . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.” 21 U.S.C. § 321(p).

² Biological products are defined as any “virus, therapeutic serum, toxin, antitoxin, vaccine . . . or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.” 42 U.S.C. § 262(i).

³ *See* 42 U.S.C. § 262(j) (stating that the FDCA applies to biological products, except that products with approved BLAs need not have approved new drug applications (“NDAs”) under the FDCA); *United States v. Pro-Ag., Inc.*, 796 F. Supp. 1219, 1224 (D. Minn. 1991) (“all biologics are by definition drugs”), *aff’d*, 968 F.2d 681, 683 (8th Cir. 1992).

must provide evidence of effectiveness. 21 U.S.C § 355(b). In 1997, Congress instructed FDA to “minimize differences in the review and approval” of products required to have approved BLAs and products required to have approved NDAs. Food and Drug Administration Modernization Act of 1997 (“FDAMA”), Pub. L. No. 105-115, § 123(f), 111 Stat. 2296, 2324 (1997), *reprinted at* 21 U.S.C. § 355 note.

Accordingly, FDA issued an industry guidance indicating that FDA applies the same effectiveness standards to BLAs and NDAs. FDA, “Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products,” May 1998, at 2-4, *available at* <http://www.fda.gov/cder/guidance/1397fnl.pdf>. Under those standards, FDA rejects approval if, *inter alia*, the information available to FDA regarding a drug is “insufficient . . . to determine whether such drug is safe for use” or if “there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have,” as established by “adequate and well-controlled investigations,” conducted by qualified experts. 21 U.S.C. § 355(d), (d)(4) & (d)(5).

The evidence of safety and effectiveness necessary for approval of BLAs is usually derived from clinical testing in humans. Because the FDCA’s general prohibition against distributing unapproved new drugs would otherwise bar clinical testing in the United States, the statute permits FDA to promulgate regulations

allowing such distribution “solely for investigational use” by qualified experts. 21 U.S.C. § 355(i)(1). Under these regulations, before a sponsor can test a new drug on humans, it must submit an investigational new drug application (“IND”) to FDA. 21 C.F.R. §§ 312.2(a); 312.20(a). FDA regulations prescribe a three-phase process for clinical trials of investigational new drugs. *Id.* § 312.21.

When the sponsor of a biological product has completed the clinical trial process, it can submit a BLA in accordance with 21 C.F.R. § 601.2(a). The required documentation in a BLA provides critical information for FDA’s evaluation of the biological product, including the results of clinical trials, the composition of the drug, manufacturing information, and sample labeling. *Id.* A team of experts at FDA reviews the complex information submitted in the BLA, weighing the benefits and risks of the drug.

2. Advisory Committees

FDA often seeks advice from advisory committees comprised of outside experts, who provide independent advice that will contribute to the quality of the agency’s decisionmaking. *See generally* 21 C.F.R. Pt. 14. Although FDA carefully considers the advice of its advisory committees as part of the overall review process, such advice is not binding, and decisions, such as whether to approve a BLA, are made by FDA alone. *See* 21 C.F.R. § 14.5 (“The Commissioner has sole discretion

concerning action to be taken and policy to be expressed on any matter considered by an advisory committee.”).

3. FDA Responses to a BLA

In response to a BLA, FDA may (1) refuse to file it if it is incomplete, 21 C.F.R. § 601.2; FDA, “Refusal to File Procedure for Biologics License Applications,” SOPP 8404, *available at* <http://www.fda.gov/cber/regsopp/8404.htm>; approve it, 21 C.F.R. § 601.4(a); (2) deny it and provide the applicant the opportunity for a hearing, *id.* § 601.4(b); or, (3) if there are deficiencies in the BLA, send a CR letter declining to approve the BLA in its current form and requesting additional information from the sponsor, *Applications for Approval to Market a New Drug*, 69 Fed. Reg. 43351, 43352 (July 20, 2004). CR letters “ensure a consistent approach to informing sponsors of needed changes before [FDA] can approve an application, *with no implication as to the ultimate approvability of the application.*” *Id.* (emphasis added.) A CR letter does not signal the end for a product; rather, it is a step FDA takes to assure that it has sufficient data to establish safety and effectiveness prior to licensure. FDA continues to work with sponsors to resolve any outstanding issues.

C. Statement of Facts

1. Background

Provenge is intended to treat a particular type of metastatic prostate cancer. Am. Compl. ¶ 15, JA ____ (R. 22). Because it uses a patient's own cells to prepare a final product designed for infusion into the patient's bloodstream to activate his immune system, *id.* ¶¶ 14, 16, JA ____, Provenge is a vaccine and thus a biological product subject to FDA regulation under the PHS Act, 42 U.S.C. § 262(i). As a therapeutic vaccine, regulatory responsibility for reviewing and, ultimately, approving or denying approval of the Provenge BLA rests with the Office of Cellular, Tissue and Gene Therapies ("OCTGT") in FDA's Center for Biologics Evaluation and Research ("CBER"). *Id.* ¶ 29, JA ____; 68 Fed. Reg. 38067, 38068 (June 26, 2003).

Dendreon has been studying Provenge's safety and effectiveness in clinical trials pursuant to an IND submitted in 1996. *See* Cellular, Tissue and Gene Therapies ("CTGT") Advisory Committee Meeting, March 29, 2007, Transcript ("Transcript"), at 20, JA ____ (R. 23, Ex. C) (*also available at* <http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4291T1.pdf>). Dendreon submitted its BLA for Provenge in late 2006, and FDA considered it to be filed in January 2007. *See* Am. Compl. ¶ 27, JA ____ (R. 22).

As part of its review, CBER sought the advice of its CTGT Advisory Committee, JA___ (R. 22 at ¶¶ 29, 33), which held a public meeting on March 29, 2007, to discuss the clinical data submitted by Dendreon. Both Dendreon and CBER staff members reviewing the BLA submitted briefing documents to the committee members before the meeting and published them on FDA’s website. *See* Dendreon Briefing Document, and FDA Clinical, Statistical, and Chemistry, Manufacturing, and Controls (“CMC”) Briefing Documents, *available at* <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4291B1-00-index.htm>.

At the meeting, Dendreon and CBER staff members presented their respective analyses of the Provenge BLA. As evidence of efficacy, Dendreon presented two Phase 3 clinical studies, D9901 and D9902A, each designed to evaluate the effect of the drug on time to disease progression. Transcript, at 22, 29, 32, 152-53, 162, JA___ (R. 23, Ex. C); FDA Clinical Briefing Document, at 13-14. Neither study demonstrated that the drug effectively delayed disease progression. Transcript, at 22, 43, 155-57, 164, 169, JA___ (R. 23, Ex. C); FDA Clinical Briefing Document, 4, 24, 35-36. Dendreon presented *post hoc* analyses of the first study, which interpreted the data as showing a statistically significant difference in survival (approximately 4.5 months) in patients treated with Provenge as compared to placebo. Transcript, at 37, 42, 151, 169, JA___ (R. 23, Ex. C); FDA Clinical Briefing Document, 37. The second

study, however, did not show a statistically significant survival difference. Transcript, at 151, 164, 169, JA__ (R. 23, Ex. C); FDA Clinical Briefing Document, 35, 37.

CBER's clinical and statistical reviewers observed that Dendreon's survival analyses had limitations that affected their reliability. Transcript, at 170-71, JA__ (R. 23, Ex. C); FDA Clinical Briefing Document, at 4 ("doubts remain about the persuasiveness of the efficacy data"). Specifically, CBER's reviewers noted that the survival analyses were *post hoc* in nature, making the results difficult to interpret, that the studies were performed with a small sample size, and that a statistically significant survival difference was seen in only one of the two studies. Transcript, at 151, 170-71, 177-182, JA__ (R. 23, Ex. C); FDA Clinical Briefing Document, at 30; *see also* FDA Statistical Briefing Document, at §§ 3.1.1, 3.2 ("The key efficacy evidence . . . is based on post-hoc analyses and . . . is not substantial from a statistical perspective.").

With respect to safety, CBER's clinical reviewer noted that there was a higher incidence of cerebral vascular accident events (strokes) in Provenge, as compared to placebo, that, while not statistically significant, indicated that the data showed a potential safety signal. Transcript, at 166, 169, JA__ (R. 23, Ex. C); FDA Clinical Briefing Document, at 3, 45.

After discussion, the advisory committee members were asked to vote on whether the evidence established that the drug was safe and effective. They voted unanimously in the affirmative with respect to safety. After some debate over the standard for establishing efficacy, the “substantial evidence” standard was identified, although there was no further discussion as to what “substantial evidence” means under the FDCA. The committee voted 13-4 in the affirmative on efficacy. Transcript, at 370-89, JA___ (R. 23, Ex. C).

On May 8, 2007, CBER issued a CR letter to Dendreon declining to approve the BLA in its current form because of various deficiencies. *See* Dendreon Corp., “Dendreon Receives Complete Response Letter from FDA for Provenge Biologics License Application,” May 9, 2007, *available at* <http://investor.dendreon.com/ReleaseDetail.cfm?ReleaseID=241649&Header=News> (“Dendreon Press Release 5/9/07”).⁴ FDA requested that Dendreon submit additional information with respect to the chemistry, manufacturing, and controls section of the BLA. *Id.* FDA also asked Dendreon to submit additional clinical data in support of its effectiveness claim. *Id.* Dendreon has since met with FDA to discuss the additional data required

⁴ The CR letter is part of a BLA file for an unapproved product and is, therefore, unavailable for public disclosure. 21 C.F.R. § 601.51(d). In addition, the letter may contain trade secret and confidential commercial information belonging to Dendreon, which FDA is likewise prohibited from disclosing to the public. 21 C.F.R. § 20.61.

to support licensure and indicated that it intends to proceed with a new Phase 3 study designed to measure survival and to submit such data to FDA when it becomes available. *See* Dendreon Corp., “Dendreon Announces FDA Confirms Data Required for Provenge Licensure,” May 31, 2007, *available at* <http://investor.dendreon.com/ReleaseDetail.cfm?ReleaseID=246500&Header=News> (“Dendreon Press Release 5/31/07”).⁵

On July 26, 2007, four days before it filed this lawsuit, CTL submitted a citizen petition to FDA, requesting that the agency “reverse its decision to deny immediate approval to Provenge.” JA____ (R. 2, Orig. Compl., Ex. B).⁶ FDA received the citizen petition on July 27, 2007, and, on July 30, 2007, acknowledged receipt of the petition in a letter to CTL. *See* 7/30/07 ltr., Jaffe to Kearney, *available at* <http://www.fda.gov/ohrms/dockets/dockets/07p0297/07p-0297-ack0001-vol1.pdf>). On January 17, 2008, FDA issued a tentative response to the citizen petition, indicating that it

⁵ At the advisory committee meeting, even before FDA decided to issue a CR letter, Dendreon stated its intention to complete an additional Phase 3 study with a significantly greater patient population of 500 and powered to measure survival as the primary endpoint. Transcript, at 84, JA____ (R. 23, Ex. C).

⁶ A citizen petition is the mechanism for formally asking the agency to take a particular action, and is a prerequisite to filing suit on the subject. *See* 21 C.F.R. §§ 10.25, 10.30, 10.45. FDA regulations require the Commissioner, within 180 days of receipt of a citizen petition, to either approve the petition, deny the petition, or, if more time is required, issue a tentative response. 21 C.F.R. § 10.30(e)(2).

was still considering CTL's request. *See* 1/17/08 ltr., Goodman to Kearney, *available at* <http://caretolive.com/wp-content/uploads/2008/01/ctlpetitiongoodman.pdf>.

2. Procedural History

On July 30, 2007, CTL filed this action in the district court, challenging FDA's failure to approve Provenge and its May 8, 2007 CR letter. JA___ (R. 2). CTL filed an amended complaint on September 5, 2007, once again naming as defendants FDA Commissioner Andrew von Eschenbach and Department of Health and Human Services Secretary Michael Leavitt, in their official capacities, as well as Drs. Richard Pazdur, an FDA employee, and Howard Scher, an advisory committee member and special government employee, in both their official and individual capacities. JA_____ (R. 22). CTL alleged that the official capacity defendants violated its members' constitutional rights to due process and equal protection and conspired to violate civil rights statutes, 42 U.S.C. §§ 1985 and 1986. *Id.* at _____ (R. 22 at 26-30). In addition, CTL sought a declaration that Provenge is not a "new drug" subject to FDA's jurisdiction. *Id.* at _____ (R. 22 at 34-37).

CTL also purported to assert claims against Drs. Pazdur and Scher in their individual capacities under the due process and equal protection clauses, 42 U.S.C. §§ 1985 and 1986, the Ohio wrongful death statute, and state tort law regarding interference with the rescue efforts of third persons, and against Dr. Scher only under

the “Good Samaritan” doctrine (Restatement (Second) of Torts § 323). *Id.* at ____ (R. 22 at 26-34).

On September 10, 2007, CTL filed a motion for a preliminary injunction. JA ____ (R. 23). On September 13, 2007, the district court held a status conference at which defendants indicated that they would be moving to dismiss for lack of subject matter jurisdiction. (R. 27). Accordingly, the district court continued consideration of CTL’s preliminary injunction motion pending consideration of defendants’ forthcoming motion to dismiss. *Id.*

On October 5, 2007, defendants moved to dismiss the official capacity claims for lack of subject matter jurisdiction, pursuant to Fed. R. Civ. P. 12(b)(1) and failure to state a claim upon which relief could be granted, pursuant to Fed. R. Civ. P. 12(b)(6). JA ____ (R. 38). Defendants also filed a separate motion to dismiss the individual capacity claims against Drs. Pazdur and Scher, asserting qualified immunity on the constitutional claims, lack of personal jurisdiction, lack of subject matter jurisdiction over the state tort claims, and failure to state a claim upon which relief could be granted . JA ____ (R. 37).

On November 21, 2007, the district court granted defendants’ motion to dismiss the official capacity claims, finding that it lacked subject matter jurisdiction under the doctrines of ripeness, finality, and sovereign immunity. JA ____ (R. 64).

The court ruled that FDA's CR letter did not constitute final agency action because it was not the consummation of the agency's decisionmaking with respect to Dendreon's BLA, but merely an interlocutory step in an ongoing administrative process. *Id.* at ____ (R. 64 at 11, 15). Because the letter neither approved nor denied Dendreon's BLA, it did not "'alter the legal regime' and 'in no way affected the legal rights of the relevant actors.'" *Id.* at ____ (R. 64 at 15) (citation omitted). Under the circumstances, the court found CTL's claims "manifestly unripe," leaving the court with no jurisdiction to hear them. *Id.* at ____ (R. 64 at 12-13).

The district court also held that CTL's claims were barred by sovereign immunity. *Id.* at ____ (R. 64 at 16-20). Having found that FDA's CR letter was "in no sense a 'final agency action,'" the court determined that CTL could not avail itself of the Administrative Procedure Act ("APA"), nor could CTL identify any other applicable waiver of sovereign immunity that would allow its claims to proceed against the government defendants. *Id.* at ____ (R. 64 at 20). Accordingly, the court dismissed all of CTL's official capacity claims for lack of subject matter jurisdiction.

On December 3, 2007, CTL filed a notice of appeal (JA ____ (R. 68)), from the district court's official capacity decision of November 21, 2007, JA ____ (R. 64). The following day, December 4, 2007, the district court dismissed CTL's individual capacity claims against Drs. Pazdur and Scher, holding that those defendants were

entitled to qualified immunity on CTL's constitutional claims because CTL failed to establish that the actions of those defendants violated a constitutional right, much less a right that was clearly established. JA ____ (R. 69 at 9-23). The court also held that it lacked jurisdiction over CTL's state law claims because CTL had failed to exhaust administrative remedies under the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671-2680. *Id.* at ____ (R. 69 at 25).

Final Judgment was entered on December 4, 2007, JA ____ (R. 70), and, on December 24, 2007, the court issued an Order clarifying that the December 4, 2007 judgment applied to the dismissal of both CTL's official capacity claims and its individual capacity claims. JA ____ (R.71). CTL has not appealed from the decision dismissing its individual capacity claims, or from the district court's final judgment, either as initially entered or as clarified.⁷

SUMMARY OF ARGUMENT

1. The district court properly dismissed CTL's official capacity claims. CTL sought review of FDA's decision to issue a CR Letter to Dendreon, the sponsor of the Provenge BLA, which, rather than approving Provenge for immediate distribution,

⁷ CTL's proof brief repeatedly misidentifies the district court's November 21, 2007, official capacity decision as "R. 69" although it is in fact docket number "R. 64." The direct quotations in CTL's proof brief are from the official capacity decision under appeal (R. 64), not the individual capacity decision (R. 69). *See, e.g.*, Br. at 16, 21, 22, 28, 32.

identified various deficiencies in the BLA and requested that Dendreon submit additional data to demonstrate the drug's safety and effectiveness. A CR letter is an intermediate step that FDA sometimes must take to assure it has sufficient data to establish efficacy and/or safety prior to licensing a new product. While FDA is sympathetic to the fact that there are very limited treatment options for the type of prostate cancer Provenge is intended to treat, FDA cannot disregard the clear statutory requirements set out by Congress, which mandate that every drug approval be based on rigorous scientific evidence, even if the drug is intended to treat a life-threatening disease. Nor could the district court ignore the jurisdictional prerequisites that must be satisfied before a plaintiff can seek redress in federal court. Because CTL did not come close to satisfying these prerequisites, the district court properly dismissed its complaint for lack of subject matter jurisdiction under the doctrines of ripeness, finality and sovereign immunity.

2. CTL's challenge to FDA's failure to grant immediate approval to Provenge was premature under the doctrines of ripeness and finality because the agency is still in the process of working with Dendreon to determine whether further data can be developed that will satisfy the BLA approval standard. FDA's CR letter neither approved nor denied Dendreon's application, but was an interlocutory step in the administrative process. Thus, the letter did not represent the consummation of the

agency's decisionmaking process, nor did it determine any legal rights or obligations or trigger a process from which legal consequences flowed. Moreover, as the district court correctly observed, any hardship to CTL from FDA's continued review of the Provenge BLA is no different than that presented by FDA review of any application for an eagerly anticipated new drug. Under the circumstances, the district court correctly characterized CTL's claims as "manifestly unripe."

On appeal, CTL contends that FDA's CR letter was the functional equivalent of a denial of the Provenge BLA and therefore final. To the contrary, Dendreon has made clear that it will provide the requested data and continue to work with FDA in pursuit of BLA approval, and its BLA remains pending before the agency just as it was before the letter issued. However understandable the desire of cancer patients to gain access to potentially promising new treatments, a decision by FDA to seek further data before deciding whether to approve a new drug or biologic application does not in any sense equate to the denial of the application and is not a final agency action subject to judicial review.

CTL fares no better with its claim that the CR letter was final agency action because it effectively ends the administrative process unless and until Dendreon supplies the additional data requested by the agency. CTL's argument confuses finality of the administrative process with final agency action. Although any

administrative proceeding can be brought to a premature conclusion should a party to the proceeding choose to no longer participate, such action on an applicant's part does not equate to final *agency* action. In any event, that is not the choice Dendreon made in this case.

3. The district court's holding that CTL's claims were barred by sovereign immunity should also be sustained. After examining each of the potential waivers of sovereign immunity advanced by CTL, the court found that CTL had failed to identify any valid waiver that would allow its claims to proceed. On appeal, CTL jettisons all of its former arguments and relies solely upon the APA. However, as the district court correctly observed, the APA waives sovereign immunity only for challenges to "final agency action." Because FDA's CR letter was in no sense final agency action, CTL failed to state a claim under the APA and cannot therefore avail itself of the APA's waiver of sovereign immunity.

For all of these reasons, and those set forth more fully below, the district court's decision to dismiss CTL's official capacity claims for lack of subject matter jurisdiction should be affirmed.

ARGUMENT

I. Standard of Review

Where a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction does not require fact-finding, the Court of Appeals reviews *de novo*. *DLX, Inc. v. Kentucky*, 381 F.3d 511 (6th Cir. 2004). To the extent that the district court is required to resolve factual disputes to decide a 12(b)(1) motion, the court's fact-finding is reviewed for clear error, and its application of the law to the facts is reviewed *de novo*. *RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1135 (6th Cir. 1996); *Ohio Nat'l Life Ins. Co. v. United States*, 922 F.2d 320, 326 (6th Cir. 1990).

A district court's denial of jurisdictional discovery on a Rule 12(b)(1) motion to dismiss is reviewed for abuse of discretion, *Hayes v. Equitable Energy Res. Co.*, 266 F.3d 560, 571 (6th Cir. 2001), as is its stay of proceedings. *Clinton v. Jones*, 520 U. S. 681, 706-07 (1997).

II. The District Court Properly Dismissed CTL's Claims for Lack of Subject Matter Jurisdiction

Ripeness and finality (as well as exhaustion of administrative remedies) are overlapping doctrines that are all "designed, in part, to permit an agency of the Executive Branch to decide issues of administrative law fully before a court

intervenes.” *Ayuda, Inc. v. Thornburgh*, 948 F.2d 742, 754 (D.C. Cir. 1991), *vacated on other grounds*, 509 U.S. 916 (1993). CTL’s primary grievance – that the FDA did not grant immediate approval for Provenge, but instead requested more information – implicates the ripeness and finality doctrines because the agency is still in the process of working with the drug sponsor to determine whether further data can be developed that will satisfy the BLA approval standard. Because FDA’s CR letter was merely an interlocutory step in the BLA administrative process, CTL’s lawsuit challenging the issuance of the letter was premature and therefore properly dismissed under the doctrines of ripeness and finality. JA____ (R. 64 at 12-13, 16).

Moreover, in the absence of final agency action, CTL’s complaint also failed to state a claim under the APA, thereby precluding CTL from availing itself of the APA’s waiver of sovereign immunity. Because CTL could identify no other applicable waiver of sovereign immunity that would allow its claims to proceed, the district court correctly concluded that its complaint was barred by sovereign immunity and subject to dismissal on that basis as well. JA____ (R. 64 at 20).

A. The District Court Correctly Concluded That CTL’s Challenge Was Not Ripe for Adjudication and There Had Been No Final Agency Action

Whether a claim is ripe for adjudication “is determinative of jurisdiction. If a claim is unripe, federal courts lack subject matter jurisdiction and the complaint must

be dismissed.” *Nationwide Mut. Ins. Co. v. Cisneros*, 52 F.3d 1351, 1361 (6th Cir. 1995) (internal quotation marks and citation omitted). The doctrine of ripeness is designed “to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Nat’l Park Hospitality Ass’n v. Dep’t of Interior*, 538 U.S. 803, 807-08 (2003) (quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-149 (1967)). “A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Pfizer v. Shalala*, 182 F.3d 975, 978 (D.C. Cir. 1999) (citing *Texas v. United States*, 523 U.S. 296, 300 (1998)).

Ripeness turns upon two primary considerations: (1) “the fitness of the issues for judicial decision” and (2) “the hardship to the parties of withholding court consideration.” *Abbott Laboratories*, 387 U.S. at 149; accord *Toilet Goods Ass’n v. Gardner*, 387 U.S. 158, 162 (1967); *Dixie Fuel Co. v. Comm’r of Soc. Sec.*, 171 F.3d 1052, 1058 (6th Cir. 1999), *overruled on other grounds by Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 157 (2003). Both prongs of the ripeness test must be satisfied. *Airline Prof’ls Ass’n Local Union No. 1224 v. Airborne, Inc.*, 332 F.3d 983, 988 (6th Cir. 2003).

1. CTL’s Challenge is Not Fit for Judicial Decision Because It Does Not Raise Purely Legal Questions and There Has Been No Final Agency Action

Whether a claim is fit for judicial resolution in turn depends upon (a) whether the claim raises purely legal questions, and (b) whether the challenged decision constitutes final agency action. *Toilet Goods Ass’n*, 387 U.S. at 163-64; *Abbott Laboratories*, 387 U.S. at 149. In this case, as the district court correctly concluded, both criteria demonstrate that CTL’s official capacity claims are not fit for judicial resolution.

a. Purely Legal Questions

Although the district court found that CTL had raised one purely legal issue (whether the denial of access to Provenge to terminally ill patients violates the Constitution), it observed that CTL had raised many other issues in its official capacity claims “that are not purely legal and instead are fact-intensive.” JA____ (R. 64 at 11). Whether and when the Provenge application can be approved, and whether the existing data adequately demonstrate safety and effectiveness, are far from purely legal issues, but are instead mixed questions of law and fact that must be resolved by the agency in the first instance. *See, e.g., Neb. HHS v. HHS*, 435 F.3d 326, 331 (D.C. Cir. 2006) (where an agency decision requires the exercise of expertise and discretion, the court reviews the agency’s final determinations as an appellate court

based on the record before the agency at the time the final decision is made); *see also Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973) (decisions regarding whether a product is a “new drug” to be made by FDA).

On appeal, CTL does not challenge the district court’s conclusion that only one of the multiple issues raised in its official capacity claims is purely legal.

b. Final Agency Action

As the district court observed, “[f]inal agency action’ is both a critical prerequisite to Article III justiciability, namely ripeness, and a necessary element of a cause of action under the APA.” JA____ (R. 64 at 11) (*citing* 5 U.S.C. § 704; *Dalton v. Specter*, 511 U.S. 462, 469 (1994)).⁸

For an agency action to be “final,” two conditions must be satisfied: “First, the action must mark the ‘consummation’ of the agency’s decisionmaking process . . . it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow,’ . . .” *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (citations

⁸ The APA authorizes judicial review only with respect to “final agency action for which there is no other adequate remedy in court.” 5 U.S.C. § 704. Thus, in addition to rendering CTL’s claims unripe (thereby depriving the district court of subject matter jurisdiction), the lack of final agency action in this case provides an independent basis for dismissal for failure to state a claim under the APA. *See* JA____ (R. 64 at 13, 20).

omitted); *see also Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992) (“The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties.”). In addition, the action must not be that of a subordinate official. *Franklin*, 505 U.S. at 797 (internal quotation marks omitted; quoting *Abbott Laboratories*, 387 U.S. at 151); *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 640 (6th Cir. 2004) (quoting same passage from *Abbott*).

As the district court correctly determined, none of these conditions is satisfied here. Indeed, the court found that CTL had “utterly failed” to apply the applicable law to its unsubstantiated factual allegations and that its conclusory assertions fell “far short” of supporting its claim that FDA’s issuance of a CR letter constitutes final agency action. JA____ (R. 64 at 14). By contrast, the court found that defendants had “convincingly shown” that the issuance of a CR letter does *not* constitute final agency action. *Id.* As the court explained:

A Complete Response Letter is an established mechanism for the FDA to request additional information from the sponsor of a BLA. FDA, *Applications for Approval to Market a New Drug*, 69 Fed. Reg. 43351, 43352 (July 20, 2004). A Complete Response Letter is meant to “ensure a consistent approach to informing sponsors of needed changes before [the FDA] can approve an application, with no implication as to the ultimate approvability of the application.” *Id.* A Complete Response Letter does not signal the end for a product; rather, it is a step the FDA takes to assure that it has sufficient data to establish safety and

effectiveness prior to licensure. The FDA continues to work with sponsors to resolve any outstanding issues. *See id.*

JA_____ (R. 64 at 14).

Consistent with the district court’s description, the CR letter at issue in this case was neither the “consummation of the agency’s decisionmaking process” nor an action that determined “rights or obligations” or from which “legal consequences” flowed. *See Bennett*, 520 U.S. at 178. The letter, issued to Dendreon on May 6, 2007, did not approve or deny Dendreon’s BLA for Provenge, but instead asked Dendreon to submit additional evidence to support the efficacy claim in its BLA. *See Dendreon Press Release 5/9/07.*

The letter thus did not “alter the legal regime” and “in no way affected the legal rights of the relevant actors.” *Bennett*, 520 U.S. at 178. Indeed, a Dendreon press release issued shortly after it received the CR letter indicated that Dendreon remained “committed to working closely with the FDA to resolve these questions in a timely and efficient manner” (Dendreon Press Release 5/9/07), reflecting Dendreon’s clear understanding that the letter was “of a merely . . . interlocutory nature.” *Bennett*, 520 U.S. at 178. Far from concluding the administrative process, the CR letter was an interim step in an ongoing process that could ultimately end in the approval of the Provenge BLA. Under these circumstances, the district court correctly held that the

letter was not a “final agency action.” *See* JA____ (R. 64 at 15).

By contrast, this Circuit held that there *was* final agency action where an agency’s order found that “the public convenience and necessity is not served” by a proposed telecommunications tower location, and ordered the petitioner to continue seeking other sites. *Telespectrum, Inc. v. Pub. Serv. Comm’n of Ky.*, 227 F.3d 414, 423 (6th Cir. 2000). This Court so held in part because the agency’s order “contain[ed] *no* language which indicates that PSC will hear *further evidence* as to the Globe site.” *Id.* (emphasis added). Here, however, FDA’s CR letter affirmatively requested *further evidence*, demonstrating that the agency’s consideration of the issue remains open.

Moreover, as the district court also observed, the CR letter was issued by a subordinate official, Dr. Ashok Batra, Director of the Division of Clinical Evaluation and Pharmacology/Toxicology (“DCEPT”), within CBER’S OCTGT. JA____ (R. 64 at 15-16). Although Dr. Batra has the authority to issue CR letters, officials at his level do *not* have the authority to approve BLAs.⁹ CBER, “Signature Authority for

⁹ Dendreon’s BLA could be approved only by the Director of the OCTGT (Dr. Batra’s supervisor); the Director of CBER; or the FDA Commissioner. *Id.*; 2 *FDA Staff Manual Guides*, SMG 1410.204 (“Issuance and Revocation of Licenses for the Propagation or Manufacture and Preparation of Biological Products”) (June 27, 2003), available at http://www.fda.gov/smg/vol2/1410/1410_204.html.

Action Letters,” Sept. 20, 2004, in *Manual of Standard Operating Procedures and Policies*, SOPP 8405, ver. 4, App. 1, available at <http://www.fda.gov/cber/regsopp/8405sign.htm>. As this Court has made clear, actions taken by subordinate officials such as Dr. Batra do not constitute “final agency action.” *Air Brake*, 357 F.3d at 640 (“While NHTSA’s Chief Counsel has considerable authority over purely legal interpretations of pertinent statutes and regulations, the Secretary has not delegated authority to the Chief Counsel to make final fact-bound determinations of compliance with NHTSA’s safety standards.”). Because the CR letter here at issue was only “the ruling of a subordinate official” to whom the FDA Commissioner has *not* delegated authority to approve BLAs, it was not a final agency action. *See Franklin*, 505 U.S. at 797.

Accordingly, because the CR letter did not represent the consummation of the agency’s process (which is still ongoing); did not determine any legal rights or obligations, or affect relevant actors’ legal rights; and was signed by a subordinate official, it was not a final agency action. *See* JA ____ (R. 64 at 15-16). Under the circumstances, the district court properly found that CTL’s claims were not fit for judicial resolution, and thus “manifestly unripe.” JA ____ (R. 64 at 12-13).

2. Withholding Court Consideration Will Not Cause Hardship

The district court also found that CTL failed to establish that it would be harmed by withholding judicial review and allowing the agency's administrative process to run its course – the second required element of the ripeness test. JA _____ (R. 64 at 12). As the court observed, “FDA’s issuance of the Complete Response Letter, at most, potentially prevents access to an unproven and speculative future benefit.” *Id.* Indeed, given that FDA has determined that the data before it to date do not satisfy the BLA approval requirements and do not establish that the product is safe and effective, CTL cannot establish harm from allowing further scientific inquiry and evaluation.

Even if there were some hardship, “the size of the harm matters tremendously in determining whether a claim is ripe.” *Airline Prof’ls*, 332 F.3d at 988 n.4. Any hardship to CTL would arise solely from the wait necessitated by the drug sponsor’s submission of additional information to FDA and FDA’s evaluation of such information prior to completing its review. But this precise situation is presented by FDA review of *any* application for *any* eagerly anticipated drug or biological product. There will always be a time delay while FDA and the sponsor engage in the interactive dynamic inherent in the review and evaluation of a drug application – a process that allows FDA to gather sufficient data to determine whether all of the

statutory requirements for approval are met. That time-lag is a necessary part of the administrative review process and does not, by itself, constitute “substantial hardship.” As the district court correctly observed, “Congress balanced such hardships against the risks and dangers of using unsafe and ineffective drugs when it set the statutory standards for approval of drugs and biologics.” JA____ (R. 64 at 12) (citing *United States v. Rutherford* 442 U.S. 544, 552-53 & n.9, 556 (1979)).

Because CTL thus failed to satisfy either of the two required elements of the ripeness test – fitness for judicial resolution and hardship from deferring judicial consideration – its claims were properly dismissed for lack of subject matter jurisdiction. JA____ (R. 64 at 12-13).

3. CTL’s Ripeness and Finality Arguments Are Meritless

On appeal, CTL raises numerous objections to the district court’s findings concerning ripeness and finality – all of them meritless.

a. CTL focuses primarily on the court’s finding that the CR letter FDA issued to Dendreon was not a final agency action, arguing, in essence, that FDA’s CR letter was the functional equivalent of a denial of Dendreon’s BLA and was thus final agency action for practical purposes, even if not labeled as such by FDA. *See, e.g.*, Br. at 18-20, 30-33, 44-46. CTL claims, for instance, that a CR letter and a denial “operate functionally exactly the same way,” and that it “makes no difference to

Dendreon and no difference to Doctors and their late stage cancer patients whether the FDA denied Provenge approval or issued a CR. The effect is exactly the same. Patients are denied access to a safe and effective treatment” Br. at 18-19; *see also* Br. at 33-34 (“The Complete Response Letter served to deny the application to allow Dendreon to market and distribute Provenge.”).

Needless to say, Dendreon does not share CTL’s view that the CR letter was tantamount to denial its Provenge BLA. To the contrary, Dendreon has made clear that it will continue to work with FDA in pursuit of approval of the BLA despite its disappointment that FDA’s request for additional data would delay the ultimate availability of Provenge. *See, e.g.*, Dendreon Press Release 5/9/07; Dendreon Press Release 5/31/07. While it is true, as CTL notes, that “Dendreon cannot market the product or make it available to anyone without FDA approval” (Br. at 34), FDA’s issuance of a CR letter did not alter the *status quo*. Dendreon’s BLA remains pending before the agency just as it was before the letter issued. As the district court explained:

To be sure, makers of biologic products cannot market them without an approved BLA. 42 U.S.C. § 262(a). But the Complete Response Letter neither approved, nor denied, Dendreon’s BLA. It thus did not alter the legal regime” and “in no way affected the legal rights of the relevant actors.” *Bennett*, 520 U.S. at 178.

JA ____ (R. 64 at 15).¹⁰

In fact, CTL acknowledges that FDA's issuance of the CR letter did not constitute a final decision on the Provenge BLA so much as it reflected a decision to postpone a final decision until further data could be developed and reviewed. *See, e.g.,* Br. at 45 ("Functionally, there is no difference in net harm to plaintiffs between postponing a decision for many years and making the decision to deny approval to the drug."). Although CTL may view these two events as functionally equivalent from a patient's point of view, they are very different from a legal point of view; a decision by FDA to seek further data before deciding whether to approve a new drug or biologic application does not in any sense equate to the denial of the application and

¹⁰ Contrary to CTL's claims, the district court did not rely on defendants' representations as to the content of the CR letter issued to Dendreon, *see, e.g.,* Br. at 17-18, 21-22, nor did the court purport to "quote[] from the unseen CR letter." Br. at 32 (the quote at issue, from page 15 of the court's official capacity decision, JA ____ (R. 64 – *not* R. 69), is from *Bennett v. Spear*, 520 U.S. at 177-78). As the court's opinion makes clear, the court looked to Dendreon's publicly available press releases, which amply describe both FDA's issuance of the letter and its pertinent content, including the agency's request for additional clinical data. *See* JA ____ (R. 64 at 15). Because the CR letter at issue is part of a BLA file, it is unavailable for public disclosure. *See* 21 C.F.R. § 601.51(d); 21 C.F.R. § 20.61. But the court had no need to examine the actual letter to resolve defendants' motion to dismiss given the ample evidence in the public record characterizing FDA's action. Indeed, a CR letter is, by definition, a non-final agency action, as the court correctly recognized. *See* JA ____ (R. 64 at 14) (citing 69 Fed. Reg. at 43352) (a CR letter "inform[s] sponsors of needed changes before [the FDA] can approve an application, with no implication as to the ultimate approvability of the application").

is simply not a final agency action that is subject to judicial review.¹¹

b. CTL fares no better with its claim that the CR letter was final agency action because it effectively ends the administrative process unless and until Dendreon supplies the additional data requested by the agency. *See, e.g.*, Br. at 19 (“the applicant and not the FDA must take further action at some unknown future date OR it’s a complete and absolutely final decision”); Br. at 32 (“if no further data is submitted then there has already unassailably been a final agency action”). Thus, according to CTL, “The FDA is done until or unless further application is made. That’s final. Any decision that takes actions by a third party to reactivate is final.” Br. at 30.

CTL’s argument reveals a fundamental misunderstanding of final agency action. Any administrative proceeding can be brought to a premature conclusion should a party to the proceeding choose to no longer participate. Indeed, the sponsor of a drug or biologic application is always free to withdraw its application or

¹¹ CTL repeatedly asserts that FDA Commissioner Andrew von Eschenbach told Provenge advocates that FDA’s decision to issue a CR letter was final and would not be reconsidered by the agency. *See, e.g.*, Br. at 31, 46. Although there is no support for this assertion in the record, CTL’s claim, even if true, does not alter the conclusion that FDA’s issuance of the CR letter was not final agency action. Irrespective of whether FDA would reconsider its decision to seek additional data before granting approval to the Provenge BLA, the issuance of the letter itself was not a final decision on the application itself but merely an intermediate step in an ongoing administrative process.

otherwise abandon the process before FDA reaches a final decision on the application. But while such action *by the applicant* would end the administrative process, it would not thereby result in final *agency* action by FDA.

CTL's contention that an agency action is final whenever it depends upon the independent actions of a third party thus cannot withstand scrutiny. If CTL were correct, virtually every agency communication to a drug sponsor would be a potentially "final" action because of the possibility that the applicant could choose to abandon the application process the next day. CTL's argument confuses finality of the administrative process with final agency action. To be sure, Dendreon could decline to provide the additional information FDA has requested and effectively abandon its effort to seek approval of its application. But such a decision *by Dendreon* would not thereby convert the *agency's* decision to request more data into a final determination on the merits of the application itself. Indeed, the only thing *FDA* has decided about the Provenge BLA to this point is that the agency needs more information before it can ultimately reach a final decision either approving or denying the application.

In any event, that is not the choice Dendreon made in this case. To the contrary, as noted above, Dendreon has made quite clear its intent to continue the ongoing administrative process and provide FDA with the requested data. *See*

Dendreon Press Release 5/9/07; Dendreon Press Release 5/31/07. Thus, CTL's speculative scenario has no bearing on this case.

c. CTL's remaining arguments on ripeness and finality merit little attention. For instance, CTL challenges the district court's observation that "[b]ecause the Provenge BLA administrative process is ongoing, the FDA may ultimately approve the application, which would render Plaintiff's claims moot." JA ____ (R. 64 at 15). *See* Br. at 22-24. Characterizing this statement as "completely incorrect" (*id.* at 23), CTL insists that the court "is wrong to say later approval of Provenge would render the claims moot" (*id.*) and asserts, moreover, that "[t]he capricious actions of the FDA will never become moot." *Id.* at 24.

In fact, it is CTL who is "completely incorrect." CTL's Amended Complaint seeks injunctive and declaratory relief to compel FDA approval of Provenge and/or access to the drug by terminally ill patients – relief that would no longer be necessary should FDA ultimately approve Dendreon's BLA. *See, e.g.*, Am. Compl. at 37-38 (Further Requests for Relief), JA ____ (R. 22). Notwithstanding CTL's desire for *immediate* access to Provenge, the ultimate goal of CTL's lawsuit would nevertheless be achieved (and its claims unquestionably rendered moot) if, upon completion of the ongoing administrative proceedings, FDA approves the Provenge BLA. In these circumstances, the district court properly stayed its hand to let the administrative

process unfold – as the ripeness doctrine plainly demands. *See Devia v. NRC*, 492 F.3d 421, 424-25 (D.C. Cir. 2007) (“[T]he “usually unspoken element of the [ripeness] rationale” is this: “If we do not decide [the claim] now, we may never need to. . . . Article III courts should not make decisions unless they have to.”) (quoting *Nat’l Treasury Employees Union v. United States*, 101 F.3d 1423, 1431 (D.C. Cir. 1996)); *see also W.R. Grace & Co. v. EPA*, 959 F.2d 360, 366 (1st Cir. 1992) (“[P]remature review not only can involve judges in deciding issues in a context not sufficiently concrete to allow for focus and intelligent analysis, but it also can involve them in deciding issues unnecessarily, wasting time and effort.”).

d. CTL also disputes the district court’s finding that the CR letter was not final agency action because it was signed by a subordinate official, Dr. Ashok Batra, Director of DCEPT within CBER’S OCTCT. JA ____ (R. 64 at 15-16). CTL appears to argue that, because a superior official must have directed Dr. Batra to issue the letter, the decision was in fact the decision of the superior official. *See Br.* at 34-35. Even if true, however, CTL’s speculation that higher agency officials approved the decision to seek additional data from Dendreon could not convert the CR letter requesting such data into a final disposition of Dendreon’s BLA or change the fact that the letter was issued by an official who lacked the authority to render such a final disposition – irrespective of whether or not a higher official concurred in the decision

to issue the letter.

CTL's efforts to distinguish *Air Brake*, 357 F.3d at 640, are likewise unavailing. *See* Br. at 36. While CTL is correct that *Air Brake* involved opinion letters issued by an agency counsel, that fact alone does not distinguish *Air Brake* from the instant case in any meaningful way. Here, as in *Air Brake*, the official issuing the letter(s) in dispute lacked authority to make a final decision on behalf of the agency with respect to the subject matter at issue – in this instance, the approval or denial of Dendreon's BLA. Thus *Air Brake* is fully on point and the district court's reliance thereon was not erroneous.

e. Finally, CTL takes issue with the district court's analysis of the hardship CTL would suffer in deferring judicial consideration – the second element of the ripeness test. *See* Br. at 25-30. JA ____ (R. 64 at 12). CTL contends that the district court "improperly applie[d] the hardship element to the particular facts of this case" (Br. at 25), objecting in particular to the court's conclusion that CTL faces no greater hardship than any other patients waiting for FDA review of potentially life-saving treatments (*id.*), and its characterization of Provenge as "unproven and speculative" (*id.* at 28). *See* JA ____ (R. 64 at 12).

Notwithstanding CTL's insistence that Provenge is "absolutely not unproven and speculative" (Br. at 28), the court's finding of fact on this issue was not clearly

erroneous. Indeed, as discussed more fully below, there is ample support in the record for the district court's statement, including the Advisory Committee transcript and FDA's Clinical and Statistical Briefing Documents, all of which set forth at some length the insufficiency of the current evidence to establish Provenge's efficacy as a cancer treating agent. *See infra* at II.C.3,

CTL also challenges the district court's conclusion that "immediate consideration" of CTL's claims "could not speed patients' access to Provenge, because the only remedy that this Court could issue is a remand to the FDA to continue its review of Dendreon's BLA." JA ____ (R. 64 at 12) (citing *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985)). Accusing the court of "simply misunderstand[ing] the law," CTL argues that the court "under-asserts its own authority" in presuming it is "powerless to do anything to the FDA other than [sic] to remand matters to the FDA for continued consideration." Br. at 29.

Contrary to CTL's claim, however, the district court properly understood and applied the law. Indeed, it is well established that, even if the administrative record does not support the agency action under review, the agency did not consider all the relevant factors, or the reviewing court cannot evaluate the challenged agency action on the basis of the record before it, "the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation. The reviewing

court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry.” *Fla. Power & Light*, 470 U.S. at 744. *See also Neb. HHS*, 435 F.3d at 331 (“When a final agency action is challenged in the district court, that court ‘sits as an appellate tribunal . . . [If it] determines that [the] agency made an error of law . . . the case must be remanded to the agency for further action consistent with the corrected legal standards.’”) (citation omitted).

In any event, even if deferred judicial consideration of FDA’s action in this case were the “cause” of real (rather than hypothetical and speculative) “hardship,” CTL must satisfy *both* prongs of the ripeness test – fitness for judicial resolution *and* hardship from delaying judicial consideration – for the district court to be able to consider its claims. *Airline Prof’ls*, 332 F.3d at 988. Because the court reasonably determined that CTL satisfied *neither* of the two elements, it properly dismissed CTL’s official capacity claims for lack of subject matter jurisdiction under the doctrines of ripeness and finality. JA____ (R. 64 at 12-13). For all of the foregoing reasons, the court’s decision should be affirmed.¹²

¹² Although not addressed by the district court, this Court may also affirm on the alternative grounds that CTL failed to exhaust administrative remedies, that it lacks standing, and that it failed to state claim upon which relief could be granted, all of which were fully briefed below. *See* JA____ (R. 38 at 19-29, 35-50).

B. The District Court Correctly Held That CTL’s Claims Were Barred by Sovereign Immunity

As a final ground for dismissal, the district court held that, “[e]ven if the official capacity claims did not lack subject matter jurisdiction based upon the doctrines of finality and ripeness,” CTL’s complaint would still be subject to dismissal “based upon the doctrine of sovereign immunity.” JA ____ (R. 64 at 16-17).

As the Supreme Court has observed, “[j]urisdiction over any suit against the Government requires a clear statement from the United States waiving sovereign immunity . . . together with a claim falling within the terms of the waiver.” *United States v. White Mountain Apache Tribe*, 537 U.S. 465, 472 (2003). Indeed, it is “axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction.” *United States v. Mitchell*, 463 U.S. 206, 212 (1983); *see also FDIC v. Meyer*, 510 U.S. 471, 475 (1994); *Reed v. Reno*, 146 F.3d 392, 398 (6th Cir. 1998) (“The United States can be sued only when it has expressly given its consent to be sued.”) (internal quotation marks and citation omitted).

Waivers of sovereign immunity “cannot be implied but must be unequivocally expressed.” *United States v. Mitchell*, 445 U.S. 535, 538 (1980) (quoting *United States v. King*, 395 U.S. 1, 4 (1969)); *Reed*, 146 F.3d at 398 (waiver must be “express,

clear and unequivocal”). Thus, absent an express waiver of sovereign immunity, a district court lacks jurisdiction over claims against the United States. *See, e.g., Mitchell*, 463 U.S. at 212.

In its decision below, the district court painstakingly analyzed all of the potential waivers of sovereign immunity identified by CTL and dispatched them *seriatam*, ultimately concluding that CTL had failed to identify any valid waiver of sovereign immunity that would allow its claims to proceed. JA____ (R. 64 at 17-20). On appeal, CTL jettisons all of its former arguments and relies solely upon the APA, arguing that the APA waives sovereign immunity and that “at a minimum the Plaintiff should have been allowed to proceed under the APA and to conduct a limited amount of discovery to determine and define the administrative record.” Br. at 36-37.

To the contrary, as the district court explained, the APA waives sovereign immunity only for challenges to “final agency action for which there is no other adequate remedy in court.” JA____ (R. 64 at 20) (quoting *Beamon v. Brown*, 125 F.3d 965, 967 (6th Cir. 1997)) (“Although the APA provides a broad waiver of sovereign immunity, codified at 5 U.S.C. § 702, the waiver is limited [U]nder the APA, a federal district court may only review ‘[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court.’”). Because, as discussed above, FDA’s issuance of the challenged CR letter

was “in no sense” final agency action, the district court properly found that the APA did not waive sovereign immunity for CTL’s claims. JA____ (R. 64 at 20). CTL has no answer to this on appeal, aside from its already-disposed-of contention that the CR letter was final agency action. Accordingly, CTL’s reliance on the APA is unavailing, and the district court’s holding that CTL’s official capacity claims are barred by sovereign immunity should be affirmed.

C. The District Court Applied the Correct Standard of Decision; Properly Decided Defendants’ Motion to Dismiss Without Discovery; and Did Not Commit Clear Error in Its Jurisdictional Fact Finding

CTL contends that the district court applied an improper standard of decision; wrongly accepted as true facts proposed by defendants, rather than competing facts asserted by CTL; and wrongly converted defendants’ motion to dismiss pursuant to Rules 12(b)(1) and 12(b)(6) into a Rule 56 summary judgment motion, without allowing CTL to conduct discovery or submit additional evidence. Br. at 16-17, 37-41.

1. The District Court Applied the Correct Standard to Defendants’ Challenge to the Factual Basis of CTL’s Jurisdictional Claim

Contrary to CTL’s suggestion, the lower court’s decision was based solely upon Rule 12(b)(1). JA____ (R. 64 at 8-9). In fact, the court’s official capacity

decision did not even *mention* – much less rule upon – defendants’ 12(b)(6) arguments (*e.g.*, that CTL’s constitutional and civil rights claims failed to state a claim for which relief could be granted).

As this Court set out in *DLX*, 381 F.3d at 516, a 12(b)(1) motion “can either attack the claim of jurisdiction on its face . . . or it can attack the factual basis for jurisdiction.” When a 12(b)(1) motion makes a facial attack on jurisdiction, “all allegations of the plaintiff must be considered as true.” *Id.* When a 12(b)(1) motion challenges the factual basis for jurisdiction, however, “the trial court must weigh the evidence and the plaintiff bears the burden of proving that jurisdiction exists.” *DLX*, 381 F.3d at 516, *quoted in* JA____ (R. 64 at 8). Defendants’ jurisdictional attack below was factual. JA____ (R. 64 at 9). The trial court was thus required to *resolve* any factual disputes, rather than (as CTL asserts, Br. at 16, 22, 37) accept CTL’s factual assertions as true or interpret them in the light most favorable to CTL. *DLX*, 381 F.3d at 516.¹³

¹³ CTL’s assertion that “[t]he District Court should have started its analysis on a motion to dismiss with the stated fact that the FDA acted capriciously and then judged ripeness and finality based on an arbitrary action that injures the Citizens of this Country” is equally misguided. Br. at 24; *see also Id.* at 33 (“this case must be adjudged by first assuming the agency action to be capricious *and then* evaluating what remedies are available to doctors and their patients who are injured by it.”) (emphasis in original). Regardless of whether the challenged agency action proves to be valid or invalid, it was CTL’s burden, as plaintiff, to establish jurisdiction to pursue its claims. *DLX*, 381 F.3d at 516.

CTL also appears to rely upon the requirement that when a court considers “matters outside the pleadings” in deciding *certain* Rule 12 motions – those made under Rule 12(b)(6) or Rule 12(c) – it must treat the motions as Rule 56 summary judgment motions and allow the parties to submit additional material. *See* Fed. R. Civ. P. 12(d). But this requirement does not apply here where, as discussed above, the district court considered only defendants’ 12(b)(1) arguments and not their 12(b)(6) arguments.

2. The District Court Did Not Abuse Its Discretion in Deciding Defendants’ 12(b)(1) Motion Without Jurisdictional Discovery

CTL suggests several times that the trial court was required to let it conduct discovery before resolving any factual issues raised by defendants’ 12(b)(1) motion. Br. at 16-17, 21-22, 37, 41. The denial of jurisdictional discovery “is within the sound discretion of the trial court,” and is reviewed only for abuse of discretion. *Hayes v. Equitable Energy Res. Co.*, 266 F.3d 560, 571 (6th Cir. 2001); *see also Chrysler Corp. v. Fedders Corp.*, 643 F.2d 1229, 1240 (6th Cir. 1981). Although CTL repeatedly asserts that it was entitled to jurisdictional discovery, Br. at 16-17, 21-22, 37, 41, it makes no claim that discovery would have helped it defeat defendants’ ripeness, finality, and sovereign immunity arguments. The district court did not abuse its discretion.

3. The District Court’s Jurisdictional Fact Finding Was Not Clearly Erroneous

CTL concedes, as it must, that “where a trial court’s ruling on jurisdiction is based in part on the resolution of factual disputes, a reviewing court must accept the district court’s factual findings unless they are clearly erroneous.” Br. at 40 (citing *Ohio Nat’l Life Ins. Co.*, 922 F.2d at 326. CTL ascribes clear error to just one finding of fact below (Br. at 40), namely, the district court’s referring to Provenge as “unproven and speculative,” in the sentence, “[t]he FDA’s issuance of the Complete Response Letter, at most, potentially prevents access to an unproven and speculative future benefit.” JA ____ (R. 64 at 12). CTL contends that the Advisory Committee transcript, with its fractured consensus, proves that this was clear error. Br. at 40-41. But the transcript reveals that neither of the two Phase 3 studies offered by Dendreon succeeded in showing that Provenge delayed disease progression. Transcript, at 22, 43, 155-57, 164, 169, JA__ (R. 23, Ex. C). In fact, the second study was terminated prematurely after the first study’s negative results indicated that the second study would not meet its designated endpoint, delaying time to disease progression. *Id.* at 162-63, JA__.

In addition, the district court also had the opportunity to review detailed clinical and statistical briefing documents prepared by FDA, which described the

agency's concerns about the reliability of Dendreon's *post hoc* survival analysis. *See supra* at 9-10; JA ____ (R. 33 at 13-14; R. 47 at 10 n.4) (citing <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4291B1-00-index.htm>). There was no clear error in the district court's conclusion that the CR letter "at most, potentially prevents access to an unproven and speculative future benefit." JA ____ (R. 64 at 12); Br. at 28.

In any event, as noted above, even if this factual finding had been clear error, it affected only the "hardship" prong of the district court's ripeness analysis. *See* JA ____ (R. 64 at 12). Given CTL's failure to satisfy the other elements of ripeness and finality, or to identify an applicable waiver of sovereign immunity, any such error would be harmless.

D. The District Court Did Not Abuse its Discretion When it Continued its Consideration of CTL's Preliminary Injunction Until Briefing Was Complete on Defendants' Motions to Dismiss; or When It Did Not Hold an Immediate Hearing on CTL's Preliminary Injunction Motion

After CTL filed its preliminary injunction motion, the district court held an informal preliminary conference with the parties on September 13, 2007, pursuant to S.D. Ohio Civ. R. 65.1(a) (2007). During the informal conference, it became clear that many of the defendants' arguments against the preliminary injunction, such as the absence of subject matter jurisdiction, would be briefed in defendants' imminent motions to dismiss. JA ____ (R. 27). Afterwards, the district court announced that

it would continue consideration of CTL’s preliminary injunction motion until briefing was complete on defendants’ motions to dismiss, and it set an expedited schedule for that briefing. *Id.* Two and a half months later, after finding it lacked jurisdiction, the district court entered *final* judgment dismissing *all* of CTL’s claims, thereby mooting its motion for *preliminary* relief. JA_____ (R. 70).

On appeal, CTL contends that it was improper for the district court to continue its decision on CTL’s motion for preliminary relief until briefing was complete on defendants’ motions to dismiss. Br. at 46-47. CTL further contends that it was error for the district court to decide the motions to dismiss without first conducting an evidentiary hearing on CTL’s preliminary injunction motion – a hearing which, according to CTL, would have provided “some sort of public accountability” and would have “forced” FDA “to give the specific rationale it has to date refused to give” members of the public for its interim decision on a marketing application submitted by non-party Dendreon. *Id.* at 47.¹⁴

¹⁴ Contrary to CTL’s apparent belief, the general public has no right to any information concerning the status of a pending drug or biologic application. Indeed, as noted above, the content of a BLA file for an unapproved product is by law unavailable for public disclosure. *See* 21 C.F.R. § 601.51(d); *see also* 21 C.F.R. § 20.61 (governing disclosure of trade secret and confidential commercial information). Although CTL purports to find a right to public disclosure in 21 U.S.C. § 355(n)(8), that provision (now redesignated as section 355(n)(7)) requires only that within 90 days of a scientific advisory panel recommendation on a marketing application, FDA “shall review the conclusions and recommendations

CTL did not seek relief from the district court’s scheduling order, JA____ (R. 27), and did not include it in its Notice of Appeal. JA____ (R. 68). It has thus waived the issue. *United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 756 (6th Cir. 1999). But even if the issue had been preserved, the district court’s power to control its own docket includes “broad discretion to stay proceedings,” and such decisions are evaluated only for abuse of discretion. *Clinton v. Jones*, 520 U.S. 681, 706 (1997) (district court abused discretion in staying trial of civil lawsuit against the President until after the end of his term).

Here, the district court ordered expedited briefing on defendants’ motions to dismiss, and that briefing was complete (following a motion for extension of time by CTL) on October 21, 2007 – just thirteen days after briefing was complete on CTL’s preliminary injunction motion, on October 8, 2007. JA____ (docket sheet for R. 39 and R. 51). CTL makes no claim that this thirteen-day delay prejudiced it. Indeed,

of the panel, and notify *the affected persons* of the *final decision* on the matter, or of the reasons that no such decision has been reached.” 21 U.S.C. § 355(n)(7) (emphases added). This provision does not confer on CTL or the general public any right to be informed of FDA action on a drug manufacturer’s pending application. The sponsor of the application – in this case, Dendreon – is the pertinent “affected person” and the entity to whom FDA sent its May 2007 CR letter within 90 days of the March 2007 advisory committee meeting. Although Dendreon was entitled to an explanation of FDA’s action (including the reasons why a final decision on its BLA is not yet possible), CTL is not, regardless of any desire for “public accountability.” *See also* JA____ (R. 47 at 9-11).

CTL acknowledges that “the Lower Court did not want to take up valuable judicial resources to determine whether an injunctive order should issue when there was the potential that such order would be later set aside if the Court dismissed all counts and causes of action on jurisdictional grounds.” Br. at 46-47. The district court did not abuse its discretion.

Nor was it an abuse of discretion for the district court to dismiss this action without holding a hearing on CTL’s motion for preliminary injunction. In the absence of subject matter jurisdiction, there could be no basis for the entry of preliminary relief and, accordingly, no harm in the denial of a hearing. In any event, the purpose of a preliminary injunction hearing is not to create a mini-trial on the case as a whole or, as CTL desired here, to give the moving party a public relations opportunity, *see* Br. at 47-50, but instead, to protect the party *against whom* the preliminary injunction is sought. *See SEC v. G. Weeks Secs., Inc.*, 678 F.2d 649, 651 (6th Cir. 1982).

The district court did not decide CTL’s preliminary injunction motion at all (either with or without a hearing), but instead promptly completed its adjudication of CTL’s entire complaint (and dismissed it for lack of jurisdiction). Moreover, had the district court considered CTL’s preliminary injunction motion, it would not have needed to receive oral testimony, because the jurisdictional facts were not contested

(the one fact CTL disputes does not affect any of the grounds of ripeness, finality, or sovereign immunity), and it did not need to make credibility determinations to decide whether injunctive relief should issue. *Certified Restoration Dry Cleaning Network, LLC v. Tenke Corp.*, 511 F.3d 535, 553 (6th Cir. 2007) (“[W]here facts are bitterly contested and credibility determinations must be made to decide whether injunctive relief should issue, an evidentiary hearing must be held. [However,] where material facts are not in dispute, or where facts in dispute are not material to the preliminary injunction sought, district courts generally need not hold an evidentiary hearing.”) (brackets in original; quoting *McDonald’s Corp. v. Robertson*, 147 F.3d 1301, 1312-13 (11th Cir. 1998)).

Accordingly, the district court did not abuse its discretion in staying preliminary injunction proceedings pending its determination of the defendants’ motions to dismiss.

E. CTL’s Due Process Argument Is Not Properly Before the Court and Fails to State a Valid Claim for Relief in Any Event

As noted above, the district court dismissed CTL’s official capacity claims solely upon jurisdictional grounds; the court did not address whether the constitutional violations alleged against the official capacity defendants could withstand scrutiny under Fed. R. Civ. P. 12(b)(6). JA____ (R. 64). CTL filed its

notice of appeal, pursuant to Fed. R. App. P. 3, on December 3, 2007, identifying the November 21, 2007, official capacity decision as the order being appealed. JA ____ (R. 68).

In its subsequent individual capacity opinion, the district court addressed CTL's constitutional claims in the context of defendants' qualified immunity defense, finding that CTL failed to establish that the individual capacity defendants violated a constitutional right that was clearly established. JA ____ (R. 69). CTL did not appeal this decision, however, which was issued after CTL filed its notice of appeal. JA ____ (R. 68). Nor did CTL appeal from the final judgment. *Id.*

Nevertheless, in its appellate brief (Br. at 51-57), CTL raises a substantive due process argument that was not part of the decision from which CTL appealed, asserting a number of constitutional "rights," the most specific of which is the "right to access safe and at least potentially life-sustaining medication where there are no good alternative government approved treatment options." *Id.* at 54. As this Court has noted, however, "the general rule is that 'if an appellant . . . chooses to designate specific determinations in his notice of appeal – rather than simply appealing the entire judgment – only the specific issues may be raised on appeal.'" *Universal Mgmt. Servs.*, 191 F.3d at 756 (citing *McLaurin v. Fischer*, 768 F.2d 98, 102 (6th Cir. 1985)).

Under Fed. R. App. P. 3(c)(1)(B), an appellant must designate the judgment or order from which an appeal is taken, a requirement that is “jurisdictional and cannot be ‘waived.’” *Universal Mgmt. Servs.*, 191 F.3d at 756 (citing *Torres v. Oakland Scavenger Co.*, 487 U.S. 312, 317 (1988)) (other citation omitted). Thus, in *Universal Mgmt Servs.*, this Court held that it lacked jurisdiction to consider issues raised in the appellant’s motion for reconsideration where the notice of appeal designated only the district court’s summary judgment opinion as the order being appealed. *Id.* Likewise, in this case, because CTL did not appeal from the only decision addressing its due process claim, this Court has no jurisdiction to consider CTL’s due process argument.

Even if this Court determines that it has jurisdiction to consider CTL’s constitutional argument, it should decline to do so because, as set forth above, the district court never reached the issue, and there are ample alternative grounds for affirming the district court’s decision to dismiss the official capacity claims. *See, e.g., Jean v. Nelson*, 472 U.S. 846, 854 (1985) (“[I]f there is one doctrine more deeply rooted than any other in the process of constitutional adjudication, it is that we ought not pass on questions of constitutionality . . . unless such adjudication is avoidable.”) (quoting *Spector Motor Co. v. McLaughlin*, 323 U.S. 101, 105 (1944)).

Because this Court should not reach CTL’s due process argument, defendants

need not repeat in detail here their Rule 12(b)(6) argument from the district court. However, it is notable that the Supreme Court recently denied a petition for writ of *certiorari* in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (*en banc*), *cert. denied*, 2008 U.S. LEXIS 836 (January 14, 2008), leaving intact a decision of the D.C. Circuit, sitting *en banc*, which rejected many of the same assertions made by CTL.

In *Abigail Alliance*, 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. The court evaluated the petitioners' substantive due process claim under *Washington v. Glucksberg*, 521 U.S. 702 (1997), and 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."¹⁵ *Abigail Alliance*, 495 F.3d at 697.

Reviewing the history of federal and state drug regulation, the *en banc* court concluded that federal law has restricted access to drugs on the basis of safety

¹⁵ The majority in *Abigail Alliance* rejected the dissent's attempt to characterize the right at issue broadly as the right "to try to save one's life," recognizing that *Glucksberg* requires "a 'careful description' of the asserted fundamental liberty interest." *Id.* at 701 n.5 (citing *Glucksberg*, 521 U.S. at 721). CTL's assertions regarding the rights "to preserve our life," "to privacy," "to personal dignity and autonomy" and other broadly described "rights," Br. at 53, must also be rejected.

considerations since the early twentieth century, and other federal and state drug laws have even deeper historical roots.¹⁶ *Id.* at 703-07. To the extent that nineteenth century drug laws were more limited in scope than their twentieth century successors, the court added that “creating constitutional rights to be free from regulation based solely upon a prior lack of regulation would undermine much of the modern administrative state, which, like drug regulation, has increased in scope as changing conditions have warranted.” *Id.* at 707. The court further held that the common law doctrines of “necessity,” “intentional interference with rescue,” and “self defense,” cited by CTL here, Br. at 56-57, and in the district court, JA___ (R. 22 at 26-28), do not establish a constitutional right of access to unapproved drugs. *Abigail Alliance*, 495 F.3d at 707-10.

Having concluded that Abigail Alliance’s substantive due process claim was not “deeply rooted” in the nation’s history and tradition, the *en banc* court found it

¹⁶ Notably, biological products, such as Provenge, have been subject to mandatory federal preapproval based upon safety, purity, and *potency* (*i.e. effectiveness*) for 60 years longer than other drugs, since the licensing requirements of the Biologics Control Act of 1902, Pub. L. No. 57-244, 32 Stat. 728 (1902). Federal regulation of *safety* for drugs other than biologics dates to the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. §§ 1-15 (1934) (repealed 1938), a precursor to the FDCA, and the 1962 amendments to the FDCA, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781 (1962) mandated federal preapproval of drugs other than biologics based upon proven safety and *effectiveness*.

unnecessary to reach *Glucksberg*'s second prong – whether the asserted interest is “implicit in the concept of ordered liberty.” *Id.* at 711 n.19. Finally, applying rational basis review, the court found that FDA’s regulations readily pass constitutional muster, for even terminally ill patients can be harmed by the use of “potentially unsafe drugs with unknown therapeutic effects.” *Id.* at 713.

The D.C. Circuit’s decision in *Abigail Alliance* is consistent with a uniform body of federal precedent; indeed, every other appellate court to consider whether patients have a substantive due process right to obtain unapproved products has squarely rejected such a claim. *See 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) (holding cancer 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.”); *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir. 1980) (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”), *on remand from* 442 U.S. 544 (1979), *cert. denied*, 449 U.S. 937 (1980).

Both here and in the district court, CTL has failed to rebut this unanimous precedent. Accordingly, if this Court reaches CTL’s constitutional argument, it should determine that CTL’s due process claim is subject to dismissal pursuant to Fed. R. Civ. P. 12(b)(6) because CTL has failed to state a claim upon which relief can be granted.

CONCLUSION

For the foregoing reasons, the November 21, 2007, decision of the district court dismissing CTL's official capacity claims should be affirmed.

Respectfully submitted,

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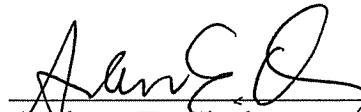
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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify that this brief has been prepared in a proportionally spaced typeface using Wordperfect 12 in Times New Roman font, 14-point type, and contains 13.375 words excluding exempt material.



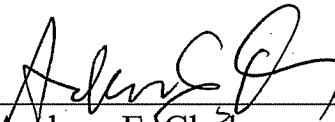
Andrew E. Clark
Counsel for Appellees

CERTIFICATE OF SERVICE

I certify that I caused the foregoing Proof Brief for the Appellees to be filed with the Court and served on counsel by mailing the original, signed brief to the Clerk of the U.S. Court of Appeals for the Sixth Circuit and by mailing one copy thereof to:

Kerry M. Donahue
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Counsel for Appellant CareToLive

this 15th day of February, 2008.



Andrew E. Clark
Counsel for Appellees

CROSS-DESIGNATION OF APPENDIX

Pursuant to 6th Cir. R. 30(b), Appellees hereby cross-designate the following parts of the record to be included in the joint appendix in addition to those parts of the record already designated by Appellant CareToLive:

<u>Record No.</u>	<u>Date</u>	<u>Description</u>
27	09/13/07	Scheduling Order
33	10/01/07	Defendants' Memorandum in Opposition to Plaintiff's Motion for Emergency Preliminary Injunctive Relief
70	12/04/07	Judgment
71	12/24/07	Order Clarifying Judgment