

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

CareToLive, et al.,

v.

Andrew von ESCHENBACH, et al.

No. 2:07-cv-00729-GLF-NMK

Judge Gregory L. Frost

Magistrate Judge Norah McCann King

**DEFENDANTS' REPLY IN SUPPORT OF
THEIR MOTION TO DISMISS
THE AMENDED COMPLAINT'S OFFICIAL CAPACITY CLAIMS**

TABLE OF CONTENTS

TABLE OF AUTHORITIES..... v

INTRODUCTION..... 1

ARGUMENT..... 2

1. CTL’s AMENDED COMPLAINT IS PREMATURE UNDER THE RIPENESS, FINALITY AND EXHAUSTION DOCTRINES..... 2

 a. CTL’s challenge is not ripe for adjudication, and there has been no final agency action on Provenge’s BLA..... 3

 CTL acknowledges that 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.” It likewise acknowledges that whether an issue is fit for judicial decision turns upon whether the issue is “purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency’s action is sufficiently final.” But CTL defends only one of its many claims as being purely legal and makes no showing that FDA’s complete response letter completed its decision-making process for Dendreon’s biologics license application (“BLA”). Finally, although CTL alleges hardship, the Court’s remedy would be to remand Dendreon’s BLA to FDA for initial decision – the same process that is already underway now.

 b. CTL confuses final agency action and exhaustion of administrative remedies, and has failed to exhaust required remedies. 7

 i. CTL’s failure to exhaust is not excused because FDA did not respond to certain other citizen petitions in 180 days. 8

 ii. CTL’s disagreement with FDA’s treatment of proprietary and trade secret information does not excuse its failure to exhaust. 9

 iii. CTL fails to demonstrate that it is exempt from exhaustion. 11

 (1) Waiver of exhaustion for constitutional claims would not exempt CTL’s numerous other claims..... 11

 (2) No “irreparable harm” excuse applies here. 12

	(3)	CTL fails to demonstrate that the “futility exception” applies.	12
	(4)	CTL’s references to bias, prejudice, and equity do not excuse its failure to exhaust.	13
2.		CTL LACKS STANDING TO CHALLENGE FDA’S ISSUANCE OF A COMPLETE RESPONSE LETTER REGARDING THE PROVENGE BLA.	14
	a.	CTL lacks representational standing.	15
		Representational standing requires that an organization be able to show that its members have suffered (1) a concrete <i>injury</i> (2) <i>caused</i> by FDA and (3) <i>redressable</i> by this Court. CTL fails to make the required showing.	
		i. CTL cannot establish standing based on alleged injuries to the public.	15
		ii. Patients and their families lack standing.	16
		CTL cannot establish any of the elements of standing as to its patient members or their families. FDA’s issuing a complete response letter means only that CTL members are momentarily deprived of an unproven, speculative, and hypothetical possible future benefit. CTL fails to identify a sufficiently concrete injury, caused by FDA, that is redressable by this Court.	
		iii. Doctors lack standing.	18
		iv. CTL cannot establish standing based on alleged injuries to the government.	19
		v. The investor/advocates lack standing.	19
		vi. CTL cannot establish third-party standing.	20
	b.	CTL lacks organizational standing.	21

In order to establish organizational standing, CTL must show that *it* has suffered (1) a concrete *injury* (2) *caused* by FDA and (3) *redressable* by this Court. Although CTL apparently engages in advocacy, and asserts that it conducts educational campaigns, it makes no showing that such activities have

been impeded by FDA’s complete response letter, or that the relief it seeks would remedy any such injury.

- c. CTL’s attempted FOIA claim cannot remedy the lack of standing. 23

After filing this lawsuit, CTL submitted a FOIA request seeking records from FDA; and then filed a premature and procedurally improper motion in *this* lawsuit to enforce its pending FOIA request. There is no FOIA claim in CTL’s amended complaint, and CTL’s FOIA motion does not grant it standing to challenge FDA’s decisions on Dendreon’s BLA.

- 3. CTL’S OFFICIAL CAPACITY CLAIMS ARE BARRED BY SOVEREIGN IMMUNITY. 25

CTL first argues against sovereign immunity by asserting that qualified immunity is unavailable here, but that doctrine applies only to individual-capacity rather than official-capacity claims. CTL next relies upon caselaw that sovereign immunity did not apply to certain quasi-governmental entities; but this caselaw is irrelevant here since FDA, as part of the Department of Health and Human Services, is part of the Executive Branch of government. Finally, CTL’s invocation of the Administrative Procedure Act (“APA”) is to no avail, because the APA waives sovereign immunity only for challenges to final agency action.

- 4. CTL’S OFFICIAL CAPACITY CLAIMS FAIL TO STATE A CAUSE OF ACTION FOR WHICH RELIEF COULD BE GRANTED. 29

CTL does not defend its equal protection, civil rights, and declaratory claims against defendants’ previous demonstration that they fail to state a claim for which relief could be granted. As to its substantial due process argument, CTL mischaracterizes the alleged right at issue as the sanctity of an individual’s control over his own person, while in fact the right CTL asserts is patients’ ability to access to an unapproved commercial product of a kind that has been subject to government regulation since Congress enacted the Biologics Control Act of 1902. CTL also fails to respond to the extensive authority from appellate courts, cited by defendants, finding that patients do not have a constitutional right to access unproven and unapproved drugs.

CONCLUSION. 32

CERTIFICATE OF SERVICE. 35

TABLE OF AUTHORITIES

CASES

ACLU v. National Security Agency,
493 F.3d 644 (6th Cir. 2007). 20

Abbott Laboratories v. Gardner,
387 U.S. 136 (1967). 3, 5

Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach,
495 F.3d 695 (D.C. Cir. 2007) (*en banc*). 30, 31

Air Brake Systems v. Mineta,
357 F.3d 632 (6th Cir. 2004). 5

Airline Professionals Association Local Union No. 1224 v. Airborne, Inc.,
332 F.3d 983 (6th Cir. 2003). 6

American Canoe Association v. City of Louisa Water & Sewer Commission,
389 F.3d 536 (6th Cir. 2004). 21

American Legal Foundation v. Federal Communications Commission,
808 F.2d 84 (D.C. Cir. 1987). 18, 21

Atlantic States Legal Foundation v. Environmental Protection Agency,
325 F.3d 281 (D.C. Cir. 2003). 3

Bangura v. Hansen,
434 F.3d 487 (6th Cir. 2006). 20

Bellsouth Corp. v. FCC,
17 F.3d 1487 (D.C. Cir. 1994). 7

Bennett v. Spear,
520 U.S. 154, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997). 4, 5, 20

Bowen v. New York,
476 U.S. 467 (1986). 13, 14

Bowen v. United States,
422 U.S. 916 (1975). 29

Camp v. Pitts,
411 U.S. 138 (1973)..... 32

Carnohan v. United States,
616 F.2d 1120 (9th Cir. 1980)..... 31

Center for Law & Education v. Department of Education,
396 F.3d 1152 (D.C. Cir. 2005)..... 21

Cleveland Board of Education v. Loudermill,
470 U.S. 532 (1985)..... 32

Coyne v. America Tobacco Co.,
183 F.3d 488 (6th Cir. 1999)..... 15

Cruzan v. Director, Missouri Department of Health,
497 U.S. 261 (1990)..... 30

Curley v. Brignoli, Curley & Roberts Associates,
915 F.2d 81 (2d Cir. 1990)..... 27

Dismas Charities, Inc. v. Department of Justice,
401 F.3d 666 (6th Cir. 2005)..... 20

Dixie Fuel Co. v. Commissioner of Social Security,
171 F.3d 1052 (6th Cir. 1999), *overruled in part by Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 157 (2003)..... 3

FDIC v. Meyer,
510 U.S. 471 (1994)..... 26

Federal Housing Administration v. Burr,
309 U.S. 242 (1940)..... 26

FW/PBS, Inc. v. City of Dallas,
493 U.S. 215 (1990)..... 19, 22

Fair Employment Council v. BMC Marketing Corp.,
28 F.3d 1268 (D.C. Cir. 1994)..... 22

Florida Power & Light Co. v. Lorion,
470 U.S. 729 (1985)..... 6, 12, 32

Franklin v. Massachusetts,
505 U.S. 788 (1992)..... 5

Galvan v. Federal Prison Industries, Inc.,
199 F.3d 461 (D.C. Cir. 1999)..... 26

Gladstone, Realtors v. Village of Bellwood,
441 U.S. 91 (1979)..... 15

Gonzales v. Raich,
545 U.S. 1 (2005)..... 31

Havens Realty Corp. v. Coleman,
455 U.S. 363 (1982)..... 21

Herrick Co. v. SCS Communications, Inc.,
251 F.3d 315 (2d Cir. 2001).. 27

Heydon v. MediaOne of Southeast Michigan, Inc.,
327 F.3d 466 (6th Cir. 2003). 28

International Telecard Association v. FCC,
166 F.3d 387 (D.C. Cir. 1999)..... 7

Jean v. Nelson,
472 U.S. 846 (1985)..... 29

Judicial Watch, Inc. v. U.S. Naval Observatory,
160 F. Supp. 2d 111 (D.D.C. 2001)..... 24

Keifer & Keifer v. Reconstruction Finance Corp.,
306 U.S. 381 (1939)..... 26

Kowalski v. Tesmer,
543 U.S. 125 (2004)..... 21

Louisiana Association of Independent Producers v. FERC,
958 F.2d 1101 (D.C. Cir. 1992)..... 32

Lujan v. Defenders of Wildlife,
504 U.S. 555 (1992)..... 18, 19

Mississippi Association of Cooperatives v. Farmers Home Administration,
139 F.R.D. 542 (D.D.C. 1991)..... 24

Mitchell v. Clayton,
995 F.2d 772 (7th Cir. 1993)..... 31

NVE Inc. v. HHS,
436 F.3d 182 (3d Cir. 2006)..... 27

National Treasury Employees Union v. United States,
101 F.3d 1423 (D.C. Cir. 1996)..... 21, 22

Nationwide Mutual Insurance Co. v. Cisneros,
52 F.3d 1351 (6th Cir. 1995)..... 3

North v. Walsh,
881 F.2d 1088 (D.C. Cir. 1989)..... 23

Office of Workers' Compensation Programs v. Newport News Shipbuilding & Dry Dock Co.,
514 U.S. 122 (1995)..... 19

Parrett v. Southeast Boll Weevil Eradication Foundation, Inc.,
155 Fed. Appx. 188 (6th Cir. 2005) (unpublished) 26

Powers v. Ohio,
499 U.S. 400 (1991)..... 21

Reconstruction Finance Corp. v. Menihan Corp.,
312 U.S. 81 (1941)..... 26

Reed v. Reno,
146 F.3d 392 (6th Cir. 1998)..... 26

Reliable Automatic Sprinkler Co. v. Consumer Product Safety Commission,
324 F.3d 726 (D.C. Cir. 2003)..... 4

Role Models America, Inc. v. White,
317 F.3d 327 (D.C. Cir. 2003) 4

Rutherford v. United States,
616 F.2d 455 (10th Cir. 1980) 31, 32

Sierra Club v. United States Army Corps of Engineers,
772 F.2d 1043 (2d Cir. 1985)..... 32

Simon v. East Kentucky Welfare Rights Organization,
426 U.S. 26 (1976)..... 18, 19, 21

Smith v. Illinois Bell Telephone Co.,
270 U.S. 587 (1926)..... 9

Standard Oil Division v. Starks,
528 F.2d 201 (7th Cir. 1975)..... 26

Szymanski v. Drug Enforcement Agency,
No. 93-1314, 1993 U.S. Dist. LEXIS 14574 (D.D.C. Oct. 5, 1993)..... 24

Telespectrum, Inc. v. Public Service Commission of Kentucky,
227 F.3d 414 (6th Cir. 2000)..... 5

Thompson v. Walbran,
990 F.2d 403 (8th Cir. 1993)..... 23, 24

Toilet Goods Association v. Gardner,
387 U.S. 158 (1967)..... 3

United States v. Burzynski Cancer Research Institute,
819 F.2d 1301 (5th Cir. 1987)..... 31

United States v. Mitchell,
463 U.S. 206 (1983)..... 26

United States v. Rutherford,
442 U.S. 544 (1979)..... 6

Warth v. Seldin,
422 U.S. 490 (1975)..... 15, 18, 19

Washington v. Glucksberg,
521 U.S. 702 (1997)..... 30

Weinberger v. Hynson, Westcott and Dunning, Inc.,
412 U.S. 609 (1973)..... 4

Whitmore v. Arkansas,
495 U.S. 149 (1990)..... 19

STATUTES

5 U.S.C. § 101 27

5 U.S.C. § 552(a)(4)(B) 23, 24, 25

5 U.S.C. § 552(a)(6)(A) 24

5 U.S.C. § 552(a)(6)(C) 24

5 U.S.C. § 704 8, 28

5 U.S.C. § 706(2)(B) 32

18 U.S.C. § 1905 10

21 U.S.C. § 331(j) 10

21 U.S.C. § 393(a) 26

28 U.S.C. § 2201 27

42 U.S.C. § 262 30

REGULATIONS

21 C.F.R. Part 10 8

21 C.F.R. § 10.25(a) 8

21 C.F.R. § 10.30(a)..... 8

21 C.F.R. § 10.30(h)(2). 9

21 C.F.R. Part 12 9

21 C.F.R. Part 13. 9

21 C.F.R. Part 14. 9

21 C.F.R. Part 15. 9

21 C.F.R. Part 16. 9

21 C.F.R. § 20.61(c).. 10

21 C.F.R. § 314.102.. 11

21 C.F.R. § 601.51(d)(1). 10, 16

FDA, *Applications for Approval to Market a New Drug*,
 69 Fed. Reg. 43351 (July 20, 2004) 4

RULES

Fed. R. Civ. P. 5(d), I. 35

Fed. R. Civ. P. 12(b)(6). 29

Fed. R. Civ. P. 23.. 20

Fed. R. Civ. P. 57.. 27

S.D. Ohio Civ. R. 5.2(a).. 35

HISTORY AND CONSTITUTIONAL PROVISIONS

Biologics Control Act, Pub. L. No. 57-244, 32 Stat. 728 (1902)
 (repealed and replaced by Public Health Services Act
 (“PHSA”), §§ 351, 611, 58 Stat. 682, 702-03, 715 (1944)
 (codified as amended at 42 U.S.C. § 262)) 31

U.S. Constitution Article I, § 8, cl. 8 10

U.S. Constitution Article III 15, 17, 20, 21, 22

INTRODUCTION

In its 110-page opposition to the defendants' motion to dismiss, plaintiff CareToLive ("CTL") offers nothing to overcome the fatal jurisdictional flaws that prevent its suit from going forward. In lieu of cogent legal analysis or argument, CTL relies primarily on emotional appeals that, for all their poignancy, cannot create subject matter jurisdiction where none exists. Nor can CTL invoke a constitutional liberty interest that is unrecognized in our jurisprudence, or state statutory claims for relief that are not cognizable under settled law.

CTL's opposition brief demonstrates a fundamental misunderstanding of the scientific and regulatory processes underlying review of a biologics license application ("BLA") by the Food and Drug Administration ("FDA"). CTL contends that "[p]atients are d[ying] without hope that access to Provenge would provide. They ask that the FDA stop their nonsense and at least give them hope." Opp. at 52. While defendants have deep sympathy for the plight of such patients, Congress requires FDA to make approval decisions based solely upon scientific data, rather than hope, precisely in order to keep manufacturers from selling false hope, deliberately or inadvertently. Indeed, FDA has requested additional scientific data to satisfy the statutory requirement for approval, as CTL's current brief acknowledges. *Id.* app. at 99 (quoting Dendreon Oct. 12, 2007 statement). Patient hopes are not a substitute.

FDA's request for additional data from Dendreon is an interlocutory step in the application process that does not constitute final agency action. And, notwithstanding the understandable desire of cancer patients to gain access to new, potentially promising treatments, CTL has no "right," whether constitutional or statutory, to dictate the direction of this administrative proceeding or to demand access to proprietary information. At bottom, CTL is a

third-party organization seeking to intervene in an ongoing administrative proceeding to which it is not a party and in which it has no valid legal interest. CTL and its members have no standing to challenge FDA's actions with respect to Dendreon's BLA for Provenge, nor does CTL have any cognizable legal basis for seeking judicial review of an intermediate step in the application review process of a proprietary biological product manufactured by a company that is not a party to this litigation.

Indeed, neither CTL's assertions of malfeasance by FDA and its officials, nor its emotional appeals on behalf of terminally ill patients, has any bearing on the justiciability of CTL's claims – which turns solely on the legal posture of the agency action CTL wishes to challenge. CTL simply cannot overcome the fact that the FDA action it seeks to overturn is part of an ongoing administrative proceeding that is in no sense “final agency action” and is manifestly unripe for judicial review. Moreover, CTL has failed to exhaust its administrative remedies, lacks constitutional standing, and has not stated a claim upon which relief can be granted under the Fifth Amendment or any other constitutional or statutory provision. CTL's amended complaint should be dismissed.

ARGUMENT

1. CTL'S AMENDED COMPLAINT IS PREMATURE UNDER THE RIPENESS, FINALITY AND EXHAUSTION DOCTRINES

As explained in defendants' opening brief, this Court lacks subject matter jurisdiction over CTL's claims under the doctrines of ripeness and finality, because a complete response letter is not final agency action. In addition, CTL failed to exhaust its administrative remedies before filing suit, which likewise requires dismissal.

a. **CTL's challenge is not ripe for adjudication, and there has been no final agency action on Provenge's BLA**

CTL does not dispute that ripeness is mandatory to establish jurisdiction. *Nationwide Mut. Ins. Co. v. Cisneros*, 52 F.3d 1351, 1361 (6th Cir. 1995) (stating that ripeness “is determinative of jurisdiction. If a claim is unripe, federal courts lack subject matter jurisdiction and the complaint must be dismissed.”) (internal quotation marks and citation omitted). Indeed, CTL literally copies the text and citations from defendants’ opening brief, *compare* Opp. at 11 with Defs.’ Official Capacity Mot. to Dismiss (Doc. 38) (hereinafter “MTD”) at 14, for the proposition that 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 v. Gardner*, 387 U.S. 136, 149 (1967); *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).

Moreover, CTL acknowledges that fitness for judicial resolution turns upon whether an issue is “purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency’s action is sufficiently final.” *Atl. States Legal Found. v. EPA*, 325 F.3d 281, 284 (D.C. Cir. 2003), *quoted in* Opp. at 10. However, CTL is able to defend only *one* of its many issues as “purely legal,” namely (in CTL’s words), “whether the FDA’s prohibition to the access of Provenge to terminally ill patients violates the Constitution.” Opp. at 28. CTL thus implicitly concedes that all *other* issues raised in its official-capacity claims – such as whether Dendreon has submitted adequate data to FDA to fulfil the requirements to obtain

approval of a BLA – are fact-intensive and not fit for judicial resolution in the absence of a full administrative record and a final agency decision that a court can review. *See, e.g., Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 627 (1973) (holding that whether a product is a “new drug” is a decision to be made by FDA in the first instance).

The second factor in whether an issue is fit for judicial determination is finality, and CTL’s arguments are equally unavailing. As defendants explained in their opening brief, complete response letters are an established mechanism for 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), *cited in* MTD at 8. CTL acknowledges the correct test to determine whether agency action is final:

For agency action to be final and subject to review under the APA, the action (1) must mark the consummation of the agency’s decision making process, rather than merely being tentative or interlocutory in nature, and the action (2) 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, 177-178, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997). “Agency action is considered final to the extent that it imposes an obligation, denies a right, or fixes some legal relationship.” *Reliable [Automatic Sprinkler Co., Inc. v. CPSC]*, 324 F.3d 726, 731 (D.C. Cir. 2003) [citing *Role Models Am., Inc. v. White*, 317 F.3d 327, 331-32 (D.C. Cir. 2003) []].

Opp. at 15 (emphases omitted). But CTL makes no attempt to *apply* any aspect of the test to the complete response letter. Instead, it contends that some unidentified “process” was “complete” when the advisory committee meeting finished on March 29, 2007, *id.* at 16, and it refers to “the decision of the FDA announced after that hearing,” *id.* at 17; apparently meaning the complete response letter’s request that Dendreon provide more information. The total of CTL’s analysis

on final agency action is the conclusory assertion that any “argument” that “there has been ‘no final decision made’ . . . lacks any merit what so ever and is close to laughable.” Opp. at 17.

To the contrary, Defendants’ opening brief fully explained why FDA’s complete response letter was not final agency action. MTD at 15-18. In sum: (1) The complete response letter requested further information, Dendreon plans to provide it, and Dendreon and FDA have reached agreement on the form of data that is needed. Opp. App. at 99 (quoting Oct. 12, 2007 Dendreon statement). FDA’s complete response letter was thus demonstrably not “the consummation of the agency’s decisionmaking process.” *Bennett*, 520 U.S. at 178; cf. *Telespectrum, Inc. v. Pub. Serv. Comm’n of Ky.*, 227 F.3d 414, 423 (6th Cir. 2000). (2) The complete response letter neither approved, nor denied, Dendreon’s BLA, and 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. (3) The complete response letter was issued by a manager authorized to issue complete response letters, but not authorized to approve BLAs. The complete response letter was thus “the ruling of a subordinate official,” and therefore “not final and therefore not subject to review.” *Franklin v. Massachusetts*, 505 U.S. 788, 798 (1992) (internal quotation marks and citation omitted); see also *Air Brake Sys. v. Mineta*, 357 F.3d 632, 640 (6th Cir. 2004). Because there is no final agency action, the matter is not fit for judicial review; and for the same reason, as CTL recognizes, it fails to state a claim under the Administrative Procedure Act (“APA”). Opp. at 13, 15.

The final element considered under ripeness is hardship to the parties in deferring consideration by the courts. *Abbott Laboratories*, 387 U.S. at 149. CTL has no response to the observation that its members face no greater hardship from waiting for a final agency decision

before bringing suit than the millions of patients who might potentially benefit from many other biologics and other drugs intended to treat life-threatening conditions that are under review by FDA at any given time. MTD at 18. Indeed, 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. *See, e.g., United States v. Rutherford*, 442 U.S. 544, 552-53 & n.9, 556 (1979) (discussing Congressional intent and legislative history, especially in context of risks borne by terminally ill cancer patients). Although CTL spends much energy asserting that its members will suffer hardship if judicial review awaits a final decision, it acknowledges that FDA did not cause patients' diseases, Opp. at 52, and FDA's issuing the complete response letter, at most, potentially prevents already very sick patients from gaining access to an unproven, speculative and hypothetical future benefit. Nor would immediate consideration by the courts speed patients' access to Provenge, because the only remedy that this Court could issue would be a remand to FDA to continue its review of Dendreon's BLA. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985); *see also* Defs.' Opp. to Pl.'s Mot. for Emergency Preliminary Inj. Relief, at 35-36 (Doc. 33). In any event, even if the Court were to find that FDA's failure to grant immediate approval to Dendreon's BLA 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 this Court to be able to consider its claims. *Airline Prof'ls Ass'n Local Union No. 1224 v. Airborne, Inc.*, 332 F.3d 983, 988 (6th Cir. 2003). As noted above, CTL attempts to demonstrate fitness for immediate judicial review for only *one* claim, namely, its substantive due process challenge, and makes *no*

meaningful attempt to demonstrate that it is challenging final agency action. The absence of ripeness and final agency action require this Court to dismiss CTL's claims.

b. CTL confuses final agency action and exhaustion of administrative remedies, and has failed to exhaust required remedies

CTL confuses exhaustion with final agency action. *See* Opp. at 20-40. Exhaustion refers to the requirement that a party must exhaust available administrative remedies for grievances before going to court. Finality refers to whether a challenged agency decision is the consummation of agency action and whether it creates legal obligations or determines parties' rights. In this case, CTL's primary grievance is that FDA did not immediately grant Dendreon's application for a biologics license, but instead sent a complete response letter requesting more information.

CTL's confusion stems from its mistaken belief that defendants contend there is no final agency action (and thus no right to judicial review) because CTL still has a citizen petition pending before the agency. CTL complains that defendants would have it wait 180 days before it could bring an action. Opp. at 6. But that is not defendants' argument.¹ To the contrary, as

¹ Indeed, CTL suggests that defendants want the Court to wait 180 days to decide the *present* action. Opp. at 6. But this is not defendants' argument either. In fact, a party may not file a lawsuit before exhausting its administrative remedies, and then ask the court to delay considering its lawsuit until after the agency completes its review. *Int'l Telecard Ass'n v. FCC*, 166 F.3d 387, 388 (D.C. Cir. 1999) ("Lest there be any misunderstanding, we expressly hold that a petition for [judicial] review filed after a bureau decision but before resolution by the full Commission is subject to dismissal as incurably premature. Ongoing agency review renders an order nonfinal for purposes of judicial review, and a petition for review of the order is incurably premature."). CTL's pending citizen petition expressly asks FDA to reconsider its decision to issue a complete response letter rather than grant immediate approval to Provenge. While a party's request for agency reconsideration remains pending before the agency, any petition for judicial review is incurably premature. *Bellsouth Corp. v. FCC*, 17 F.3d 1487, 1490 (D.C. Cir. 1994).

defendants' opening brief explained, there is no final agency action (and thus no right to judicial review) because the agency action CTL challenges – FDA's issuance of the complete response letter – was not a final agency action. CTL cannot challenge the agency's issuing the complete response letter because, as discussed above, the doctrine of ripeness requires final agency action, and also because (as pertinent here) the APA authorizes judicial challenges only to final agency action. 5 U.S.C. § 704.

The absence of a final agency action, however, is a separate and distinct issue from CTL's filing a citizen petition but not waiting for FDA to respond before commencing this lawsuit. Because CTL did not allow FDA the opportunity to respond to its citizen petition before seeking judicial relief, CTL did not exhaust its administrative remedies, which – as it recognizes, Opp. at 24 – is required before it can seek recourse to the courts.² But the “non-finality” of the administrative process with respect to CTL's pending citizen petition is wholly distinct from the non-finality of the agency action CTL is challenging in this lawsuit, namely, FDA's issuing a complete response letter to Dendreon.

i. CTL's failure to exhaust is not excused because FDA did not respond to certain other citizen petitions in 180 days

Against that background, CTL's remaining arguments about exhaustion are swiftly dismissed. CTL observes in several places that FDA does not respond to all citizen petitions

² CTL mistakenly asserts that “if there is no final agency action then there is no right to the administrative remedy which is the filing of a Title 21 section 10 citizen petition.” Opp. at 14. To the contrary, any “interested person” has a right to seek an administrative remedy by filing a citizen petition. *See* 21 C.F.R. §§ 10.25(a), 10.30(a). There is no requirement that FDA take final agency action before an interested person may file a citizen petition.

within 180 days. Opp. at 21-22, 29, 32. Although true, this observation does not excuse CTL's failure to allow FDA the opportunity to respond to *its* citizen petition.³

CTL likewise repeatedly cites various cases holding that exhaustion is excused when doing so would require waiting "indefinitely" before seeking judicial relief. Opp. at 28-29, 39-40 (both passages quoting *Smith v. Ill. Bell Tel. Co.*, 270 U.S. 587, 591-92 (1926)). But in contrast to the telephone company in *Smith*, 270 U.S. at 591, which had been seeking a response from a rate-making commission for two years, CTL waited all of three *days* after filing its citizen petition before commencing this lawsuit. There is no reason to believe that exhausting its administrative remedies in this case would entail an "indefinite" wait while FDA considers the issues raised in CTL's citizen petition.

ii. CTL's disagreement with FDA's treatment of proprietary and trade secret information does not excuse its failure to exhaust

CTL contends that FDA failed to provide what CTL considers an adequate public explanation for requesting more information from Dendreon rather than adopting the advisory committee recommendation, Opp. at 12-13, 18, 28, 30, 31, 44, 79, and complains that FDA failed to publish its complete response letter and generally does not publicize its communications with manufacturers concerning their applications for approval of new drugs or biologics, *id.* at 6, 8, 18, 19, 23-24.

³ CTL suggests that it might not get a hearing or even notice of a hearing. Opp. at 21. To be sure, the agency can, but is not obligated to, hold a hearing on citizen petitions. But if it does hold a hearing, 21 C.F.R. § 10.30(h)(2) would require it to be held pursuant to 21 C.F.R. Parts 12, 13, 14, 15, or 16, each of which requires advance public notice.

CTL's contention is based upon a fundamental misunderstanding of the BLA process. CTL's claim that "the public whose health is at stake" has greater rights than drug manufacturers, Opp. at 23, neglects that under the Constitution, Congress is authorized "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const., Art. I, § 8, cl. 8. Congress has made it a *crime* for a government official to divulge proprietary or trade secret information except as allowed by law. 18 U.S.C. § 1905.

The contents of a BLA, like those of a new drug application ("NDA"), are usually highly proprietary, and it is statutorily required – and essential for all participants in the process – for the sponsor to be able to communicate with FDA as part of FDA's review. To ensure a candid and scientifically valuable exchange, FDA and its employees and officials are prohibited from disclosing the sponsor's trade secret and confidential information. 21 U.S.C. § 331(j); 21 C.F.R. § 20.61(c). The regulations governing BLAs provide that "no data or information contained in the [BLA] file is available for public disclosure before such license is issued, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, *e.g.*, at an open session of a Food and Drug Administration advisory committee." 21 C.F.R. § 601.51(d)(1).⁴ Because approval of an NDA or BLA requires applying scientific and regulatory standards, the process typically requires extensive direct and confidential communications

⁴ The second clause of this provision authorized the redacted FDA clinical, statistical, and CMS briefing papers publicly posted on FDA's website before the advisory committee meeting, *available at* <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4291B1-00-index.htm>, and also authorized public access to the meeting itself. Those documents set out in detail the publicly available views of FDA staff on the merits of Dendreon's BLA.

sponsor, in which FDA reviewers raise issues and concerns that the sponsor may then try to address. *See, e.g.*, 21 C.F.R. § 314.102 (“Communications between FDA and applicants”). If a manufacturer suspected that its communications with FDA would be made public, it would be more difficult for FDA to obtain the necessary detailed information. As noted, by statute and regulation such communications with sponsors while a BLA remains under review are generally not subject to public disclosure with limited exceptions, such as the disclosure of certain information at an open advisory committee meeting, which in fact occurred here. While CTL is free to disagree with the way in which Congress currently directs FDA (and other federal agencies) to protect private intellectual property, such policy disagreements are no excuse for CTL’s failure to exhaust its administrative remedies before filing suit.

iii. CTL fails to demonstrate that it is exempt from exhaustion

(1) Waiver of exhaustion for constitutional claims would not exempt CTL’s numerous other claims

CTL argues at length that it is exempt from exhaustion. *Opp.* at 24-40. Its most substantive argument draws on a line of cases holding that constitutional challenges to administrative decisions need not be exhausted before the agency prior to seeking judicial review. *Opp.* at 25-28. Even assuming that line of cases applies here, though, it would only mean that exhaustion was not required for CTL’s constitutional arguments, *e.g.*, its argument that patients have a substantive due process right to access biological products that FDA has not approved as safe, pure and potent. This would not excuse CTL from exhausting available administrative relief for its remaining official capacity claims, most notably its request for a declaration that Provenge is not a “new drug” subject to FDA pre-approval, and its demand that

the Court order FDA to approve the Provenge BLA immediately, on grounds that Dendreon has submitted sufficient data to FDA.

(2) **No “irreparable harm” excuse applies here**

CTL next contends that an “irreparable harm” exception to exhaustion applies, on grounds that patients would suffer irreparable harm if the Court required CTL to exhaust its administrative remedies. Opp. at 29-30. But any harm CTL or its members might suffer while awaiting FDA consideration of its citizen petition is purely hypothetical and speculative, as defendants have pointed out above, *see* page 6 *supra*, and would not be redressable by this lawsuit in any event, *Fla. Power & Light*, 470 U.S. at 744; Defs.’ Opp. to Pl.’s Mot. for Emergency Preliminary Inj. Relief, at 35-36 (Doc. 33). CTL can make no valid showing that its members would suffer “irreparable harm” unless the Court excuses its failure to exhaust its administrative remedies before filing this suit.

(3) **CTL fails to demonstrate that the “futility exception” applies**

CTL argues that it is excused from exhaustion due to the futility exception – an exception which, it acknowledges, applies “when following the administrative remedy would be futile because of *certainty* of an adverse decision.” Opp. at 33 (emphasis added; internal quotation marks and citation omitted). Rather than demonstrate that an adverse decision is “certain” – the crux of the futility exception – CTL again observes that FDA does not respond promptly to all citizen petitions. *Id.* at 34, 37. CTL mistakenly suggests that citizen petitions should be determined in part by whether FDA is “barraged” with “public outrage,” *id.* at 35, 37-38; even if there were anything to support this view, it would have nothing to do with whether

CTL is excused from exhausting its administrative remedies. Moreover, FDA's inability to respond to CTL's citizen petition within three *days* in no way demonstrates that an adverse decision is "certain." CTL also asserts that at a meeting on June 4, 2007, Commissioner von Eschenbach "was firm in the FDA's decision to request more Provenge data and not grant immediate approval." Opp. at 36. But CTL does not explain how Dr. von Eschenbach's alleged statement makes an adverse decision "certain," much less why – if it did make an adverse decision "certain" – it nonetheless submitted its allegedly futile petition a month and a half *after* Dr. von Eschenbach's alleged statement. Indeed, CTL is still asking members who visit its website to lobby FDA by commenting on its citizen petition. CareToLive, "CareToLive Vs. Andrew von Eschenbach, et al.," <http://www.caretolive.com/LawsuitLinks.html> (last visited Oct. 26, 2007). Although defendants' opening brief raised the question, MTD at 11-12, 22, CTL makes no attempt to explain why it is asking its members to support a petition it would have this Court believe is "certain" to be denied. CTL's attempt to invoke the futility exception must be rejected.

(4) CTL's references to bias, prejudice, and equity do not excuse its failure to exhaust

CTL next raises the specter of bias and prejudice. Opp. at 38-39. However, CTL makes no claim to have had any prior dealings with FDA, much less that FDA is biased against it. Likewise, CTL fails to explain why it filed a citizen petition even though it asserts that FDA has prejudged the issues. Finally, CTL cites *Bowen v. New York*, 476 U.S. 467, 486 (1986), in which the Supreme Court upheld a district court's waiving exhaustion for disability applicants whose grievance was that they had been harmed by a Social Security Administration decision

process they didn't know about, and thus could not timely challenge before the agency. *See* Opp. at 39. By contrast, CTL makes no claim here that it was unable to seek timely administrative relief, nor could it: Unlike the disability applicants in *Bowen*, CTL did seek administrative relief.

For all the reasons set forth above, CTL's challenge to FDA's complete response letter is premature under the ripeness, finality and exhaustion doctrines, and its amended complaint should therefore be dismissed for lack of subject-matter jurisdiction.

2. CTL LACKS STANDING TO CHALLENGE FDA'S ISSUANCE OF A COMPLETE RESPONSE LETTER REGARDING THE PROVENGE BLA

Defendants' opening brief set forth several reasons why the Court should dismiss CTL's amended complaint for lack of standing. Specifically, CTL failed to establish organizational standing because it failed to satisfy any, much less all, of the required elements of standing – (1) a concrete *injury* (2) *caused* by FDA and (3) *redressable* by this Court – for any of its members. *See* MTD at 25-27. In addition, defendants showed that the amended complaint did not establish standing for member advocates, doctors, and patients' families because it did not allege cognizable injuries to them, and it could not establish third-party standing. *Id.* at 28-29.

CTL now argues that it has representational standing based on alleged injuries not only to patients, but also to the public, patients' families, doctors, the government, and investors. Opp. at 43-57. CTL also asserts that it has organizational standing based on alleged injuries to CTL itself. *Id.* at 57-60. None of these arguments is sufficient to establish standing.

a. **CTL lacks representational standing**

i. **CTL cannot establish standing based on alleged injuries to the public**

CTL first claims that it has standing because it represents “the public and the citizenry,” alleging that “[a]lmost every household in the United States is affected in some way by the ravagous [*sic*] of cancer” and that FDA has a “duty of accountability” that requires it to explain to the public its reasons for issuing a complete response letter declining to approve the Provenge BLA at this time. Opp. at 44-45. However, a plaintiff cannot rely on a generalized grievance shared by a large segment of the populace to establish Article III standing. *Gladstone, Realtors v. Vill. of Bellwood*, 441 U.S. 91, 100 (1979); *Warth v. Seldin*, 422 U.S. 490, 499 (1975). *See also Coyne v. Am. Tobacco Co.*, 183 F.3d 488, 494-95 (6th Cir. 1999) (plaintiffs did not suffer a legally cognizable injury sufficient to confer standing where injury to plaintiffs was not distinct from injury shared by all state taxpayers and public employees). In addition, as set forth in greater detail below, CTL cannot represent the interests of third parties who are not members of CTL. Accordingly, CTL’s claim of standing on behalf of the public must fail.

Nor, as explained above, *see* pages 9-11, *supra*, is there any merit to the assertion that FDA has improperly denied information to the public. FDA has fully explained its reasoning to Dendreon, the sponsor of the Provenge BLA, and, contrary to CTL’s claims, is not obliged to share such information with the public. Although CTL may take a great interest in the disclosure of the Provenge application, Dendreon retains proprietary rights to its unapproved BLA, and FDA is forbidden from disclosing proprietary and trade secret information except as allowed by law.

Nonetheless, in this case, consistent with the limited exception allowed under FDA regulations, *see* 21 C.F.R. 601.51(d)(1), FDA's safety and effectiveness concerns were made public at the March 29, 2007 advisory committee meeting. As defendants set forth in their opposition to CTL's motion for preliminary injunction (Doc. 33 at 12-14, 26-28), FDA discussed in detail the shortcomings of Dendreon's data—including the failure of Dendreon's studies to meet their intended endpoints, the *post hoc* nature of Dendreon's survival analysis, the inconsistency of survival results in Dendreon's two studies, the small size of the studies, and the potential safety signal related to strokes—in both its public briefing documents and its presentation at the public meeting. Accordingly, CTL's standing claim on behalf of the public has no basis in law or in fact.

ii. Patients and their families lack standing

Defendants' opening memorandum fully explains the defects in CTL's claim of standing with respect to its member patients, and CTL has failed to effectively rebut defendants' arguments. CTL attached to its response the executed affidavit of Mr. Howard Cassell and letters from member patients Messrs. Ted Girgus and David Friedline. Opp. Exs. E, F, & G (Docs. 43-7, 43-8, & 43-9). However, all of those documents contain vague allegations, similar to those already raised by CTL and previously addressed by defendants, that such patients *could or would* benefit from Provenge and that they want it to be approved.⁵ CTL also asserts, without

⁵ Mr. Friedline states that his disease is progressing despite hormone therapy, Opp. Ex. G (Doc. 43-9), and Mr. Girgus indicates that he is currently taking hormones, but fears that he will soon be hormone refractory, Opp. Ex. F (Doc. 43-8), which is the patient population for which Provenge is intended. In addition, Mr. Friedline states that his doctors have remarked that Provenge "would likely benefit" him and that it "may 'work well,'" Opp. Ex. G (Doc. 43-9), and Mr. Girgus states that his doctors have said that they would prescribe it. Opp. Ex. F (Doc. 43-8).

supporting affidavits, that other patients want Provenge, were disappointed when it was not approved, and have already benefitted from it. Opp. at 46-48.

As previously set forth by defendants, such claims do not establish the concrete and particularized injury caused by FDA and redressable by the Court necessary to establish standing. CTL acknowledges that FDA “may not have originally caused the patients’ disease,” but alleges that “there is an excellent chance it caused, through omission, its continuation.” Opp. at 52. There is no basis for this statement. FDA’s complete response letter merely maintained the *status quo*, and at most, potentially denied already very sick patients a speculative and hypothetical future benefit. This is not a sufficiently concrete injury to establish Article III standing.⁶ Even if it were, however, CTL has not established that future injuries that may be suffered by patients are “fairly traceable to,” *i.e.*, caused by, the complete response letter, rather than the result of circumstances beyond FDA’s control. Nor has CTL established that it is likely that any such injury will be redressed by a favorable decision, as the only remedy that this Court can issue would be a remand to FDA for further proceedings on Dendreon’s BLA, and such processes are, in fact, already ongoing.

The same analysis establishes that patients’ families also lack standing. Contrary to CTL’s suggestion (Opp. at 45), defendants do not discount the suffering of prostate cancer patients or their family members. However, any potential injury to the families from FDA’s

⁶ CTL misapprehends defendants’ argument concerning the type of injury needed to establish standing. CTL mistakenly claims that defendants would require CTL to allege that an individual patient was injured by an FDA enforcement action after distribution of Provenge, or that an individual patient must apply for and be denied “individual use approval,” *i.e.*, FDA permission to use Provenge outside of approved clinical trials. Opp. at 54-55, 66-67. Defendants have made no such arguments.

issuance of the complete response letter is linked to the potential injury to the patients themselves. Because the patients here lack standing, so do their families.⁷

iii. Doctors lack standing

CTL also argues that doctors have standing to assert both patients' rights and their own rights, and claims that doctors are being directly denied the right to prescribe Provenge to patients whom they believe would benefit from it. Opp. at 48. In support, CTL submitted letters from Drs. Rostock and Calise,⁸ Opp. Exs. H & I, who claim that they would prescribe Provenge to unnamed patients who may or may not be members of CTL. CTL also references the previously submitted affidavit of Dr. Bennett who also wants Provenge for unnamed patients.

These claims also fail. A plaintiff cannot rest a claim to standing on the rights and interests of third parties. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992); *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 44-45 (1976); *Warth*, 422 U.S. at 499.⁹ Accordingly, doctors cannot assert patients' rights to obtain standing. Moreover, a physician's inability to

⁷ CTL submits letters from Mr. Stephen Study, and claims that Mr. Study's father, a prostate cancer patient, incurred expenses of \$80,000 to travel to Manila and obtain a treatment similar to Provenge. See Opp. at 45 & Ex. D. However, CTL did not allege this in its amended complaint or sue the official capacity defendants for damages. Even had it done so, such alleged injuries were not caused by FDA and would not be redressable by the Court. Accordingly, this newly alleged injury does not confer standing on CTL on behalf of Mr. Study.

⁸ Dr. Calise's letter is just one example of a statement made by an individual who purports to support CTL's cause but does not claim to be a member of CTL. Such statements do not help CTL establish representational standing on behalf of its members. To establish representational standing, an organization must have "members," as opposed to mere "supporters." *Am. Legal Found. v. FCC*, 808 F.2d 84, 89-90 (D.C. Cir. 1987).

⁹ Although a party with standing may assert the interests of a third-party in limited circumstances, those circumstances are not present here. See MTD at 28-29; and discussion below at page 20, *infra*.

prescribe an unapproved drug to his or her patients, which is the legal *status quo* in the United States, does not constitute a “distinct and palpable” injury to physicians that is “concrete in both a qualitative and temporal sense.” *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990).

iv. CTL cannot establish standing based on alleged injuries to the government

CTL next attempts to establish standing by alleging that FDA’s actions have hurt the government. Such allegations are irrelevant because CTL does not represent the government, and CTL cannot establish standing based on injuries to a third party. *Lujan*, 504 U.S. at 562; *Simon*, 426 U.S. at 44-45; *Warth*, 422 U.S. at 499.

v. The investor/advocates lack standing

Finally, CTL lists “investors” as a group of injured parties. Opp. at 44. It further asserts that “investors turned advocates” have “been hurt by the conduct of the FDA” because they are “not privy to the inside information that funnels out of the FDA.” *Id.* at 51. These assertions do not establish standing on the part of investors.

First, CTL did not include any allegations of harm to investors in its amended complaint. Standing cannot be “inferred argumentatively from averments in the pleading,” but, rather, plaintiffs “must allege . . . facts essential to show jurisdiction.” *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990) (citations omitted). CTL is not permitted to rely on its litigation memoranda to establish standing.

Second, investors are not within the zone of interests meant to be protected by the statute in question, and thus do not have standing to challenge the government’s application of the statute. *Office of Workers’ Comp. Programs v. Newport News Shipbuilding & Dry Dock Co.*,

514 U.S. 122, 127 (1995). To determine whether a plaintiff has standing under the zone of interest test, the Court must examine “the substantive provisions of the statute, the alleged violations of which serve as the gravamen of the complaint.” *ACLU v. NSA*, 493 F.3d 644, 708 (6th Cir. 2007) (quoting *Bennett*, 520 U.S. at 175). The Court must then determine the purposes of those substantive provisions, and whether plaintiff’s alleged injuries are protected by those purposes. *Bangura v. Hansen*, 434 F.3d 487, 499 (6th Cir. 2006). Plaintiff has not and cannot point to anything in the BLA approval provisions that demonstrates a Congressional intent to protect the financial interests of investors in companies that sponsor biological products. *See Dismas Charities, Inc. v. DOJ*, 401 F.3d 666, 673-674 (6th Cir. 2005) (indirect financial benefit frequently not within zone of interest). Accordingly, the investors lack standing.

vi. CTL cannot establish third-party standing

CTL also attempts to establish standing on behalf of “an estimated 96,000 AIPC patients in the U.S.” who are “immediately affected by the FDA actions.” Opp. at 58. CTL does not and cannot represent “all 96,000 AIPC cancer patients.” To do so, plaintiff would need to seek class certification. *See Fed. R. Civ. P. 23*. Instead, CTL attempts to avoid that process by asserting third-party standing, but that doctrine was not developed to encompass this sort of attempt at class certification.

As discussed in defendants’ opening brief, litigants are generally barred from asserting the rights of third-parties, unless the litigant [1] demonstrates Article III standing in its own right, and *also* establishes the following:

[2] the litigant must have a close relation to the third party; and [3] there must exist some hindrance to the third party’s ability to protect his or her own interests.

Powers v. Ohio, 499 U.S. 400, 411 (1991) (citations omitted); *see also Kowalski v. Tesmer*, 543 U.S. 125, 130-33 (2004) (“we have not looked favorably upon third-party standing”). Plaintiff cannot satisfy this standard here. As noted in defendants’ opening brief, CTL has failed to establish first-party standing in its own right, or any hindrance to the ability of its member patients to protect their own interests. Now that plaintiff has revealed its intention to represent “all 96,000/AIPC cancer patients,” plaintiff has failed to satisfy another requirement as well – establishing evidence of a close relationship to the third party. *See, e.g., Kowalski*, 543 U.S. at 131 (finding that close relationship must be actual not hypothetical). For this reason, as well as the reasons set forth above and in defendants’ opening memorandum, CTL’s attempts to establish third-party standing fail.

b. CTL lacks organizational standing

In addition to representational standing, a plaintiff organization may attempt to establish standing on its own behalf. To establish organizational standing, plaintiff organizations must satisfy the same standing requirements that apply to individuals: injury-in-fact, that is fairly traceable to the challenged action, and that will likely be redressed by a favorable decision. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378-79 (1982); *Am. Legal Found.*, 808 F.2d at 89. An organization cannot rely on frustration of its mission to establish Article III injury. *Simon*, 426 U.S. at 40; *Ctr. for Law & Educ. v. Dep’t of Educ.*, 396 F.3d 1152, 1161 (D.C. Cir. 2005); *Nat’l Treasury Employees Union v. United States*, 101 F.3d 1423, 1427, 1429 (D.C. Cir. 1996). Instead, there must be a “concrete and demonstrable injury to the organization’s activities - with the consequent drain on the organization’s resources.” *Havens Realty Corp.*, 455 U.S. at 379; *see also Am. Canoe Ass’n v. City of Louisa Water & Sewer Comm’n*, 389 F.3d 536, 547 (6th

Cir. 2004). Thus, “[i]ndividual persons cannot obtain judicial review of otherwise non-justiciable claims simply by incorporating, drafting a mission statement, and then suing on behalf of the newly formed and extremely interested organization.” *Nat’l Treasury Employees Union*, 101 F.3d at 1429. Further, self-inflicted injury in the form of budgetary choices, such as opting to bring suit against the government rather than provide educational services, does not constitute Article III injury. *Fair Employment Council v. BMC Mktg. Corp.*, 28 F.3d 1268, 1276-77 (D.C. Cir. 1994).

CTL has failed to show Article III injury under that standard. The amended complaint is devoid of any allegations that demonstrate a concrete and demonstrable injury to CTL, which, by itself, is sufficient reason for the Court disregard CTL’s argument. *See FW/PBS, Inc.*, 493 U.S. at 231 (plaintiffs “must allege . . . facts essential to show jurisdiction”). Even if CTL were permitted to establish standing through its brief, its assertions fall short of the mark. It asserts in its brief that it “organized and began advocacy efforts” shortly after FDA’s issuance of the complete response letter, although it concedes that it did not incorporate until sometime later. *Opp.* at 57.¹⁰ It further asserts that it “seeks to help educate patients, doctors, families and the world about Provenge,” *Opp.* at 58, but it provides no facts to support this allegation, or any explanation of how FDA has impeded its alleged educational efforts. Indeed, this appears to be a classic case of an organization that was formed solely for the purpose of bringing suit and that chooses to expend its resources on litigation rather than activities.

¹⁰ Indeed, CTL did not incorporate until July 20, 2007, just 10 days before filing this lawsuit. *See* CTL Certificate of Incorporation, available at <http://www2.sos.state.oh.us/reports/rwservlet?imgc&Din=200720400264>.

c. **CTL's attempted FOIA claim cannot remedy the lack of standing**

In the middle of its standing argument, CTL asserts that the “failure of FDA to comply with the Freedom of Information Act (FOIA) is an actionable cause in its own right” and that “the FOIA claim alone is sufficient basis for the court to have jurisdiction as set forth in the FOIA and allow plaintiffs to move forward with some discovery and an injunctive hearing.” Opp. at 57. However, as fully briefed in defendants’ opposition to CTL’s motion seeking to compel FDA to comply with FOIA (Doc. 41), this Court does not have jurisdiction over CTL’s newfound FOIA “claim,” and even if it did, such jurisdiction would not remedy the Court’s lack of jurisdiction and the other defects in the claims CTL actually did allege in its amended complaint.

FOIA provides that “*on complaint*, [a] district court of the United States . . . has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant.” 5 U.S.C. § 552(a)(4)(B) (emphasis added). Because CTL did not assert any FOIA claim in its complaint or amended complaint, but instead attempted to raise its claim in a motion to compel, this Court lacks jurisdiction to grant relief under FOIA. *See, e.g., North v. Walsh*, 881 F.2d 1088, 1094 (D.C. Cir. 1989); *Thompson v. Walbran*, 990 F.2d 403, 405 (8th Cir. 1993).

This Court also lacks jurisdiction over any attempted FOIA claim because CTL failed to exhaust its administrative remedies. FDA received CTL’s FOIA request on September 11, 2007. Thus, under FOIA, FDA had until October 10, 2007, to respond. *See* 5 U.S.C. § 552(a)(6)(A), (C) (providing for administrative exhaustion if the agency does not process a FOIA request within 20 business days of *receipt*). CTL, however, filed its amended complaint

on September 5, 2007, before the required FDA office even received its FOIA request, much less before its administrative remedies were exhausted. And even if a FOIA claim could be asserted through a motion to compel, rather than a complaint (and it cannot be, as shown above), CTL filed its motion September 28, 2007 (Doc. 29), before FDA's response date had elapsed in any event. A FOIA claim that is not mature because a party did not exhaust its mandatory administrative remedies before filing its complaint "is subject to dismissal for lack of subject matter jurisdiction." *Judicial Watch, Inc. v. U.S. Naval Observatory*, 160 F. Supp. 2d 111, 112 (D.D.C. 2001).

In a belated attempt to create jurisdiction, and without providing any legal grounds to support its request, CTL "seeks leave for 7 days" to again amend its complaint to add a FOIA claim, "[i]f the court deems necessary." Opp. at 57. CTL's request should be denied because the proposed amendment "would radically alter the scope and nature of the case and bears no more than a tangential relationship to the original action." *Miss. Ass'n of Coops. v. Farmers Home Admin.*, 139 F.R.D. 542, 544-45 (D.D.C. 1991); *see also Szymanski v. DEA*, No. 93-1314, 1993 U.S. Dist. LEXIS 14574, at *5-*7 (D.D.C. Oct. 5, 1993) (striking plaintiff's amended complaint because it sought to add claims and parties that were unrelated to a straightforward FOIA dispute).¹¹

¹¹ CTL's request for leave to amend to add a FOIA claim should also be denied because CTL cannot obtain relief under FOIA against these defendants. Neither the agency head nor other agency officials are proper parties to a FOIA suit; the only proper defendant is the agency itself. *See* 5 U.S.C. § 552(a)(4)(B); *Thompson*, 990 F.2d at 405 ("FOIA authorizes suit against federal agencies and does not create [a] cause of action against individual employees of the agency.") (internal quotation marks and citation omitted)

Even if this Court had jurisdiction over CTL's attempted FOIA claim, however, such jurisdiction would be limited to "enjoin[ing] the agency from withholding agency records and to order[ing] the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B). Such jurisdiction with respect to agency records would not allow this Court to overlook the numerous jurisdictional defects in CTL's other claims. Nor, as CTL suggests, would such jurisdiction allow this case to "move forward with some discovery and an injunctive hearing," Opp. at 57, on the other issues that are wholly unrelated to CTL's attempted FOIA claim.

3. CTL'S OFFICIAL CAPACITY CLAIMS ARE BARRED BY SOVEREIGN IMMUNITY

Defendants' opening brief demonstrated that CTL's official capacity claims were barred by sovereign immunity because the APA's waiver of sovereign immunity – the only such waiver even potentially applicable to this case – is unavailable to CTL due to its failure to state a valid claim for relief under the APA or any other statutory or constitutional provision. MTD at 34. CTL tries to escape this conclusion, but none of its arguments are availing.

First, CTL contends that "[t]here is no immunity for intentional conduct done with malice that rises to the level of a constitutional tort" and thus asserts that "[n]either the government itself nor the government officials Dr. von Eschenbach, Dr. Scher and Dr. Pazdur have immunity from being sued." Opp. at 80. This argument, however, confuses sovereign immunity with concepts of absolute and qualified immunity that are applicable only to CTL's claims against Drs. Pazdur and Scher in their individual capacity. CTL's reliance on caselaw concerning the standards for imposing individual liability on government officials is thus misplaced. Opp. at 80-82. Whether or not immunity shields these defendants from liability in

their individual capacities, sovereign immunity, unless waived, is an absolute bar to any claim against the United States or its agencies or officials. *See FDIC v. Meyer*, 510 U.S. 471, 475 (1994); *United States v. Mitchell*, 463 U.S. 206, 212 (1983); *Reed v. Reno*, 146 F.3d 392, 398 (6th Cir. 1998). Thus, CTL's arguments about qualified and absolute immunity do not relieve it of its obligation to identify an applicable waiver of sovereign immunity before it may bring suit against any government official in his official capacity.

CTL's next argument centers on a series of Supreme Court decisions from the 1930s and 1940s that dealt with government-chartered corporations authorized to conduct financial business transactions and "sue and be sued" in their own name. *Opp.* at 81 (citing *Keifer & Keifer v. Reconstruction Fin. Corp.*, 306 U.S. 381 (1939) (Reconstruction Finance Corp.); *FHA v. Burr*, 309 U.S. 242 (1940) (Federal Housing Administration); *Reconstruction Fin. Corp. v. Menihan Corp.*, 312 U.S. 81 (1941) (Reconstruction Finance Corp); and *Standard Oil Div. v. Starks*, 528 F.2d 201 (7th Cir. 1975) (U.S. Postal Service)). The rulings in those cases were based on findings that Congress had not meant to endow such entities with sovereign immunity. Although its brief does not explicitly connect the dots, CTL presumably means to argue that FDA likewise lacks immunity from suit.

Even assuming these decisions are still good law, however, *but see Parrett v. Se. Boll Weevil Eradication Found., Inc.*, 155 Fed. Appx. 188, 191 (6th Cir. 2005) (unpublished) (questioning continued authority of *Keifer* and its progeny); *Galvan v. Fed. Prison Indus., Inc.*, 199 F.3d 461, 467 (D.C. Cir. 1999) (same), FDA is not a quasi-governmental business entity or private corporation like the Reconstruction Finance Corporation or the Postal Service, nor can it sue and be sued in its own name. Rather, the agency is part of the Department of Health and

Human Services, 21 U.S.C. § 393(a), which Congress has established as one of the fourteen Executive Branch departments, 5 U.S.C. § 101. Sovereign immunity is thus fully applicable to actions brought against FDA and/or its officials. *See, e.g., NVE Inc. v. HHS*, 436 F.3d 182, 189 (3d Cir. 2006) (holding that challenge to FDA regulation banning dietary supplements containing ephedra must proceed under APA because Dietary Supplement Health and Education Act did not provide a private cause of action or “contain a waiver of sovereign immunity that would permit [plaintiff] to sue a federal agency”).

CTL also argues that this Court should “exercise its power of equity jurisdiction” in this case, by which CTL presumably means the Court’s power to enter injunctive or other equitable relief where a plaintiff “has no adequate legal remedy.” *Opp.* at 82-83. Although it is unclear whether CTL asserts this argument as a means to avoid the bar of sovereign immunity or for some other purpose, it goes without saying that a court’s exercise of equitable authority depends in the first instance on the existence of subject matter jurisdiction. *See Herrick Co. v. SCS Commc’ns, Inc.*, 251 F.3d 315, 321 (2d Cir. 2001) (“subject matter jurisdiction remains ‘an unwaivable *sine qua non* for the exercise of federal judicial power’”) (quoting *Curley v. Brignoli, Curley & Roberts Assocs.*, 915 F.2d 81, 83 (2d Cir. 1990)). Certainly, nothing in the cases CTL cites on this subject in any way suggests that a court can enter equitable relief (or any other form of relief) when, as in this case, it lacks subject matter jurisdiction over the plaintiff’s claims.

For the same reason, CTL’s reference to declaratory relief under Fed. R. Civ. P. 57 is equally unavailing. *Opp.* at 85. As noted in defendants’ opening brief, MTD at 32, the Declaratory Judgment Act, 28 U.S.C. § 2201, does not waive sovereign immunity or create an independent basis for jurisdiction, but merely provides courts with the discretion to fashion a

remedy. See *Heydon v. MediaOne of Se. Mich., Inc.*, 327 F.3d 466, 470 (6th Cir. 2003). Thus, declaratory relief, like injunctive relief, is only available if the court otherwise has subject matter jurisdiction over the action.

Finally, CTL turns to the APA, observing (correctly) that, although the APA does not itself confer subject matter jurisdiction, it does waive sovereign immunity for certain non-monetary claims against the United States. Opp. at 84. As noted above and in defendants' opening brief, however, MTD at 15-18, CTL has not stated a valid claim under the APA because the action it seeks to challenge is non-final. Under the APA, a 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." 5 U.S.C. § 704 (emphasis added). Here, FDA's issuance of a complete response letter to Dendreon was not final agency action on the Provenge BLA, and CTL has cited no other statute under which it could properly seek review of FDA's determination to request further data from Dendreon rather than granting immediate approval of its BLA. Because CTL has failed to state a valid claim for non-monetary relief against the official capacity defendants under the APA or any other applicable statute or constitutional provision,¹² it cannot avail itself of the APA's waiver of sovereign immunity, and its complaint must be dismissed for lack of subject matter jurisdiction.

¹² As noted above, CTL cannot overcome the jurisdictional and other defects in this action by relying on an unpled FOIA claim. Thus, CTL's assertion that "both the APA and the FOIA have built in waivers of government immunity," Opp. at 5, is of no moment. CTL has not asserted a claim under FOIA in this action and should not be granted leave to amend its complaint to do so.

4. CTL'S OFFICIAL CAPACITY CLAIMS FAIL TO STATE A CAUSE OF ACTION FOR WHICH RELIEF COULD BE GRANTED

As set forth in defendants' opening brief, even if CTL could establish jurisdiction, this Court must dismiss CTL's claims pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. CTL did not respond to defendants' 12(b)(6) arguments with respect to CTL's equal protection, civil rights, and declaratory claims. MTD at 43-50. In addition, the arguments it does advance with respect to its due process claim fall far short of rebutting the extensive authority cited by defendants. Accordingly, all of CTL's official capacity claims must be dismissed.

In an attempt to save its constitutional claims from dismissal, CTL first contends that "since Courts are not supposed to make constitutional rulings until they are absolutely necessary that at this stage of the proceedings the Court need not make constitutional decisions." Opp. at 68. There is no reason for the Court to postpone dismissal of CTL's constitutional claims. CTL is correct that a court should not reach constitutional questions if there are other grounds for fully disposing of a case. *See, e.g., Jean v. Nelson*, 472 U.S. 846, 854 (1985) ("If there is one doctrine more deeply rooted than any other in the process of constitutional adjudication, it is that we ought not to pass on questions of constitutionality . . . unless such adjudication is unavoidable.") (citation omitted); *Bowen v. United States*, 422 U.S. 916, 920 (1975) (courts should be "reluctan[t] to decide constitutional questions unnecessarily"). However, such cases do not stand for the proposition that meritless cases should be prolonged just to postpone consideration of constitutional issues. Thus, while there is no need for the Court to reach the constitutional issues because there are ample ripeness, exhaustion, standing, and immunity grounds to fully dispose of

the case without considering them, the Court is free to, and should, dismiss such claims on the merits if the Court does reach them.

CTL also misunderstands the fundamental rights analysis that underlies substantive due process claims. CTL states that “[f]orcing patients to beg for permission from FDA officials is a fully realized violation of the constitutionally protected liberty and autonomy.” Opp. at 75. However, the alleged right involved here is not the sanctity of an individual’s control over his own person, but access to an unapproved, regulated, commercial product.¹³ Although CTL asserts without citation to authority that “drugs were unregulated for most of our Nation’s history,” Opp. at 72, CTL does not dispute that Provenge is a biological product, and does not dispute that, ever since the Biologics Control Act of 1902, Congress has required the manufacturers of biologics to demonstrate their product’s safety, purity, and potency (*i.e.*, efficacy) and to receive a license from a federal authority *before* they could legally market their products. Biologics Control Act, Pub. L. No. 57-244, 32 Stat. 728 (1902) (repealed and replaced by Public Health Services Act (“PHSA”), §§ 351, 611, 58 Stat. 682, 702-03, 715 (1944) (codified as amended at 42 U.S.C. § 262)). As demonstrated in defendants’ opening brief,

¹³ CTL’s reliance upon *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), is misplaced. As the Supreme Court subsequently explained, “the right assumed in *Cruzan* [namely, the right to refuse lifesaving hydration and nutrition] was not simply deduced from abstract concepts of personal autonomy.” *Washington v. Glucksberg*, 521 U.S. 702, 725 (1997). Instead, it depended on “the common law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment.” *Id.* Here, by contrast, denying access to an unapproved commercial product to a person who intends to ingest it does not implicate the same concern for bodily integrity as in *Cruzan*, and there is no forcible intrusion into the body that could constitute battery. See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 711 n.19 (D.C. Cir. 2007) (*en banc*) (“a tradition protecting individual *freedom* from life-saving, but forced, medical treatment does not evidence a constitutional tradition of providing *affirmative access* to a potentially harmful . . . commercial good.”) (emphases in original).

manufacturers were required to demonstrate efficacy for new biologics sixty years before they were required to do so in 1962 for new drugs. MTD at 41 n.20. Nor does CTL's assertion that patients and doctors want Provenge change the result; in fact, the Supreme Court has held that "the dispensing of new drugs, even when doctors approve their use, must await federal approval." *Gonzales v. Raich*, 545 U.S. 1, 28 (2005).

Moreover, as set forth in defendants' opening brief, MTD at 41-42, every appellate court to consider whether patients have a substantive due process right to bypass FDA's drug approval requirements and obtain unapproved products has squarely rejected such a claim. *See Abigail Alliance*, 495 F.3d at 703-07 (surveying the Nation's history of drug regulation and holding that based upon that history, terminally ill patients have no "deeply rooted" due process right of access to investigational new drugs that have undergone some testing but that FDA has not approved); *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”). CTL does not respond to these cases, and provides no reason for this Court to reject their reasoning.

CTL’s assertion of a procedural due process claim must also fail. *See* Opp. at 40-42 (asserting that FDA’s citizen petition process is unconstitutional); *id.* at 69 (stating, “The Plaintiffs are at the very least entitled to have a procedural due process, which process not be arbitrary and capricious, before they are denied a possibly life saving and life enhancing therapy.”). But only if plaintiffs can identify a cognizable property or liberty interest need the Court even consider “what process is due.” *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985) (internal quotation marks and citation omitted). CTL makes no claim that its members have a property right, and as set forth above and in defendants’ opening brief, there is no fundamental liberty interest at stake here.

Finally, contrary to CTL’s assertions, *see* Opp. at 69, CTL is not entitled to discovery on its constitutional claims, which arise under the APA. 5 U.S.C. § 706(2)(B). In cases seeking judicial review of agency action under the APA, the scope of judicial review is properly limited to the administrative record that was before the agency at the time it took the actions under review. *See Fla. Power & Light Co.*, 470 U.S. at 743–44; *Camp v. Pitts*, 411 U.S. 138 (1973); *La. Ass’n of Indep. Producers v. FERC*, 958 F.2d 1101, 1117 (D.C. Cir. 1992); *Sierra Club v. U.S. Army Corps of Eng’rs*, 772 F.2d 1043, 1051 (2d Cir. 1985).

CONCLUSION

For all of the foregoing reasons, as well as those in defendants’ opening brief, defendants respectfully move that the Amended Complaint’s official capacity claims be

dismissed for lack of subject-matter jurisdiction; for failure to state a claim upon which relief can be granted; or both.

Respectfully submitted,

Dated: October 26, 2007
Washington, D.C.

GREGORY G. LOCKHART
United States Attorney
Southern District of Ohio

MARK D'ALESSANDRO
JOHN STARK
Assistant United States Attorneys
Southern District of Ohio
303 Marconi Blvd.
Suite 200
Columbus, OH 43215

PETER D. KEISLER
Assistant Attorney General

EUGENE M. THIROLF, Director

By: /s/ {FILED ELECTRONICALLY}
ANDREW CLARK, Attorney
DANIEL K. CRANE-HIRSCH, Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386

Of Counsel:

DANIEL MERON
General Counsel
GERALD F. MASOUDI
Associate General Counsel, Food and Drug Division
ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation, Food and Drug Division

JENNIFER CARUSO

Attorney, Food and Drug Division

United States Department of Health & Human Services

Office of the General Counsel

5600 Fishers Lane

Rockville, MD 20857

CERTIFICATE OF SERVICE

Pursuant to S.D. Ohio Civ. R. 5.2(a) and Fed. R. Civ. P. 5(d), I hereby certify that the above “Defendants' Reply in Support of Their Motion to Dismiss the Amended Complaint's Official Capacity Claims” is being filed through this Court’s Electronic Case Filing system, and will thereby be served upon plaintiff’s counsel.

Dated: October 26, 2007
Washington, D.C.

By: /s/ {FILED ELECTRONICALLY}

DANIEL K. CRANE-HIRSCH, Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386