UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABIGAIL ALLIANCE FOR BETTER ACCESS TO DEVELOPMENTAL DRUGS *et al.*,	:		
Plaintiffs,	:	Civil Action No.:	03-1601 (RMU)
v.	:	Document Nos.:	4, 7
MARK B. McCLELLAN, *et al.*,	:		
Defendants.	:		

MEMORANDUM OPINION

GRANTING THE DEFENDANTS' MOTION TO DISMISS; DENYING THE PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGEMENT

I. INTRODUCTION

This matter comes before the court on defendants Mark B. McClellan, Commissioner of the Food and Drug Administration and Tommy G. Thompson, Secretary of Health and Human Services' (collectively "the defendants") motion to dismiss or in the alternative for summary judgment and plaintiffs Abigail Alliance for Better Access to Developmental Drugs ("Abigail Alliance") and Washington Legal Foundation's (collectively "the plaintiffs") Cross-Motion for Summary Judgment. Plaintiff Abigail Alliance is a non-profit organization comprised of terminally ill patients and their supporters that advocates for access to developmental drugs. Plaintiff Washington Legal Foundation is a public-interest law and policy center. The plaintiffs challenge as unconstitutional a United States Food and Drug Administration ("FDA") policy barring the sale of investigative drugs to terminally ill patients. The defendants argue that (1) the

court lacks subject matter jurisdiction because the claim is not yet ripe, the plaintiffs did not challenge a final agency action, and the plaintiffs did not exhaust all administrative remedies; and (2) the plaintiffs failed to state a claim upon which relief can be granted because there is no constitutional right of access to unapproved drugs. Because the plaintiffs do not articulate a fundamental constitutional right and Congress' action is rational, the court grants the defendants' motion to dismiss.[1]

II. BACKGROUND

A. Factual Background

In 1938, Congress enacted the Food, Drug, and Cosmetic Act ("FDCA") in part to regulate the sale of manufactured drugs. Compl. at 3; 21 U.S.C. §§ 301 *et seq*. The FDCA mandated that no "new drugs" enter interstate commerce without approval by the FDA. 21 U.S.C. § 355(a). But Congress exempted new drugs intended for research from the ban on unapproved drugs. 21 U.S.C. § 355(i).

Pursuant to its authority under the FDCA, the FDA promulgated rules to regulate the use of investigational drugs. 21 C.F.R. § 312.21. During the later phases of testing, the FDA allows drug sponsors to sell certain drugs to those in desperate need through "compassionate use"

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[1] Although the court has considered extrinsic evidence in the form of a letter from FDA Associate Commissioner For External Relations Peter J. Pitts to Frank Burroughs and Steven T. Walker, the court proceeds to decide the case under Rule 12(b)(6). When deciding a motion to dismiss, a court may consider extrinsic documents "whose terms and effect are relied upon by the plaintiff in drafting the complaint." *Gryl ex rel. Shire Pharms. Group PLC v. Shire Pharms. Group PLC*, 298 F.3d 136, 140 (2d Cir. 2002); *accord Pryor v. National Collegiate Athletic Ass'n*, 288 F.3d 548, 560 (3d Cir. 2002) (noting that a court may consider extrinsic documents if the contents of the documents are alleged in the complaint and authenticity is undisputed). Here, the plaintiff refers to the contents of the letter in its complaint and the defendant does not dispute the letter's authenticity. Compl. ¶ 26.

programs, but only at a cost-recovery price. Compl. ¶ 15; 21 C.F.R. § 312.7 (d). FDA regulations forbid the commercial distribution of an investigational drug. 21 C.F.R. § 312.7 (b).

In January 2003, Abigail Alliance submitted a proposal to the FDA for new legislation that would make investigational drugs available for purchase at the earliest stages of testing, labeling the proposal "Tier 1 Initial Approval." Defs.' Mot. at 9. In March 2003 it submitted a revised proposal without reference to new legislation. *Id.* On April 25, 2003, FDA Associate Commissioner Peter J. Pitts wrote to Abigail Alliance regarding its proposal, stating "[w]e have concluded that your 'Tier 1 Initial Approval' proposal would upset the appropriate balance that we are seeking to maintain[]." Compl. ¶ 26; Letter from Pitts to Frank Burroughs and Steven T. Walker dated April 25, 2003 at 5.

In June 2003, Abigail Alliance filed with the FDA a Citizen's Petition, which expanded its initial "Tier 1 Initial Approval" proposal.[2] Compl. ¶ 27, Def's Mot. at 10. Subsequently, the plaintiffs filed suit in this court.

B. Procedural Background

The plaintiffs filed this action on July 28, 2003 to enjoin the defendants from enforcing the FDA's policy of barring unapproved drugs from interstate commerce, insofar as it has the effect of prohibiting terminally ill patients with no other treatment options from purchasing investigational drugs. Compl. ¶¶ 1, 2. Specifically, the plaintiffs challenge the policy of barring the sale of investigational drugs "showing initial evidence of safety and efficacy in clinical

[2] A Citizen's Petition is a mechanism for formally asking the agency to take a particular action. 21 C.F.R. § 10.25. By law the FDA has 180 days to respond to a Citizen's Petition. 21 C.F.R. § 10.30(e)(2).

trials." *Id.* ¶ 2. The plaintiffs claim that because of the FDA's prohibition on for-profit sale of drugs in "compassionate use" programs, drug sponsors are disinclined to participate sufficiently to meet the demands of more than just "a fraction of those in desperate need." *Id.* ¶ 15. The plaintiffs assert that this policy violates terminally ill patients' constitutional privacy and liberty rights, as well as their due process rights to life. *Id.* ¶ 1.

The defendants responded with a motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), or in the alternative for summary judgment. Defs.' Mot. at 1. The defendants assert that there is no constitutional right of access to investigational drugs, and that the suit should therefore be dismissed under Rule 12(b)(6). *Id.* at 2. The defendants claim, moreover, that the court does not have subject matter jurisdiction over the case because it is not yet ripe, the agency action challenged is not final, and the plaintiffs failed to exhaust all administrative remedies. *Id.* at 2-3. The plaintiffs opposed this motion with a cross-motion for summary judgment. Pls.' Cross-Mot. The court now turns to the parties' motions.

III. ANALYSIS

A. A Brief Discussion of the Reviewability Doctrines' Legal Standards: Ripeness, Finality, and Exhaustion

The overlapping doctrines of ripeness, finality, and exhaustion each play a role in ensuring that courts do not unnecessarily and untimely interfere with the administrative processes. *Ticor Title Ins. Co. v. Fed. Trade Comm'n*, 814 F.2d 731, 735 (D.C. Cir. 1987). (Edwards, J., separate opinion). In this circuit the three doctrines have met with some confusion in their application. For example, in one circuit case all three judges disagreed about which of

the three doctrines should be employed to deny review to a single claim – one circuit judge held the claim failed exhaustion, one that it failed ripeness, and the other that it failed finality. *Ticor*, 814 F.2d at 732. Courts have occasionally treated finality as an aspect of exhaustion. *Marine Mammal Conservancy, Inc. v. Dept. of Agric.*, 134 F.3d 409, 411 (D.C. Cir. 1998) (explaining that unexhausted remedies suspend finality of administrative decisions). Sometimes courts have applied finality merely as a factor of ripeness. *Ciba-Geigy Corp. v. Envtl. Prot. Agency*, 801 F.2d 430, 435 (D.C. Cir. 1986); *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 34 (D.D.C. 1995). Other times courts analyze ripeness, finality and exhaustion as independent concepts. *Darby v. Cisneros*, 509 U.S. 137, 144 (1993); *Fox Television Stations, Inc. v. Fed. Communications Comm'n*, 280 F.3d 1027, 1037 (D.C. Cir. 2002); *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726 (D.C. Cir 2003). Because the defendants have raised all three doctrines in their brief, Def.'s Mot. at 19, and because the jurisprudence on this subject is unclear, the court examines ripeness, finality, and exhaustion as distinct requirements.

1. Ripeness

The ripeness doctrine lays on the foundation of Article III of the Constitution, which limits the jurisdiction of federal courts to cases or controversies. U.S. CONST. ART. III, § 2, cl. 1; *Ticor*, 814 F.2d at 735 (Edwards, J., separate opinion). The case-or-controversy requirement reflects the "common understanding of what it takes to make a justiciable case." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998). More generally, the ripeness doctrine is among the various prudential doctrines developed by the courts to test the fitness of controversies for judicial resolution. *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 47-48 (D.C.

Cir. 1999). In the agency review context, ripeness "is concerned primarily with the institutional relationships between courts and agencies, and the competence of the courts to resolve disputes without further administrative refinement of the issues." *Ticor*, 814 F.2d at 735 (Edwards, J., separate opinion).

The ripeness doctrine asks "whether the case has been brought at a point so early that it is not yet clear whether a real dispute to be resolved exists between the parties." 15 FED. PRAC. 3d § 101.70[2]. Reflecting both constitutional and prudential considerations, the doctrine "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." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967)); *see also Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 57 n.18 (1993) (stating that "[the] ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction").

Toward that end, a court must examine whether a dispute is fit for judicial review and whether withholding court consideration would cause hardship to the parties. *Ohio Forestry*, 523 U.S. at 733; *Wyoming Outdoor Council*, 165 F.3d at 48. To measure fitness, the court looks to "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." *Atl. States Legal Found. v. Envtl. Prot. Agency*, 325 F.3d 281, 284 (D.C. Cir. 2003). If a claim "rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all," it is not ripe for

adjudication. *Id.* As for hardship, the court looks to see whether the party can show that it will suffer injury in the interim. *Id.* Importantly, "[c]ourts confronted with close questions of ripeness are appropriately guided by the presumption of reviewability[]." *Ciba-Geigy*, 801 F.2d at 434 (citing *Cont'l Air Lines, Inc. v. Civil Aeronautics Board*, 522 F.2d 107, 125 (D.C. Cir 1974)).

2. Finality Of Agency Action Under the APA

Finality, a factor in the two-pronged ripeness balancing test, can also stand on its own as a distinct legal doctrine. *Darby*, 509 U.S. at 144; *Ticor*, 814 F.2d at 745-46. The finality requirement is expressed in section 704, of the Administrative Procedure Act ("APA"). 5 U.S.C. §§ 551, *et seq*. Section 702 of the APA creates a cause of action against agencies by granting a general right of judicial review of agency actions, section 704 narrows the scope of reviewability to "final agency action" only. 5 U.S.C. § 704. The finality requirement has several purposes including the protection of agency rulemaking from judicial interference, which hinges on separation of powers concerns, as well as conserving judicial resources by allowing the agency to correct any error there may be in its action. *Reliable*, 324 F.3d at 732.

For agency action to be final and subject to review under the APA, the action (1) must mark the consummation of the agency's decisionmaking 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 (1997). "Agency action is considered final to the extent that it imposes an obligation, denies a right, or fixes some legal relationship." *Reliable*, 324 F.3d at 731 (citing *Role Models Am., Inc. v. White*, 317 F.3d 327, 331-32 (D.C. Cir. 2003).

The finality requirement, however, must be applied in a "flexible and pragmatic way." *Ciba-Geigy*, 801 F.2d at 435 (internal quotation omitted). Rather than relying on some formal regulatory definition of final agency action, the court "look[s] primarily to whether the agency's position is 'definitive' and whether it has a 'direct and immediate . . . effect on the day-to-day business' of the parties challenging the action." *Ciba-Geigy*, 801 F.2d at 436 (quoting *Fed. Trade Comm'n v. Standard Oil*, 449 U.S. 232, 239 (1980)); *see also Wash. Legal Found.*, 880 F. Supp. at 34.

3. Exhaustion of Administrative Remedies Under the APA

Related to ripeness and finality is the notion that a plaintiff challenging agency action must exhaust all administrative remedies before seeking judicial review. The exhaustion requirement is also found in section 704 of the APA. 5 U.S.C. § 704 ; *Darby*, 506 U.S. at 138. The exhaustion requirement serves four purposes: (1) it ensures that persons do not flout legally established administrative processes; (2) it protects the autonomy of agency decisionmaking; (3) it aids judicial review by permitting factual development of issues relevant to the dispute; and (4) it promotes judicial economy by avoiding repetitious administrative and judicial factfinding and by resolving some claims without judicial intervention. *Pub. Citizen Health Research Group v. Comm'r, Food & Drug Admin.*, 740 F.2d 21, 29 (D.C. Cir. 1984). But, "the exhaustion doctrine is not jurisdictional in nature and should not be applied blindly when the interests that the doctrine protects would not be served." *Id*. at 33. Moreover, the Supreme Court has made clear that courts have no discretion to require exhaustion of remedies beyond those clearly mandated by congressional statute or agency regulation. *Darby*, 509 U.S. at 146.

B. The Plaintiffs' Claim is Reviewable

The defendants argue that because the plaintiffs brought suit before the FDA was required to respond to the plaintiffs' Citizen's Petition, their claim cannot be sustained under the APA insofar as it failed to satisfy the ripeness, finality, and exhaustion requirements. Defs.' Mot. at 21. Because the FDA received the plaintiffs' petition in June 2003, it was required under the 180-day response period allowed by 21 C.F.R. § 10.30(e)(2) to respond by December 2003. The complaint in this action was filed on July 28, 2003, well before the required deadline for agency response. The defendants assert that the Citizen's Petition is a prerequisite to judicial review of an agency policy, Defs.' Mot. at 10, 19, 22 (citing 21 C.F.R. §§ 10.25, 10.30, 10.45; *Garlic v. Food & Drug Admin.*, 783 F. Supp. 4, 5 (D.D.C. 1992)), an assertion that the plaintiffs flatly deny. Pls.' Statement of Genuine Issues at 2.

1. The Plaintiff's Are Exempted From the Exhaustion Requirement

The plaintiffs respond to the reviewability arguments by pointing out that their claim is constitutional in nature and is not, as misidentified by the defendants, an "arbitrary and capricious" claim arising under the APA. Pls.' Reply at 10. The plaintiffs fail to cite any authority to support their unstated presumption that constitutional claims against agency actions need not satisfy the requirements of ripeness, finality, and exhaustion. But a constitutional claim, just like any other claim challenging agency action, must challenge final agency action and must be ripe for adjudication. *See e.g., Ticor*, 814 F.2d 731 (holding that a constitutional claim failed either ripeness, finality, or exhaustion); *Wash. Legal Found*., 880 F.Supp. 26 (holding that the plaintiff satisfied exhaustion and that the constitutional claim was ripe because it challenged a

final agency action).

Constitutional claims are sometimes exempted only from the exhaustion requirement, but this is not a bright-line rule. *Marine Mammal*, 134 F.3d at 413. The basis for this exception is that agencies do not have the expertise or competence to rule on constitutional issues. *Califano v. Sanders*, 430 U.S. 99, 109 (1977). But courts can and do dismiss constitutional claims for failure to exhaust all administrative remedies. *See e.g., Marine Mammal*, 134 F.3d at 413-414 (dismissing claim of deprivation of property without due process where exhaustion would promote many of the policies typically underlying exhaustion doctrine); *see also Ticor*, 814 F.2d at 741 (Edwards, J., separate opinion).

In this case, several of the purposes of the exhaustion requirement – "giving agencies the opportunity to correct their own errors, affording parties and courts the benefits of agencies' expertise, compiling a record adequate for judicial review, [and] promoting judicial efficiency" – apply even though the claim is constitutional in nature. *Marine Mammal*, 134 F.3d at 414. Moreover, the importance of avoiding premature adjudication may even be heightened in constitutional cases, as courts are not to unnecessarily decide constitutional questions when those cases may be resolved on some other grounds. *Ticor*, 814 F.2d at 211 (Edwards, J., separate opinion) (citing e.g. *Jean v. Nelson*, 472 U.S. 846, 854 (1985)). Thus, the court concludes that the fact that the plaintiffs' claim is constitutional does not excuse them from the exhaustion requirement.

Alternatively, the plaintiffs suggest that their petition was not a necessary step toward obtaining judicial review of their claim because the April 25 letter definitively stated the FDA's position on the challenged policy. Pls.' Cross-Mot. at 11. The court interprets this suggestion as

an argument for application of the futility exception to the exhaustion requirement. This exception applies "when following the administrative remedy would be futile because of certainty of an adverse decision." *Randolph-Shepard Vendors of America v. Weinberger*, 795 F.2d 90, 105 (D.C. Cir. 1986) (quoting 3 K. Davis, *Administrative Law Treatise* § 20.07 (1958)). An adverse decision can be certain if the agency has articulated a very clear position on the issue which it has demonstrated it would be unwilling to reconsider. *Randolph-Sheppard.*, 795 F.2d at 105; *see also Fox Television*, 280 F.3d at 1040 (holding that where the agency had "just determined" in a report "that the rules in question were still necessary to the public interest, it would obviously have been futile for the petitioners to have petitioned the agency for a rulemaking to repeal them."). A request for an administrative remedy is not futile just because it will "probably fail," because "most appeals fail." *Randolph-Sheppard.*, 795 F.2d at 106; *Health Equity Res. Urbana, Inc. v. Sullivan*, 927 F.2d 963, 966 (7th Cir. 1991). Rather, the appeal must be "clearly useless" and denial of relief must be a "certainty" to excuse failure to exhaust administrative remedies. *Marine Mammal*, 134 F.3d at 413; *Shoshone Bannock Tribes v. Reno*, 56 F.3d 1469, 1476 (D.C. Cir. 1995); *Randolph-Sheppard*, 795 F2d at 105.

The FDA unequivocally rejected the initial Tier 1 Approval proposal in the April 25, 2003 letter from Associate Commissioner Pitts. The letter indicated that "several senior FDA officials have now carefully reviewed and considered [the plaintiff's] concept paper and numerous letters" and that officials had "concluded" that the proposal would "upset the appropriate balance [the FDA] is trying to maintain." Letter from Pitts to Burroughs and Walker dated April 25, 2003 at 1, 5. By rejecting the proposal, the FDA served notice that it was not receptive to the idea of allowing the commercial sale of investigative drugs in the early stages of

testing. Given this FDA proclamation, any further administrative procedure, like a Citizen's Petition, was "clearly useless," because it made clear that the agency had a "preconceived" and "unyielding" stance on the issue. *Randolph-Sheppard*, 795 F.2d at 107. Without ruling on the question of whether FDA regulations *require* an aggrieved party to file a petition before gaining judicial review, Defs.' Mot. at 10, 19, 22, the court concludes that the plaintiffs are exempted from the exhaustion requirement because further recourse to the FDA would clearly have been futile.

2. The Plaintiffs Meet the Finality Requirement

The finality issue is likewise resolved by the April 25 letter. While the FDA asserts that its policy of barring sale of investigational drugs could not be final until the Citizen's Petition was answered, "[t]he label an agency attaches to its action is not determinative." *Wash. Legal Found.*, 880 F. Supp. at 34 (citing *Cont'l Air Lines*, 522 F.2d at 124). The D.C. Circuit in *Ciba-Geigy* held that an informal letter from an agency constituted a final agency action, because it amounted to an unequivocal statement of the agency's position and had a direct effect on the regulated party. 801 F.2d at 437-439. *See also Wash. Legal Found.*, 880 F. Supp. at 34 (concluding that because an agency's informal threat of enforcement had the effect of regulating the industry, it was a final agency action). Furthermore, in *Fox Television*, the D.C. Circuit determined that an FCC report in which the Commission voiced its "last word" that the challenged policy was "necessary in the public interest" constituted a final agency action, even though the agency claimed it was not. 280 F.3d at 1038.

In light of the D.C. Circuit's pronouncement that finality must be applied in a "flexible and pragmatic way," the court may consider whether the April 25 letter, although an informal

action, constituted a final agency action. *Ciba-Geigy*, 801 F.2d at 435 (internal quotation omitted). In the letter, the FDA conclusively rejected the notion that investigational drugs should be available for commercial sale. Letter from Pitts to Burroughs and Walker dated April 25, 2003 at 5 (rejecting the idea of "giving almost total weight to the goal of early availability and giving little recognition to the importance of marketing drugs with reasonable knowledge for patients and physicians of their likely clinical benefit and their toxicity"). The last page of the letter includes a handwritten note from Mr. Pitts, apologizing for the delay in responding to Abigail Alliance's proposal stating – "I wanted to be complete and thoughtful." *Id.* at 6. The letter, six pages long with four additional pages of attachments, was clearly the result of a reasoned thought processes. As noted, "several senior FDA officials" were involved in the consideration of and rejection of Abigail Alliance's proposal. *Id.* at 1. The rejection represented the consummation of the agency's decisionmaking, was definitive and had a direct and immediate effect on the plaintiffs – it barred them from access to potentially life-saving investigational drugs. *Ciba-Geigy*, 801 F.2d at 436. Accordingly, the court holds that the finality requirement has been met.

3. The Plaintiffs Satisfy the Ripeness Requirement

This case also satisfies the ripeness requirements of fitness for review and hardship to the parties. As for fitness, the issue raised by the plaintiff – whether the FDA's prohibition on the sale of investigational drugs to terminally ill patients violates the Constitution – is purely legal. *Atl. States Legal Found.*, 325 F.3d at 284. The alleged injury does not rest on some contingent future events; rather it has already occurred and continues to occur. Accordingly, the dispute is fit for review. *Id*.

In terms of hardship, although the plaintiffs allege no specific acts of enforcement by the FDA resulting in injury, such an allegation is unnecessary in this instance. The challenged policy is of such a nature that it need not be enforced against those in the class of the plaintiffs, that is, terminally ill patients, to affect their rights. Because the policy prohibits drug companies from selling investigational drugs, it bars patients access even without any particular enforcement or threat against them directly. Thus, the plaintiffs need not challenge a specific instance of enforcement against them. Furthermore, the defendants do not question the plaintiffs' assertion that the FDA's policy has had the effect of denying investigational drugs to members of the plaintiffs. For these reasons, the case would benefit little if at all from the development of a particular factual setting. *See e.g.*, *Wash. Legal Found.*, 880 F. Supp. at 36 (holding that whether an FDA policy violates the First Amendment is primarily a legal rather than a factual inquiry). Whatever minor benefit might emerge from a more concrete setting is more than offset by the alleged hardship the plaintiffs face upon delay of review – further denial of potentially life-saving drugs.

In light of the discussions above, the fact that the defendants do not challenge the plaintiffs' assertion that the April 25 letter constituted final agency action and made exhaustion of administrative remedies futile, and the presumption in favor of judicial reviewability, the court holds that the challenged policy is a final agency action and further exhaustion of administrative remedies would be futile. *Ciba-Geigy*, 801 F.2d at 434. Thus, the suit is now ripe for review on its merits.

C. Legal Standard for Motion to Dismiss

A Rule 12(b)(6) motion to dismiss tests the legal sufficiency of a complaint. *Browning v.*

Clinton, 292 F.3d 235, 242 (D.C. Cir. 2002). The complaint need only set forth a short and plain statement of the claim, giving the defendant fair notice of the claim and the grounds upon which it rests. *Kingman Park Civic Ass'n v. Williams*, 348 F.3d 1033, 1040 (D.C. Cir. 2003) (citing FED R. CIV. P. 8(a)(2) and *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). "Such simplified notice pleading is made possible by the liberal opportunity for discovery and the other pre-trial procedures established by the Rules to disclose more precisely the basis of both claim and defense to define more narrowly the disputed facts and issues." *Conley*, 355 U.S. at 47-48 (internal quotation marks omitted). It is not necessary for the plaintiff to plead all elements of his prima facie case in the complaint, *Swierkiewicz v. Sonoma N.A.*, 534 U.S. 506, 511-14 (2002), or "plead law or match facts to every element of a legal theory." *Krieger v. Fadely*, 211 F.3d 134, 136 (D.C. Cir. 2000) (internal quotation marks and citation omitted).

Accordingly, "the accepted rule in every type of case" is that a court should not dismiss a complaint for failure to state a claim unless the defendant can show beyond doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief. *Warren v. District of Columbia*, 353 F.3d 36, 37 (D.C. Cir. 2004); *Kingman Park*, 348 F.3d at 1040. Thus, in resolving a Rule 12(b)(6) motion, the court must treat the complaint's factual allegations – including mixed questions of law and fact – as true and draw all reasonable inferences therefrom in the plaintiff's favor. *Macharia v. United States*, 334 F.3d 61, 64, 67 (D.C. Cir. 2003); *Holy Land Found. for Relief & Dev. v. Ashcroft*, 333 F.3d 156, 165 (D.C. Cir. 2003); *Browning*, 292 F.3d at 242. While many well-pleaded complaints are conclusory, the court need not accept as true inferences unsupported by facts set out in the complaint or legal conclusions cast as factual allegations. *Warren*, 353 F.3d at 39; *Browning*, 292 F.3d at 242.

D. The Plaintiffs Fail to State a Recognized Due Process Claim

The plaintiffs allege that the FDA's ban on the sale of investigational drugs violates their members' privacy and liberty rights, as well as their rights to life, pursuant to the due process clause of the 5th Amendment. Compl. ¶ 1. The "substantive component" of due process "forbids the government to infringe certain 'fundamental' liberty interests *at all* . . . unless the infringement is narrowly tailored to serve a compelling state interest." *Reno v. Flores*, 506 U.S. 292, 302 (1993) (emphasis in original). Fundamental rights are rights that are "implicit in the concept of ordered liberty," *Palko v. Connecticut*, 302 U.S. 319, 325-36 (1937), or "deeply rooted in this Nation's history and tradition." *Flores*, 507 U.S. at 303; (internal quotations omitted). If the implicated right is not a fundamental right, substantive due process requires only that the challenged government action be rationally related to a legitimate state interest. *Flores*, 507 U.S. at 305.

The plaintiffs seem to argue that there is a fundamental right of access to investigational drugs by analogizing this "right" with fundamental rights recognized by the Supreme Court, such as: (1) privacy rights as applied to contraceptives, Pls.' Cross-Mot. at 7 (citing *Griswold v. Connecticut*, 381 U.S. 470 (1965); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972)); and (2) liberty rights as applied to the right to refuse medical treatment, Pls.' Cross-Mot. a 8-9 (citing *Washington v. Glucksberg*, 521 U.S. 702, 723 (1997); *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 279 (1990)).

The D.C. Circuit has admonished lower courts against creating "new constitutional rights" without "guidance from the Constitution or . . . from articulated Supreme Court principle." *Dronenburg v. Zech*, 741 F.2d 1388, 1396 (D.C. Cir. 1984). The plaintiffs claim that

they seek no "new" right, but only "recognition and enforcement of a right that is explicitly stated on the face of the Due Process Clause." Pls.' Reply at 1-2.

The court is not persuaded that the plaintiffs seek a recognized right. While the due process clause clearly states the rights of life and liberty, and courts have recognized the right to privacy, the plaintiffs propose a novel interpretation of the due process clause. It is telling that the plaintiffs rely on cases they consider to be analogous, rather than citing any cases directly on point. No court whose authority binds this court has ever extended the due process clause to cover a terminally ill patient's right to *receive* medical treatment.

The plaintiffs note that the Supreme Court in *Griswold* invoked the right of marital privacy to strike down a state law regulating access to contraceptives and subsequently expanded that right beyond the marital context in *Eisenstadt*. Pls.' Cross-Mot. at 7 The plaintiffs then argue that the due process clause has been used to recognize a "right to die" in *Cruzan* and *Glucksberg*. *Id.* at 8. The plaintiffs seek to connect these holdings to their own case, asserting that "deeply personal decision[s]" are protected by the due process clause against government intrusion. *Id.* (quoting *Cruzan*, 497 U.S. at 281). Like the choice of whether to die by refusing needed medical treatment, the right to choose to sustain one's life by obtaining needed medical treatment is, the plaintiffs claim, a "deeply personal decision" worthy of due process protection. *Id.*, Pls.' Reply at 5.

The plaintiffs fail to note, however, that the Supreme Court in *Glucksberg* distinguished some "personal" decisions from others. Although "many of the rights and liberties protected by the Due Process Clause sound in personal autonomy [that] does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected." 521

U.S. at 727. The Court recognized *Cruzan*'s right to refuse medical treatment, but did not extend that freedom to the right to an assisted suicide. "The decision to commit suicide with the assistance of another may be just as personal and profound as the decision to refuse unwanted medical treatment, but it has never enjoyed similar legal protection." *Id.* at 725.

Instead, the Court protects only those rights are "identified as so deeply rooted in our history and traditions, or so fundamental to our concept of ordered liberty, that they are protected by the Fourteenth Amendment." *Id.* at 727. The plaintiffs argue that their case involves such a historically recognized right because "the Nation's longstanding legal tradition has been to attempt to *preserve life*." Pls.' Cross-Mot. at 9 (emphasis in original). But, like assisted suicide in *Glucksberg*, the plaintiffs here cannot possible claim that the specific right claimed has a longstanding tradition. *Glucksberg*, 521 U.S. at 711. In fact, the plaintiffs themselves acknowledge, for the sake of ripeness and finality, that the challenged policy of prohibiting access to unapproved drugs is a "longstanding policy." Pls.' Cross-Mot. at 11.

The plaintiffs also contend that *Cruzan* and *Glucksberg*, which they interpret as recognizing a right to choose death by refusing medical treatment, imply a right to choose life by obtaining investigational drugs. Pls.' Reply at 5. A fair reading of those cases has *Cruzan* establishing a freedom from government-imposed medical treatment and *Glucksberg* denying the extension of that freedom to assisted suicide. *Glucksberg*, 521 U.S. at 720 (citing *Cruzan* for the proposition that due process "protects the traditional right to refuse unwanted lifesaving medical treatment."); *Blouin ex. rel. Estate of Poulit v. Spitzer*, 356 F.2d 348, 360 (2d Cir. 2004) (explaining that in *Glucksberg* and other cases, "[t]he Supreme Court has taken pains to avoid expanding *Cruzan* beyond the context of a competent person to refuse lifesaving treatment").

Moreover, the court is not persuaded by the plaintiffs' suggestion that the freedom to refuse medical treatment and the freedom to access medical treatment are "opposite sides of the same coin," and thus that one implies the other. Pls.' Reply at 5. First, the plaintiffs cite no authority for the idea that recognition of one "side of the coin" implies the legal validity of the "opposite side," nor for the particular application of that idea to this case. Second, the court is not convinced that the metaphor is apt. *Cruzan* recognized a right of freedom against government imposition, namely the imposition of unwanted medical treatment. The plaintiffs in the instant case seek recognition of an entirely different sort of right – not freedom from government imposition, but an affirmative right of access to medical treatment. Such a right neither flows naturally from the holdings in *Glucksberg* and *Cruzan* nor has been recognized by higher courts in this context.

Neither the Supreme Court nor the D.C. Circuit has "created a right which, fairly defined, covers the case before us." *Dronenburg*, 241 F.2d at 1396. Nor have they "defined a mode of analysis, a methodology, which, honestly applied, reaches the case we must now decide." *Id.* The plaintiffs have stated the holdings of *Glucksberg*, *Cruzan*, and *Griswold* too broadly in their attempt to apply the privacy and liberty rights to the instant case. Likewise, the plaintiffs cite no authority for the proposition that the due process right to life extends to requiring affirmative access by terminally ill patients to investigational drugs.

E. The FDA Policy is Rationally Related to a Legitimate State Interest

Because there is no recognized fundamental right involved, the court must undertake a rational basis analysis. *Glucksberg*, 521 U.S. at 727. Under the rational basis test, the

challenged action "need not be in every respect logically consistent with its aims to be constitutional, and it is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it." *Williamson v. Lee Optical of Okla.*, 348 U.S. 483, 487-88 (1955). The plaintiff bears the burden of showing that there is no rational connection between the FDA actions and the interests it asserts. *Harrah Indep. Sch. Dist. v. Martin*, 440 U.S. 194, 198 (1979).

In *United States v. Rutherford*, 442 U.S. 544 (1979), the Supreme Court suggested that the prohibition on the sale of insufficiently tested drugs would pass a rational basis test. Specifically, the court noted that the vast "historical evidence" of exploitation of vulnerable cancer patients by "resourceful entrepreneurs" with claims of false cures "suggest[s] why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise." *Id.* at 558. On remand in *Rutherford*, the Tenth Circuit concluded that the FDCA's requirement of testing before marketing drugs is "within the area of governmental interest in protecting public health." *United States v. Rutherford*, 616 F.2d 455, 457 (10th Cir.), *cert. denied*, 449 U.S. 937 (1980).

If the court understands the plaintiffs correctly, they appear to argue that the challenged policy's effect of prohibiting the sale of investigational drugs to terminally ill patients without other treatment options is *not* rationally related to public health. Pls.' Cross-Mot. at 3-4. The plaintiffs believe the FDA policy actually hinders public health by dramatically reducing access to potentially helpful drugs. *Id.* (stating that investigational drugs are generally available only to those who are accepted in a clinical trial, leaving a large number of patients who cannot get into a clinical trial are left without investigational drug access).

As noted, the challenged action "need not be in every respect logically consistent with its aims to be constitutional." *Lee Optical*, 348 U.S. at 487-88. The policy need not be the best way imaginable of solving a particular problem, but must be a reasonable solution to that problem. *Flores*, 507 U.S. at 305 (concluding that a policy that impairs an interest that is "lesser" than a fundamental right need not be narrowly tailored, but need only be a "reasonable fit" with the government purpose). The plaintiffs have failed to demonstrate that the challenged policy is in no way rationally related to the FDA's public health purpose. In fact, the record contains solid evidence that the policy at issue is indeed rationally related to public health. The FDA, for example, notes that revocation of the challenged policy may have a negative impact on the clinical trial system. Letter from Pitts to Burroughs and Walker dated April 25, 2003 at 4. If the court were to grant the plaintiffs' requested relief, the testing required for investigational drugs would have to be performed subsequent to their release into the market. *Id.* at 5. The FDA has found from experience "that it has often been difficult to obtain [studies of drugs after their release into the market], which would mean that a product approved on the basis of almost no data would have prolonged distribution without knowledge of who is likely to benefit and how to manage toxicity." *Id.* Furthermore, untested drugs may have adverse side effects that can have dramatic consequences for a patient's remaining quality of life. *Id.* at 4. The plaintiffs have not denied the validity of these concerns.

The plaintiffs have failed to demonstrate that the challenged FDA policy is not a rational method of addressing the foregoing concerns. The court therefore concludes that the policy of barring all potentially unsafe and ineffective drugs from interstate commerce until proven by a rigorous testing process, even when it has the effect of barring access to investigational drugs by

terminally ill patients with no other treatment options, is rationally related the legitimate state interest of protecting public health.

While the court understands the appeal of the plaintiffs' motives, it is bound by the law as it currently exists and does not have the authority to create new policy. The plaintiffs do not invoke a recognized constitutional right and the challenged FDA policy is rationally related to a legitimate state purpose. Accordingly, the court dismisses the complaint for failure to state a claim. *Browning*, 292 F.3d at 242.

IV. CONCLUSION

For the foregoing reasons, the court grants the defendants' motion to dismiss and denies the plaintiffs' cross-motion for summary judgment. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 30th day of August, 2004.

RICARDO M. URBINA
United States District Judge