UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABIGAIL ALLIANCE FOR BETTER ACCESS TO DEVELOPMENTAL DRUGS, 1518 North Buchanan St. Arlington, Va. 22205, and **WASHINGTON LEGAL FOUNDATION**, 2009 Massachusetts Ave., N.W. Washington, D.C. 20036, Plaintiffs, v. **MARK B. McCLELLAN, M.D.,** in his official capacity as Commissioner, Food and Drug Administration, 14-71 Parklawn Bldg. 5600 Fishers Lane Rockville, MD 20857, and **TOMMY G. THOMPSON**, in his official capacity as Secretary, U.S. Dept. of Health and Human Services, 200 Independence Ave., S.W. Washington, D.C. 20201, Defendants.	**Civil Action No. ____**

COMPLAINT

1. This is an action brought by the Abigail Alliance for Better Access to Developmental Drugs (Abigail Alliance) and the Washington Legal Foundation (WLF), to enjoin the Food and Drug Administration (FDA) from continuing to enforce a policy that violates the constitutional privacy and liberty rights of terminally ill patients, including numerous Abigail Alliance members, and their constitutional guarantee against deprivation of life without due process.

2. The challenged policy prohibits mentally competent patients with no other treatment options from purchasing investigational drugs -- medicines showing initial evidence of safety and efficacy in clinical trials, but not yet approved -- even though their physicians

recommend these drugs as their best hope of surviving or of prolonging their lives.

Jurisdiction and Venue

3. The Court has jurisdiction over this action under 28 U.S.C. § 1331, in that the action arises under the laws of the United States. Plaintiffs' right to judicial review of the actions complained of is secured by the Fifth and Fourteenth Amendments to the U.S. Constitution, as well as by the Administrative Procedure Act (APA), 5 U.S.C. § 702 and 704.

4. Venue for this action properly lies in this Court under 28 U.S.C. § 1391(e).

Parties

5. Plaintiff ABIGAIL ALLIANCE is a nonprofit organization based in Arlington, Virginia. ABIGAIL ALLIANCE was founded in 2001 by Frank Burroughs, who is now its president. The group is named for Burroughs’s daughter, Abigail, an honors student at the University of Virginia. Abigail died of cancer on June 9, 2001, after she was stymied in her efforts to obtain new cancer drugs that her oncologist believed could save her life, but which were still in clinical trials. Abigail Alliance has numerous members and supporters who are suffering from terminal illness or who have lost family members to terminal illness. Among its members are terminally ill individuals whose best chance of survival is to obtain access to certain drugs with a record of clinical success in pre-approval testing, but which have not yet been approved by the FDA for marketing.

6. Plaintiff WLF is a nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. WLF

devotes a substantial portion of its resources to defending and promoting individual rights and a limited and accountable government, including in the area of patients' rights. For example, WLF successfully challenged the constitutionality of Food and Drug Administration restrictions on the ability of doctors and patients to receive truthful information about off-label uses of FDA-approved medicines. See Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D. D.C. 1998), appeal dism'd, 202 F.3d 331 (D.C. Cir. 2000).

7. Defendant MARK B. McCLELLAN, M.D., is the Commissioner of the Food and Drug Administration and is charged with supervising the activities of FDA. Dr. McCLELLAN is being sued in his official capacity. FDA is an agency within the U.S. Department of Health and Human Services and is an "agency" within the meaning of the APA.

8. Defendant TOMMY G. THOMPSON is Secretary of the U.S. Department of Health and Human Services, an agency of the federal government and an "agency" within the meaning of the APA. Defendant THOMPSON is being sued in his official capacity.

Statement of the Claim

A. FDA's Statutory Authority

9. Congress adopted the Federal Food, Drug, and Cosmetic Act (the "FDC Act"), 21 U.S.C. §§ 301 et seq., in 1938 to regulate the sale of manufactured drugs to the general public. FDA was created to undertake that regulation. Id. Section 505(a) of the FDC Act, 21 U.S.C. § 355(a), provides that no "new drugs" may be introduced into interstate commerce unless they are approved as safe and effective by FDA.

10. The FDA's mandate from Congress to regulate drug efficacy is

couched in quite general terms. For full marketing approval, the statute simply requires "substantial evidence that the drug will have the effect it purports or is represented to have." 21 U.S.C. § 355(d). Substantial evidence, in turn, is not defined in terms of a specific methodology, but instead as "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have." Id. For investigational use, the statute simply allows the agency to demand "preclinical tests . . . adequate to justify the proposed clinical testing." 21 U.S.C. § 355(i).

B. FDA's Application of Its Authority to Investigational Drugs

11. The FDA has used its administrative discretion to define several stages for human testing of new drugs after animal testing. "Phase 1" studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. "Phase 2" includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies involve more patients than Phase 1 studies, but still a small number, usually no more than several hundred subjects. "Phase 3" studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence of the drug's effectiveness has

been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects. 21 C.F.R. § 312.21.

12. At each phase of the clinical trial process, a considerable period of time passes as the drug's sponsor obtains FDA approval of the proposed study protocols, as investigators carry out the clinical trials, and as the sponsor obtains FDA approval or rejection of the results at each stage. On average, the total time for clinical trials and approvals across all stages for a new drug is approximately 6.9 years. See Tufts Center for the Study of Drug Development, Outlook 2003 at 1.

13. By virtue of the structure of the FDA approval process, initial evidence of a drug's safety and efficacy with respect to a given condition will appear following phase 1 or phase 2 trials. For the great majority of patients who are not suffering from life-threatening conditions, or who have other approved treatment options, the FDA's policy requiring extensive further testing of a promising new drug does not have life-or-death consequences. On the contrary, this further testing (if not unduly prolonged) may be considered a reasonable protective measure.

14. For patients with life-threatening conditions, who have exhausted other treatment options, the situation is quite different. FDA's restrictions on pre-approval availability amount to a death sentence for these patients. At present, on account of FDA's restrictions, patients with life-threatening illnesses cannot purchase promising new medications from willing drug sponsors during the years of clinical testing and review required by the FDA.

15. Non-commercial options provide relief to a very small number of patients. Participants in clinical trials may obtain the new drug; spaces in these trials are very limited, however, in relation to the need. Clinical trials are also narrowly limited as to the type of patient who qualifies for a a given trial, in terms of their condition and treatment history, so that data from the studies will be more meaningful. Existing "compassionate use" programs for new drugs, under which drug companies may opt voluntarily to provide drugs to a limited number of patients during this pre-approval period, accommodate only a small number of patients –- again, a fraction of those in desperate need. "Compassionate use" programs are small, when they exist at all, because drug sponsors may not charge more than a cost recovery amount to participants. Promising new drugs thus remain generally unavailable to patients even though there is evidence of the drugs' safety and efficacy, and even though the patients have no alternative to the drugs other than to wait for their own death.

C. The FDA's Policy in Operation

16. Terminally ill patients are typically willing to assume risks if their physicians advise them that a treatment may save or prolong their lives and if they have no other viable options.

17. Drug companies are in business to make a profit from the sale of medicines to patients who choose those drugs in consultation with their physicians.

18. The effect of FDA policy regarding investigational drugs is to deny patients this choice, as illustrated by the cases of Abigail Burroughs, David Baxter, Alita Randazzo, and Joel Oppenheim.

i) Abigail Burroughs

19. Abigail Burroughs learned at the age of nineteen that she had head and neck cancer. For the next eighteen months, Abigail fought

the cancer by undergoing painful chemotherapy and radiation treatments, to no avail. Abigail was told in March of 2001 that she had run out of FDA-approved options. Abigail's cancer cells had very high EGFR (Epidermal Growth Factor Receptors) expression. Her renowned oncologist at Johns Hopkins knew there was a significant chance of saving her life if she could get the new EGFR cancer drugs Iressa and Erbitux. Abigail could not get Iressa, however, because the clinical trials were very limited as to the number and type of patients who could qualify -- as is usual for clinical drug trials. The Erbitux clinical trials were for colon cancer patients only. Abigail never obtained Iressa or Erbitux, and thus a chance to live, and so she died on June 9, 2001, at the age of twenty-one.

ii) David Baxter

20. High school student David Baxter was diagnosed with colorectal cancer in the spring of 2001. David was unable to participate in clinical trials of promising new cancer drugs because clinical trials are usually open only to patients eighteen and older. In the following months he endured various types of chemotherapy. Of one of his hospital stays, he wrote, "You hear a lot of scary stories about cancer patients, and let me tell you right now that they are true -- every single one of them. From the stories of nurses coming in at two in the morning to take your vitals for some awful reason, to the noises from the room across the hall -- either screams or moans of who knows what." David died in his sleep at home on October 6, 2001, shortly after his seventeenth birthday.

iii) Alita Randazzo

21. Alita Randazzo, age thirty-five, was diagnosed with colorectal cancer in the spring of 2000. Alita responded well at first to Eloxatin (Oxaliplatin), but she had to endure the expense and

physical demands of traveling to France to get the drug. She did not qualify for the clinical trial of Eloxatin in the U.S. and was not fortunate enough to get into the drug's limited compassionate use program. (Before finally being approved in the U.S. in May of 2003, Eloxatin had been approved in Europe six years earlier.) After eight months, Eloxatin stopped helping Alita and her doctors believed her last chance was Erbitux. Alita was unable to obtain Erbitux, and died on July 20, 2002.

iv) Joel Oppenheim

22. Joel Oppenheim was first diagnosed with multiple myloma in 1995 but the disease did not become active until 1999. At that time, he was treated with dexamethadrone ("dex"), which had unpleasant side effects and was only minimally effective. Thalidomide, which is not approved for multiple myeloma, was added to the dex by Joel's doctors. This off-label use of thalidomide was possible because thalidomide had been approved for leprosy, and is thus available for doctors to prescribe for other conditions as they see fit. Thalidomide has become the first line of treatment for multiple myeloma.

23. As Joel's disease worsened in 2000, his oncologists recommended that he seek to participate in clinical trials of Revamid or PS-341 Velcade. Revamid is a derivative of thalidomide that avoids thalidomide's side effects (which extend well beyond its notorious effect on pregnant women). Joel was unable to obtain a place in the Revamid trials or Velcade trials because his prior treatment with dex put him outside the narrow protocols of the trial. The massive number of patients who applied for the trials would have rendered it unlikely for Joel to win a place, in any event. Thus, Joel was prevented from using Revamid, which was safer and more effective than his thalidomide treatment.

24. In light of Joel's inability to obtain Revamid or Velcade, his oncologists recommended an autologous bone marrow transplant, which he underwent on April 15, 2001. This is a dangerous and damaging medical procedure. Joel survived the transplant, but was disabled from working and still suffers from an impaired immune system. A disease such as the West Nile virus that would typically have mild effects on other people would probably kill Joel.

25. Approximately a year and a half after the bone marrow transplant, Joel's cancer worsened again. He again attempted to enter numerous trials for Velcade, but was rejected. He was disqualified from some trials on account of his prior dex treatment, and from others on account of his transplant (which had been made necessary by his lack of access to Velcade or Revamid). To increase his chances of acceptance into a trial, on his doctors' advice, Joel stopped taking dex or any other treatment; one of the criteria of the trials was no dex or other drugs within the prior six months. The trials were repeatedly delayed. Without medication, Joel's cancer grew much worse. Finally, in June of 2003, through the efforts of one doctor, Joel was admitted to a trial of Revamid. Over the last three years, FDA restrictions on investigational drugs have caused countless patients like Joel to die or suffer from bone marrow procedures.

E. Citizen Petition

26. On June 11, 2003, the Abigail Alliance and the Washington Legal Foundation filed a Citizen Petition with the FDA pursuant to 21 C.F.R. § 10.30. The Citizen Petition is attached hereto as Attachment 1.

27. The Citizen Petition urged the FDA to expand availability of investigational drugs to the terminally ill by allowing compassionate use programs to begin at an earlier stage of the approval process; by

adopting a proposal called “Tier 1 Initial Approval” to allow sponsors of investigational drugs to make those drugs available to patients with no other approved treatment options; and by encouraging drug sponsors to participate in “Tier 1 Initial Approval” through allowing them to charge for the drugs (above the current regulatory limit that permits only cost recovery). The Citizen Petition did not raise any constitutional claims.

28. The FDA has acknowledged receipt of the Citizen Petition, but has otherwise not responded to it in any way.

COUNT I

29. Plaintiffs incorporate herein by reference the allegations of Paragraphs 1 through 28.

30. FDA's policy prohibiting the sale of investigational drugs to willing and mentally competent patients with no other treatment options interferes with the ability of Abigail Alliance’s patient-members and other terminally ill patients to choose the appropriate treatment for terminal illnesses, in violation of rights secured to those individuals by the rights to privacy and liberty of the U.S. Constitution.

COUNT II

31. Plaintiffs incorporate herein the allegations of Paragraphs 1 through 30.

32. FDA's policy prohibiting the sale of investigational drugs to willing and mentally competent patients with no other treatment options operates as a death sentence for those patients, including the Abigail Alliance’s patient-members, in violation of the guarantee in the Fifth Amendment of the U.S. Constitution against deprivation of

life without due process.

WHEREFORE, Plaintiffs Abigail Alliance and WLF respectfully request the following relief:

(1) that the Court enter a declaratory judgment that the FDA policies described herein violate the rights of Abigail Alliance's members under the Fifth and Fourteenth Amendments to the Constitution;

(2) that the Court enter preliminary and permanent injunctions against Defendants, preventing them from enforcing, relying on, or otherwise giving effect to the above-described policies;

(3) that the Court award Plaintiffs the costs of this action and attorney fees; and

(4) that the Court award such other relief as it determines to be just.

Respectfully submitted,

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