

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF VIRGINIA  
CHARLOTTESVILLE DIVISION**

ROBERT F. STEEVES,

*Plaintiff,*

v.

ANDREW C. VON ESCHENBACH,  
COMMISSIONER OF FOOD AND DRUGS,

*Defendant.*

CIVIL No. 3:07cv00011

MEMORANDUM OPINION

JUDGE NORMAN K. MOON

This matter is before the Court on Defendant's Motion to Dismiss Plaintiff's Amended Complaint (docket entry no. 19) pursuant to Federal Rule of Civil Procedure 12(b)(6). Because Plaintiff has failed to state a claim upon which relief can be granted, I will GRANT Defendant's motion to dismiss and ORDER this case stricken from the docket.

**I. BACKGROUND**

The plaintiff, Robert F. Steeves, is a freelance writer and contributor to *FDA Webview*, a daily Internet newsletter which reports and analyzes health care products and marketing activities regulated by the U.S. Food and Drug Administration ("FDA"). Plaintiff has filed this action *pro se*<sup>1</sup> to challenge the FDA's policy of withholding information that he believes to lie properly in the public domain.

Plaintiff originally filed this suit on March 28, 2007, pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, to compel production of the "approvable letter"<sup>2</sup> sent

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<sup>1</sup> Plaintiff filed this matter *pro se*, but appears, based upon court filings, to be an attorney licensed to practice in the Commonwealth of Virginia. (Compl. 4; Am. Compl. 5).

<sup>2</sup> An "approvable letter" indicates to an applicant that an application for a new drug substantially meets the requirements of 21 C.F.R. § 314 provided that the applicant supplies specific additional information or if the applicant agrees to specific conditions. *See* 21 C.F.R. § 314.110.

by the FDA to GlaxoSmithKline (“GSK”) on April 6, 2006, regarding GSK’s new drug application (“NDA”) for the drug Alli (orlistat).<sup>3</sup> In April 2006, Plaintiff submitted a FOIA request to the FDA for a copy of the approvable letter for Alli. At that time the NDA for Alli had not been approved; therefore, the FDA denied his FOIA request, pursuant to 5 U.S.C. § 552(b)(4), 18 U.S.C. § 1905, and 21 C.F.R. §§ 20.61(c) and 314.430, because it contained privileged trade secrets and confidential commercial information. Plaintiff did not allege that he appealed the denial of his FOIA request pursuant to 45 C.F.R. § 5.34.

In January 2007, Plaintiff submitted a new FOIA request for the Alli approvable letter. The FDA did not respond to this request within the required twenty-day period. *See* 5 U.S.C. § 552(a)(6)(A)–(B) (requiring agency to notify the person making a FOIA request of the agency’s determination within 20 days or, in specified unusual circumstances, 30 days). Plaintiff contacted the FDA on February 12, 2007 by electronic mail to inquire about the status of his request. Plaintiff was informed that Roy Castle was the FOIA officer assigned to work on his request, and he attempted to contact Mr. Castle on February 13, 2007 to determine when his request would be adjudicated. Plaintiff alleges that Mr. Castle did not respond to his inquiry. As a result, Plaintiff filed this suit on March 28, 2007, requesting the Court to compel the FDA to turn over the Alli approvable letter. On April 18, 2007, the FDA provided Plaintiff a redacted copy of the letter. The FDA then provided an unredacted copy of the approvable letter on May 9, 2007, and moved to dismiss this suit as moot.

Plaintiff amended his Complaint on July 24, 2007, to challenge the FDA’s policy of withholding records and information, which he believes do not fall within the trade secret or confidential commercial information exception. In his Amended Complaint, Plaintiff dismissed

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<sup>3</sup> The April 2006 approvable letter notified GSK that the FDA had completed its review of the NDA for Alli (NDA 21-887), and that the NDA was approvable, but could not be approved until several identified issues were addressed. (Am. Compl. Ex. 1.) The FDA subsequently approved the Alli NDA on February 7, 2007, permitting GSK to sell Alli to the public without a prescription.

his earlier claim requesting a copy of the Alli approvable letter and added three new claims, requesting (1) declaratory and injunctive relief to prevent the FDA from further abridging his freedom of the press in violation of the First Amendment; (2) declaratory and injunctive relief to prevent the FDA from unlawfully relying, in an arbitrary and capricious manner, upon the trade secret and confidential commercial information exception to FOIA to deny Plaintiff and the public due process under the Fifth Amendment; and (3) compensatory damages of \$50,000.

The Defendant again moved to dismiss this suit pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), arguing that Plaintiff had not alleged conduct that violates either the First or Fifth Amendment and that Plaintiff's claim of compensatory damages is barred by sovereign immunity. Plaintiff subsequently withdrew his claims for damages and for violating his right to due process of law, but continues to assert that the FDA improperly uses the trade secret and confidential commercial information exceptions of FOIA to deny Plaintiff and others similarly situated access to information which should be available to the press, thereby controlling the news and public debate on significant issues of public policy. (Pl.'s Mem. Opp'n Def.'s Mot. Dismiss 2, 8.) Plaintiff argues that this practice is so pervasive that it rises to the level of a First Amendment violation.

## **II. STANDARD OF REVIEW**

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the sufficiency of a complaint to determine whether the plaintiff has properly stated a claim; it does not “resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses.” *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992). Although a complaint “does not need detailed factual allegations, a plaintiff's obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v. Twombly*,

127 S. Ct. 1955, 1964–65 (2007) (citations omitted). Instead, “[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Id.* at 1965 (citations omitted).

Although the complaint of a *pro se* plaintiff is held to a less stringent standard than one prepared by an attorney, *Haines v. Kerner*, 404 U.S. 519, 520 (1972), the court will not abrogate basic pleading essentials in a *pro se* suit, *Wells v. Brown*, 891 F.2d 591, 594 (6th Cir. 1989). Moreover, the less stringent standard for a *pro se* plaintiff does not require a court to manufacture facts not pled to support conclusory allegations. *McDonald v. Hall*, 610 F.2d 16, 19 (1st Cir. 1979). Therefore, while Rule 12(b)(6) does “not require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face;” even *pro se* plaintiffs must “nudge[] their claims across the line from conceivable to plausible” or “their complaint must be dismissed.” *Twombly*, 127 S. Ct. at 1974.

### III. DISCUSSION

The preservation of an “untrammelled press” is essential to maintain an informed public because an “informed public opinion is the most potent of all restraints upon misgovernment.” *Grosjean v. Am. Press Co.*, 297 U.S. 233, 250 (1936). For that reason, the Framers prohibited Congress from making any law that “abridg[es] the freedom . . . of the press.” U.S. CONST. amend. I. This prohibition protects both the dissemination and receipt of information and ideas. *See, e.g., Va. Pharmacy Bd. v. Va. Citizens Consumer Council*, 425 U.S. 748, 764–65 (1976).

This right does not, however, provide a right of access to government information. *Houchins v. KQED, Inc.*, 438 U.S. 1, 16 (1978) (Stewart, J., concurring) (“The First and Fourteenth Amendments do not guarantee the public a right of access to information generated or controlled by government, nor do they guarantee the press any basic right of access superior to that of the public generally.”); *see also Lanphere & Urbaniak v. Colorado*, 21 F.3d 1508, 1511

(10th Cir. 1994) (“[T]here is no constitutional right, and specifically no First Amendment right of access to government records.”). As the Supreme Court has explained, “[t]he Constitution itself is neither a Freedom of Information Act nor an Official Secrets Act.” *Houchins*, 438 at 14 (Burger, C.J., plurality) (citation omitted).

This plain language notwithstanding, Plaintiff argues that *Richmond Newspapers, Inc. v. Virginia*, 448 U.S. 555 (1980), compels a different result. This argument is inapplicable to the instant case. *Richmond Newspapers, Inc.* did indeed establish a right of access to certain government information, *id.* at 575–77, but only in the limited circumstances of criminal proceedings where such information had been traditionally available to the public. *See, e.g., Ctr. for Nat’l Sec. Studies v. U.S. Dep’t of Justice*, 331 F.3d 918, 935 (D.C. Cir. 2003) (“[T]he Supreme Court has [n]ever indicated that it would apply the *Richmond Newspapers* test to anything other than criminal judicial proceedings.”). Because this case does not entail criminal matters, Plaintiff does not have a constitutional right to the information requested.<sup>4</sup> Accordingly, his Complaint must be dismissed for failure to state a claim upon which relief can be granted.

#### IV. CONCLUSION

For the reasons stated herein, I find the Plaintiff has failed to state a claim upon which relief can be granted as there is no constitutional or First Amendment right to the access he has requested. Moreover, the Defendant has disclosed the requested document to Plaintiff, thereby making this matter moot. Accordingly, I will GRANT the Defendant’s Motion to Dismiss Plaintiff’s Amended Complaint (docket entry no. 19) in an order to follow.

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<sup>4</sup> Although there is no constitutional right, Plaintiff has a statutory right of access to government information pursuant to FOIA. Federal agencies may, however, withhold a document or other information under those limited exceptions established by Congress within FOIA. *See* 5 U.S.C. § 552(b). If Plaintiff believes an agency to be withholding a document improperly or without justification, he may challenge that nondisclosure in federal court pursuant to *Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1974), and the agency will have to provide a *Vaughn* index describing each document withheld with “sufficiently detailed information to enable a district court to rule whether it falls within an exemption provided by FOIA.” *Ethyl Corp. v. EPA*, 25 F.3d 1241, 1244 n.1 (4th Cir. 1994). In this case, Defendant has disclosed the requested document, which makes this issue moot.

It is so ORDERED.

The Clerk of the Court is hereby directed to send a certified copy of this Memorandum Opinion to both parties.

ENTERED: \_\_\_\_\_  
United States District Judge

\_\_\_\_\_  
Date

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ORDER

JUDGE NORMAN K. MOON

This matter is before the Court on Defendant's Motion to Dismiss Plaintiff's Amended Complaint (docket entry no. 19) pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons stated in the accompanying Memorandum Opinion, Defendant's motion is GRANTED.

This matter is hereby TERMINATED and stricken from the Court's docket.

It is so ORDERED.

The Clerk of the Court is hereby directed to send a certified copy of this Order to both parties.

ENTERED: \_\_\_\_\_

United States District Judge

\_\_\_\_\_  
Date