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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF FLORIDA**
**TAMPA DIVISION**

ANDREW THIBAULT
11828 Castine Street
New Port Richey, FL 34654,

Plaintiff,

v.

U.S. FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20024,

Defendant.

8:15-cv-1813-T-36TGW

Civil Action No.

**COMPLAINT FOR DECLATORY AND INJUNCTIVE RELIEF**

Plaintiff Andrew Thibault, *Pro se*, brings this action against Defendant United States Food and Drug Administration ("FDA") to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"). As grounds therefor, Plaintiff alleges as follows:

**JURISDICTION AND VENUE**

1. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

2. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

**PARTIES**

3. Plaintiff is a private citizen and blogger having his principal place of



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residence at 11828 Castine Street, New Port Richey, FL 34654. Plaintiff seeks to promote public awareness of pharmaceutical drug manufacturer false claims relating to the efficacy and safety of psychotropic medications. In furtherance of his public interest mission, Plaintiff regularly requests access to the public records of federal, state, and local government agencies, entities, and offices, and disseminates his findings to the public via the website Pharmabuse.com and social media.

4. Defendant FDA is an agency of the United States Government. Defendant FDA has its principal place of business at 5600 Fishers Lane, Rockville, MD 20857. Defendant has possession, custody, and control of records to which Plaintiff seeks access.

**STATEMENT OF FACTS**

5. On October 2, 2014, Plaintiff sent a FOIA request to Defendant FDA seeking access to records relating to seven-hundred sixteen (716) reports to the FDA Adverse Event Reporting System ("AERS") of homicide as an adverse effect of psychotropic medications. Plaintiff's FOIA request contained the relevant AERS case numbers and drug names to facilitate Defendant FDA's retrieval of the requested records.

6. On October 5, 2014, Defendant FDA acknowledged receipt of Plaintiff's FOIA request, and assigned it reference number 2014-8101.

7. On October 6, 2014, Defendant FDA employee Harold Stepper telephoned Plaintiff to request the previously submitted case identifying information in spreadsheet format. Plaintiff emailed Mr. Stepper the requested spreadsheet later the same day.

8. Defendant FDA was required by 5 U.S.C. § 552(a)(6)(A)(i) to respond

fully to Plaintiff's FOIA request 2014-8101 within twenty (20) business days, or on or about November 3, 2014.

9. As of the date of this Complaint, Defendant FDA has failed to produce any records responsive to Plaintiff's FOIA request 2014-8101 or demonstrate that the requested records are exempt from production.

10. On November 12, 2014, Plaintiff emailed Mr. Stepper, seeking a status update on FOIA request 2014-8101. Mr. Stepper replied to Plaintiff via email the same day, indicating he would contact Plaintiff the following day with regard to the status of FOIA request 2014-8101.

11. On November 13, 2014, Mr. Stepper telephoned Plaintiff and stated that Defendant FDA was trying to work out some disclosure issues relating to FOIA request 2014-8101. When Plaintiff sought clarification, Mr. Stepper indicated that the issues were internal, and he was not able to discuss them. Plaintiff then requested an estimated date of production. Mr. Stepper stated that he was going to be out of the office the last couple weeks of December 2014, that he would make FOIA request 2014-8101 a priority upon his return in early January 2015, and estimated the date of production would be in late January 2015. Mr. Stepper then made unsolicited comments to Plaintiff that the subject matter of the requested reports did not make for fun reading, and that Plaintiff should take into account psychiatric diagnoses of the patients, as if to offer another plausible cause of homicide, other than as a reported side effect of psychotropic drugs.

12. On November 24, 2014, having identified an additional seven (7) reports

to the AERS of homicide as an adverse effect of psychotropic medications, Plaintiff contacted Mr. Stepper via email to enquire as to whether he could append the seven (7) additional reports to FOIA request 2014-8101, or whether he would need to submit a separate FOIA request. Mr. Stepper emailed Plaintiff back on the same day instructing, "Please make a separate FOI request. When you request 10 or less cases, it goes into a simple queue and is answered in 5 days."

13. On November 24, 2014, Plaintiff sent a second FOIA request to Defendant FDA seeking access to records relating to an additional seven (7) reports to the AERS of homicide as an adverse effect of psychotropic medications. Plaintiff's second FOIA request contained the relevant AERS case numbers and drug names to facilitate Defendant FDA's retrieval of the requested records.

14. On November 24, 2014, Defendant FDA acknowledged receipt of Plaintiff's second FOIA request, and assigned it reference number 2014-9342.

15. Defendant FDA was required by 5 U.S.C. § 552(a)(6)(A)(i) to respond fully to Plaintiff's FOIA request 2014-9342 within twenty (20) business days, or on or about December 23, 2014.

16. As of the date of this Complaint, Defendant FDA has failed to produce any records responsive to Plaintiff's FOIA request 2014-9342 or demonstrate that the requested records are exempt from production.

17. On January 7, 2015, Plaintiff emailed Mr. Stepper seeking a status update on his FOIA requests 2014-8101 and 2014-9342, and an estimated date of production.

On the same day, Mr. Stepper emailed Plaintiff stating, "You have been more than patient, but I cannot facilitate the processing of the cases for reasons Ms. Lee will fully explain," referring Plaintiff to Defendant FDA Lead Regulatory Counsel Elizabeth Lee, Esq.

18. On January 8, 2015, Plaintiff spoke to Ms. Lee via telephone. Ms. Lee informed Plaintiff that the "sensitive topic" of his FOIA requests 2014-8101 and 2014-9342 prompted Defendant FDA to revise its existing records redaction policy. Ms. Lee indicated that Defendant FDA had prepared draft redactions corresponding to FOIA request 2014-9342 which were pending her supervisor's approval. Plaintiff expressed concerns to Ms. Lee over the length of time it was taking to obtain the requested records, that once obtained the records could be overly redacted, and that redaction should be the same for homicide as for any other reported drug side effect. Plaintiff informed Ms. Lee he required Defendant FDA to provide him a date certain of production by the end of the next week, on January 16, 2015.

19. On January 16, 2015, Plaintiff spoke to Ms. Lee again via telephone. Ms. Lee informed Plaintiff that Defendant FDA would produce records corresponding to the "simple" FOIA request 2014-9342 by the end of January 2015. Ms. Lee also indicated that Defendant FDA would produce records corresponding to the larger FOIA request 2014-8101 in two (2), possibly three (3) more manageable batches rather than all at once, which she noted would have the added benefit of allowing Plaintiff to begin reviewing records sooner, rather than waiting for every report to be redacted before being able to

begin reviewing them.

20. On February 3, 2015, Plaintiff emailed Ms. Lee seeking a status update on his FOIA requests 2014-8101 and 2014-9342, reminding her that she had previously assured him that Defendant FDA would produce records corresponding to FOIA request 2014-9342 by the end of January 2015, and informing her that to date he had not received any records.

21. On February 3, 2015, Plaintiff spoke again to Ms. Lee via telephone. Ms. Lee indicated that she had met with her supervisor on January 20, 2015 to discuss the matter, and that she had another meeting scheduled with her supervisor on February 6, 2015 to further discuss the matter. Ms. Lee informed Plaintiff that Defendant FDA was still trying to decide what to redact due to the "sensitive topic," and that she could not provide Plaintiff with any further guidance as to when he might expect to receive the case files, recommending that Plaintiff contact her in a couple of weeks for another status update. Plaintiff informed Ms. Lee that he required Defendant FDA to provide him a date certain of production by the close of business on February 6, 2015.

22. On February 6, 2015, Ms. Lee responded to Plaintiff's email for a status update dated February 3, 2015 stating, "I will follow-up with you sometime after my 3:00pm meeting with my supervisor today." Later on the same day, Ms. Lee sent Plaintiff another email stating, "I met with my supervisor today. We will complete your simple request, FOI 2014-9342, within the next 2 months."

23. On May 20, 2015, Plaintiff sent a third FOIA request to Defendant FDA

seeking access to records relating to an additional nine (9) reports to the AERS of homicide as an adverse effect of psychotropic medications. Plaintiff's third FOIA request contained the relevant AERS case numbers and drug names to facilitate Defendant FDA's retrieval of the requested records.

24. On May 21, 2015, Defendant FDA acknowledged receipt of Plaintiff's third FOIA request, and assigned it reference number 2015-4050.

25. Defendant FDA was required by 5 U.S.C. § 552(a)(6)(A)(i) to respond fully to Plaintiff's FOIA request 2015-4050 within twenty (20) business days, or on or about June 18, 2015.

26. As of the date of this Complaint, Defendant FDA has failed to produce any records responsive to Plaintiff's FOIA request 2015-4050 or demonstrate that the requested records are exempt from production.

27. On May 20, 2015, Plaintiff sent a fourth FOIA request to Defendant FDA seeking access to records relating to an additional nine (9) reports to the AERS of homicide as an adverse effect of psychotropic medications. Plaintiff's fourth FOIA request contained the relevant AERS case numbers and drug names to facilitate Defendant FDA's retrieval of the requested records.

28. On May 22, 2015, Defendant FDA acknowledged receipt of Plaintiff's fourth FOIA request, and assigned it reference number 2015-4090.

29. Defendant FDA was required by 5 U.S.C. § 552(a)(6)(A)(i) to respond fully to Plaintiff's FOIA request 2015-4090 within twenty (20) business days, or on or

about June 19, 2015.

30. As of the date of this Complaint, Defendant FDA has failed to produce any records responsive to Plaintiff's FOIA request 2015-4090 or demonstrate that the requested records are exempt from production.

31. On May 20, 2015, Plaintiff sent a fifth FOIA request to Defendant FDA seeking access to records relating to an additional nine (9) reports to the AERS of homicide as an adverse effect of psychotropic medications. Plaintiff's fifth FOIA request contained the relevant AERS case numbers and drug names to facilitate Defendant FDA's retrieval of the requested records.

32. On May 22, 2015, Defendant FDA acknowledged receipt of Plaintiff's fifth FOIA request, and assigned it the reference number 2015-4091.

33. Defendant FDA was required by 5 U.S.C. § 552(a)(6)(A)(i) to respond fully to Plaintiff's FOIA request 2015-4091 within twenty (20) business days, or on or about June 19, 2015.

34. As of the date of this Complaint, Defendant FDA has failed to produce any records responsive to Plaintiff's FOIA request 2015-4091 or demonstrate that the requested records are exempt from production.

35. On June 29, 2015, Plaintiff sent a sixth FOIA request to Defendant FDA seeking access to records relating to an additional six (6) reports to the AERS of homicide as an adverse effect of psychotropic medications. Plaintiff's sixth FOIA request contained the relevant AERS case numbers and drug names to facilitate Defendant FDA's

retrieval of the requested records.

36. On July 1, 2015, Defendant FDA acknowledged receipt of Plaintiff's sixth FOIA request, and assigned it the reference number 2015-5256.

37. Defendant FDA was required by 5 U.S.C. § 552(a)(6)(A)(i) to respond fully to Plaintiff's FOIA request 2015-5256 within twenty (20) business days, or on or about July 30, 2015.

38. In correspondence dated July 7, 2015, Defendant FDA Director of Division of Freedom of Information Sarah Kotler assured Plaintiff, "The responding agency office will process your request [2015-5256] in the order in which it was received." Based on information and belief, Plaintiff's FOIA request 2015-5256 was not processed in the order in which it was received. As Mr. Steppler indicated in previously cited correspondence, "When you request 10 or less cases, it goes into a simple queue and is answered in 5 days."

39. As of the date of this Complaint, Defendant FDA has failed to produce any records responsive to Plaintiff's FOIA request 2015-5256 or demonstrate that the requested records are exempt from production.

40. On June 29, 2015, Plaintiff sent a seventh FOIA request to Defendant FDA seeking access to records relating to an additional nine (9) reports to the AERS of homicide as an adverse effect of psychotropic medications. Plaintiff's seventh FOIA request contained the relevant AERS case numbers and drug names to facilitate Defendant FDA's retrieval of the requested records.

41. On July 1, 2015, Defendant FDA acknowledged receipt of Plaintiff's seventh FOIA request, and assigned it the reference number 2015-5262.

42. Defendant FDA was required by 5 U.S.C. § 552(a)(6)(A)(i) to respond fully to Plaintiff's FOIA request 2015-5262 within twenty (20) business days, or on or about July 30, 2015.

43. In correspondence dated July 7, 2015, Ms. Kotler assured Plaintiff, "The responding agency office will process your request [2015-5262] in the order in which it was received." Based on information and belief, Plaintiff's FOIA request 2015-5262 was not processed in the order in which it was received. As Mr. Steppler indicated in previously cited correspondence, "When you request 10 or less cases, it goes into a simple queue and is answered in 5 days."

44. As of the date of this Complaint, Defendant FDA has failed to produce any records responsive to Plaintiff's FOIA request 2015-5262 or demonstrate that the requested records are exempt from production.

45. Records responsive to Plaintiff's FOIA requests are not exempt from disclosure. Defendant FDA regularly produces AERS records – including individual case reports with narratives – upon request and without unreasonable delay, and has done so previously in response to a prior FOIA request submitted by Plaintiff, assigned reference number 2014-6267. The distinguishing characteristic of Plaintiff's FOIA request 2014-6267 was that it did not pertain to homicide as a reported side effect of psychotropic drugs. However, Plaintiff's FOIA request 2014-6267 involved pediatric deaths and life-

threatening outcomes. In records produced in response to Plaintiff's FOIA request 2014-6267, Defendant FDA did not redact, for example, the manner in which a child attempted suicide (e.g. electrification using an electric cord).

46. Plaintiff is concerned by credible reports that Defendant FDA-approved psychotropic medications, which Defendant FDA has warned can cause serious psychiatric adverse events, were prescribed to and taken by mass killers prior to committing atrocities:

a) A Wyoming jury found the manufacturer of Paxil (paroxetine) civilly liable in the murders of Rita Schell, Deborah Tobin, and Alyssa Tobin, and in the suicide of Donald Schell. *Tobin v. SmithKline Beecham*, 164 F. Supp. 2d 1278 (D. Wy. 2001). Defendant FDA approved a label for Paxil informing patients of reports of agitation, aggressiveness, hostility, impulsivity, irritability, and suicidality. However, Defendant FDA has not warned consumers that Paxil may cause homicidal ideation or homicidal behavior.

b) "Autopsy results revealed [Columbine mass killer Eric] Harris had a therapeutic level of Luvox [fluvoxamine maleate] in his system when he committed suicide, which belied reports that he had stopped taking the medication." *The Report of Governor Bill Owens' Columbine Review Commission* (2001) 18. Defendant FDA has warned patients taking Luvox to contact their health care provider or 911 in case of emergency if "acting on dangerous impulses" or "acting aggressive or violent." However, Defendant FDA has not

warned consumers that Luvox may cause homicidal ideation or homicidal behavior.

c) In her televised trial testimony on June 16, 2015, convicted mass killer James Holmes' former psychiatrist Dr. Lynne Fenton, M.D. confirmed prescribing Mr. Holmes 150 mg of sertaline (Zoloft) and .5 mg of Klonopin (clonazepam) prior to the Aurora Colorado theater massacre on July 20, 2012. District Attorney George Brauchler asked Dr. Fenton during direct examination, "Did [Mr. Holmes] ever tell you that he wanted to stop the sertraline?" The witness replied, "No." A recent Karolinska Institutet study found an elevated risk of homicide associated with benzodiazepines, and to a lesser extent antidepressants. Jari Tiihonen et al., *Psychotropic drugs and homicide: a prospective cohort study from Finland*, 14(2) World Psychiatry (2015) 245-247. Defendant FDA has warned that sertaline and clonazepam increase the risk of depression, aggressiveness, impulsivity, and akathisia. However, Defendant FDA has not warned consumers that sertraline and clonazepam may cause homicidal ideation or homicidal behavior.

d) The investigation report relating to the second Fort Hood shootings on April 2, 2014 lists four (4) psychotropic medications in association with mass killer Ivan Lopez-Lopez: Celexa (citalopram hydrobromide), Wellbutrin (bupropion hydrochloride), Ambien (zolpidem tartrate), and Lunesta (eszopiclone). United States Army, *Fort Hood Shooting AR 15-6 Investigation*

*Report* (2014) App 3 Tab B 1-3. Other cases of homicide associated with concomitant usage of zolpidem and an antidepressant in patients with no history of violence have been documented in the scientific literature. Cheryl M. Paradis et al., *Two Cases of Zolpidem-Associated Homicide*, 14(4) Prim Care Companion CNS Disord. (2012). Defendant FDA has warned that Celexa, Wellbutrin, Ambien, and Lunesta increase the risk of depression and suicidal thinking; and that hallucinations have also been reported in patients taking the drugs. Defendant FDA has warned that serious neuropsychiatric symptoms including homicidal ideation, aggressiveness, psychosis, etc. have been reported in patients taking Wellbutrin. Defendant FDA has warned that aggressiveness, impulsivity, and akathisia have been reported in patients taking Celexa. However, Defendant FDA has not warned consumers that Celexa, Ambien, and Lunesta may cause homicidal ideation; or that Celexa, Wellbutrin, Ambien, and Lunesta may cause homicidal behavior.

e) Toxicology tests revealed mass killer Elliot Rodger had "benzodiazepines and alprazolam present within the body" at the time of his death. Santa Barbara County Sheriff's Office, *Isla Vista Mass Murder May 23, 2014 Investigative Summary* (2015) 58. Defendant FDA has warned that reported side effects of benzodiazepines and alprazolam include depression, agitation, disinhibition, akathisia, hallucinations and depersonalization. A recent study found an elevated risk of homicide associated with benzodiazepines. Tiihonen et

al., *supra*. However, Defendant FDA has not warned consumers that alprazolam or other benzodiazepines may cause homicidal ideation or homicidal behavior.

f) Toxicology results from the University of Florida Pathology Laboratories indicate Florida State University mass shooter Myron May had amphetamine in his system at the time of his death. Toxicology test results, University of Florida Toxicology Laboratories (December 11, 2014), available at http://www.pharmabuse.com/blogs/93. Plaintiff has interviewed Mr. May's former girlfriend, a medical doctor, who indicated that Mr. May was prescribed Vyvanse (lisdexamfetamine dimesylate), Wellbutrin (bupropion hydochloride) and Seroquel (quietiapine fumarate). Defendant FDA has warned patients to "consider discontinuing Vyvanse" if psychotic symptoms, e.g. hallucinations, delusional thinking occur. Defendant FDA has warned that serious neuropsychiatric symptoms including homicidal ideation, aggressiveness, psychosis, paranoia, delusions, hallucinations, etc. have been reported in patients taking Wellbutrin. Defendant FDA has mandated a black box warning, the strongest possible, on Seroquel of increased risk of depression and suicide. However, Defendant FDA has not warned consumers that Vyvanse and Seroquel may cause homicidal ideation; or that Vyanse, Wellbutrin, and Seroquel may cause homicidal behavior.

g) According to Montgomery County Pennsylvania Medical Examiner toxicology results, mass killer Bradley Stone had trazodone and

Risperdal (risperidone) in his system at the time of his death. Montgomery County Office of the District Attorney, *Stone Investigation* (December 23, 2014) 2, available at http://www.montcopa.org/ArchiveCenter/ViewFile/Item/2128. Defendant FDA has warned patients taking trazodone to contact their health care provider right away if "acting aggressive, being angry or violent" or "acting on dangerous impulses." Defendant FDA warns that suicide has been reported as an adverse reaction of Risperdal. However, Defendant FDA has not warned consumers that trazodone and Rispderal may cause homicidal ideation or homicidal behavior.

h) Corroborating reports link psychotropic medications to other mass killers, such as Joseph Wesbecker (Prozac, lithium, trazodone, temazepam), Kipland Kinkel (Prozac, Ritalin), Andrea Yates (Effexor, Wellbutrin, Haldol, Remeron), Edward Lutes (Luvox), Jeffrey Weise (Prozac), Steven Kazmierczak (Prozac, Xanax, Ambien), Robert Stewart (Celexa, Xanax), Aaron Alexis (trazodone), et cetera.

47. Defendant FDA must ensure that drug labeling contains a summary of the scientific information needed for safe and effective use, pursuant to 21 C.F.R. § 201.56(a)(1). If new drug safety information is reported after approval, Defendant FDA may require a Risk Evaluation and Mitigation Strategy (REMS), pursuant to 21 U.S.C. § 355–1(a)(2)(A). Upon a finding of imminent hazard to public health, Defendant FDA is required by 28 U.S.C. § 355(e)(1)-(2) to immediately suspend or withdraw approval of

unsafe drugs. Despite receiving seven hundred sixty-five (765) reports of homicide as a side effect of psychotropic medications, Defendant FDA has not ensured that drug labeling contains a summary of the scientific information pertaining to reports of homicidal ideation and homicidal behavior needed for safe and effective use of psychotropic drugs, has not required REMS for approved psychotropic drugs, and has not suspended or withdrawn approval of the drugs. In addition to failing to uphold the agency's own mandates to protect the public's safety, Defendant FDA is further thwarting the efforts of others to warn the public of the homicide risks of psychotropic medications by unlawfully withholding public records relating to adverse event reports of homicide.

48. Defendant FDA's unlawful withholding of public information pertaining to homicide as a reported side effect of psychotropic medications has profound ramifications for public safety, public policy, criminal defense, civil liability, and the agency's own potentially criminal role in covering up medicinal risk of homicide:

a) Defendant FDA's unlawful withholding of public information relating to reports of homicide as a side effect of psychotropic medications poses a grave and immediate danger to public safety. An expert review of data from AERS, the system from which Plaintiff has requested case reports involving psychotropics and homicide, found: "These data provide new evidence that acts of violence towards others are a genuine and serious adverse drug event that is associated with a relatively small group of drugs." Thomas J. Moore et al., *Prescription Drugs Associated with Reports of Violence Towards Others*, 5(12)

PLoS ONE (2010).

b) Defendant FDA's unlawful withholding of public information relating to homicide as a side effect of psychotropic medications impedes meaningful public policy debate relating to proposed strategies to prevent mass killings. Major pharmaceutical company and mental health industry donation recipient Rep. Tim Murphy of Pennsylvania has introduced a bill in Congress to enforce psychotropic medication compliance of the mentally ill. Helping Families in Mental Health Crisis Act of 2015, H.R. 2646 §§ 103(c)(1)(D)(i), 204(d)(2), 206(c)(1)(D), 206(c)(2)(D), 206(c)(3)(A)(ii), 401(a)(1), 114th Cong. (2015). During guest appearances on national television, Rep. Murphy has claimed his enforced psychotropic medication compliance legislation would have prevented mass killings by the likes of Elliot Rodger (alprazolam), Ivan Lopez-Lopez (Celexa, Wellbutrin, Ambien, Lunesta), Aaron Alexis (trazodone), et cetera. Meanwhile, Defendant FDA is steadfastly concealing from the American public hundreds of reports of homicide as a side effect of psychotropic medications, which tend to disprove the fraudulent claim that psychotropic medications prevent homicide.

c) Defendant FDA's unlawful withholding of public information relating to reports of homicide as a side effect of psychotropic medications effectively erodes the fundamental rights of accused murderers who were taking psychotropic medications at the time of their alleged crime(s) to present a defense

and call witnesses in their favor. *U.S. Const. amend. VI.* In a Florida case, a defendant accused of the double homicide of her twin four (4) year-old sons was prevented, after a *Frye* hearing, from asserting an involuntary intoxication defense and from calling expert witnesses, who would have testified that psychotropic medications played a contributing role in the crimes. *Florida v. Demeniuk*, 888 So. 2d 655 (Fla. 5th DCA 2004); *Demeniuk v. Florida*, 965 So. 2d 295 (Fla. 5th DCA 2007). In another Florida case, a defendant in the homicide of his mother reportedly accepted a plea bargain to avoid the death penalty, whereas three (3) doctors published a case study – years later – indicating that an anti-epileptic drug (AED) may have had a contributing role in the defendant's postictal aggression. Stephan Eisenschenk et al., *Homicide During Postictal Psychosis*, Epilepsy & Behavior Case Reports, 2 (2014) 118-120. By unlawfully obstructing the freedom of information, Defendant FDA is preventing the hypothesis that psychotropic medications may increase the risk of homicidal ideation and homicidal behavior from being fully studied, let alone being peer-reviewed, published, and gaining widespread acceptance within the relevant scientific community, factors considered under Fed. R. Civ. P. 702 and the applicable standard for assessing the admissibility of expert witness testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

d) Defendant FDA's unlawful withholding of public information relating to homicide as a reported side effect of psychotropic medications aligns

with the agency's expressed strategy of positioning itself as having the sole and final word as to civil product liability claims, with the intent of shielding drug manufacturers and health care practitioners from common law failure-to-warn claims "related to dissemination of risk information to patients beyond what is in the labeling." Dept. of HHS FDA, *Comments on Product Liability Implications of the Proposed Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3,933-3,936 (January 24, 2006) (to be codified at 21 C.F.R. §§ 201, 314, 601). Defendant FDA does not want "lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public—the central role of FDA." *Ibid.* The Defendant FDA's preemption strategy has the added benefit of shielding the agency itself from civil liability under 28 U.S.C. § 1346, pursuant to 28 U.S.C. § 2680(a), since labeling is at the agency's discretion. *Forsyth v. Eli Lilly & Co.*, 904 F. Supp. 1153 (D. Hawaii 1995). However, Defendant FDA's compliance with FOIA is not discretionary. Defendant FDA's self-interested obstructionism has provoked the ire of Congress in the past: "The FDA serves the American people. We are the client. The mission of the FDA is not to protect the FDA, but to promote and protect the public health by... disclosing accurate, science-based information." *FDA's Role in Protecting the Public Health: Examining FDA's Review of Safety and Efficacy Concerns in Anti-Depressant Use By Children: Hearing Before the Subcomm. on Oversight and Investigation of the*

*House Comm. on Energy and Commerce*, 108th Cong., 2nd Sess. (2004) (statement of Hon. Peter Deutsch, Subcomm. Ranking Member).

e) To the extent that Defendant FDA, by unlawfully withholding public information relating to reports of homicide as a side effect of psychotropic medications in violation of FOIA, is committing an unlawful act not amounting to a felony that results in the unlawful killing of a human being without malice, the agency and its employees may be criminally responsible for involuntary manslaughter as defined in 18 U.S.C. § 1112(a). In *Tobin*, a jury found that Paxil and its manufacturer's negligent failure to warn was the proximate cause of the murders of Rita Schell, Deborah Tobin, and Alyssa Tobin. *Tobin*, 164 F. Supp. 2d at 1278. After ingesting Adderall prescribed by psychiatrist Dr. Thomas Peterson, M.D. for attention deficit, Ryan Ehlis shot and killed his infant daughter, and then shot himself in an unsuccessful suicide attempt. "Ehlis was charged with murder, but the charges were dismissed after various doctors testified about Ehlis's mental condition, reporting Ehlis suffered from an 'Amphetamine-Induced Psychotic Disorder' and did not have the necessary criminal responsibility." *Ehlis v. Shire Richwood Inc.*, 367 F. 3d 1013 (8th Cir. 2004). In a statement to Plaintiff on July 15, 2015, Mr. Ehlis indicated that he was not warned of potentially serious psychiatric side effects of Adderall, and had he known of same, he never would have taken the medication. In addition to the two aforementioned cases, Defendant FDA is in possession of seven-hundred sixty-three (763) other reports

to the AERS of homicide as a side effect of psychotropic medications, many of which were submitted to the agency by health care practitioners. Defendant FDA's unlawful withholding of public information relating to homicide as a side effect of psychotropic medications may amount to criminal complicity in avoidable medication-induced killings.

49. Defendant FDA's unlawful withholding of public records relating to homicide as a reported side effect of psychotropic medications is reminiscent of the agency's reluctance to release information relating to increased risk of suicidal ideation and suicidal behavior in children taking antidepressants, the subject of multiple Congressional hearings and bipartisan condemnation:

> Shockingly, the FDA made a deliberate decision to withhold information on the clinical failures from parents as well as pediatricians and other prescribers. But it gets even worse.
>
> When Wyeth found evidence of elevated risk of suicidal ideation and hostility among adolescents taking its drug and tried to change its label to warn parents and providers about this increased danger, the FDA said no label change to reflect those warnings is permissible.
>
> It is incredible that this agency charged with protecting the public health would stop a company from warning the public about risks associated with the use of its products by children. But the FDA was far from finished with its cover-up at that point.
>
> As information flooded in from the industry and the British authorities who had banned the use of these drugs in kids, the FDA began a review of the 15 studies that had been done on pediatric use of SSRIs. They turned the project over to a scientist, Dr. Andrew Mosholder, a medical doctor, psychiatrist and epidemiologist in the Office of Drug Safety.
>
> Dr. Mosholder's analysis of multiple studies concluded that there was indeed an elevated risk of suicidal behavior discernible from the pediatric studies. Dr. Mosholder was scheduled to present his findings before the Advisory Committee charged with recommending action to the FDA on anti-depressant drugs in February.

> Someone within the FDA did not want those conclusions to be public and ripped his presentation from the program. Perhaps it was the same people who thought Wyeth shouldn't warn the public either.

Hon. Peter Deutsch, *supra*.

> In March of this year, the committee requested records from the FDA and also requested interviews with key FDA officials. Unfortunately, over the last months, the committee has been met mostly with stonewalling, slow rolling, plain incompetency from the FDA. That is not acceptable. The FDA's lack of cooperation with the committee in obtaining relevant and responsive information in a timely fashion on a matter that involves the safety of our children leaves me wondering whether this is sheer ineptitude or something worse. The examples of the course of conduct extend for over 5 months of this committee attempting to do its job and oversee an agency on a topic of grave concern.

*Publication and Disclosure Issues in Antidepressant Pediatric Clinical Trials: Hearing Before the Subcomm. on Oversight and Investigation of the House Comm. on Energy and Commerce*, 108th Cong., 2nd Sess. (2004) (statement of Hon. Joe Barton, Subcomm. Chairman).

50. The volume of AERS reports of homicide as a side effect of psychotropic medications bears witness to the genuine nature, large scale, and extreme urgency of the threat to public safety. To put the amount of AERS reports of homicide as a side effect of psychotropic medications into perspective, at the behest of Congress and the President of the United States, pursuant to the Investigative Assistance for Violent Crimes Act of 2012, 28 U.S.C. § 530C(b)(1)(M)(i), the Federal Bureau of Investigation (FBI) recently conducted an investigation of mass killings in this country, finding there were four-hundred eighty-six (486) fatalities from mass killings over a fourteen (14) year period from 2000 through 2013. FBI, *A Study of Active Shooter Incidents in the United States*

*between 2000 and 2013* (2014). In comparison, during an eleven (11) year period from 2004 through 2014, Defendant FDA has received seven-hundred sixty-five (765) reports of homicide as a side effect of psychotropic medications. Based on information and belief, many of the AERS reports also involve multiple homicides. Moreover, many of the cases enumerated by the FBI in their mass killings investigation report purportedly involved psychotropic medications, e.g. Jeffrey Weise (Prozac), James Holmes (sertraline, clonazepam), Aaron Alexis (trazadone), Steven Kazmierzak (Prozac, Xanax, Ambien), Robert Stewart (Celexa, Xanax), et cetera. Defendant FDA's unlawful withholding of public information relating to reports of homicide as a side effect of psychotropic medications is an affront to its public safety mission.

51. On June 10, 2014, three (3) days after the fatal shooting spree of confessed killer Aaron Ybarra (Prozac, Risperdal) at Seattle Pacific University, President of the United States Barack Obama fielded questions from citizens moderated by Tumblr Founder and Chief Executive Officer David Karp in the White House State Dining Room. Nick Dineen, former Residential Assistant of University of California Santa Barbara mass killing victim George Chen, whom a Coroner's investigation and autopsy determined was killed with a knife along with two other of the six victims of Elliot Rodger (alprazolam), asked the President what could be done about mass killings. The President replied, "The United States does not have a monopoly on crazy people. It's not the only country that has psychosis. And yet we kill each other in these mass shootings at rates that are exponentially higher than any place else." The straightforward observations

of our nation's highest elected official point to two obvious conclusions: 1) mass killings are a grave public safety concern of utmost urgency reaching the highest office in the land, and 2) pre-existing psychiatric conditions alone do not account for the higher rate of mass killings in this country.

52. Because Defendant FDA has failed to comply with the time limit set forth in 5 U.S.C. § 552(a)(6)(A)-(B), Plaintiff is deemed to have exhausted any and all administrative remedies with respect to his FOIA requests, pursuant to 5 U.S.C. § 552(a)(6)(C).

**COUNT 1**
**(Violation of FOIA, 5 U.S.C. § 552)**

53. Plaintiff realleges Paragraphs 1 through 52 as if fully stated herein.

54. Defendant FDA is unlawfully withholding public records requested by Plaintiff pursuant to 5 U.S.C. § 552.

55. Plaintiff is being irreparably harmed by reason of Defendant FDA's unlawful withholding of requested public records, and Plaintiff will continue to be irreparably harmed unless Defendant FDA is compelled to conform its conduct to the requirements of the law.

WHEREFORE, Plaintiff respectfully requests that this Honorable Court: (1) expedite consideration of this Complaint pursuant to 28 U.S.C. § 1657; (2) declare the records requested by Plaintiff to be public records pursuant to 5 U.S.C. § 552 and must be disclosed; (3) declare the records requested by Plaintiff to be not exempt from disclosure; (4) declare Defendant FDA's failure to comply with FOIA to be unlawful; (5) order

Defendant FDA to produce, by a date certain, any and all records responsive to Plaintiff's FOIA requests; (6) enjoin Defendant FDA from continuing to withhold any and all records responsive to Plaintiff's FOIA requests; (7) grant Plaintiff an award of attorneys' fees and other litigation costs reasonably incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and (8) grant Plaintiff such other relief as the Court deems just and proper under the circumstances herein.

Dated: August 4, 2015

Respectfully submitted,

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