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[redacted]

May 20, 2020

The Honorable Jamie Raskin
United States House of Representatives
412 Cannon House Office Building
Washington, DC 20515

Dear Representative Raskin,

I am a constituent and a former FDA reviewer and whistleblower. I first contacted your office in 2017 and promised that I would follow up after I had completed a detailed write-up to guide investigations. I believed this was necessary as past attempts to have things looked into have been dismissed using a variety of excuses including a lack of detail. Due to the extensive nature and complexity of the evidence it has taken until now to fully document things. Additionally in past whistleblowing I focused on safety issues and did not focus on issues of whistleblower retaliation. However I am changing this approach as I now more fully understand the Constitutional issues involved and believe that addressing them is equally important. Thus I am asking for your personal involvement in these matters not only because it's your duty as my representative to present my grievances and petitions, but especially as I was fired for seditious libel for exercising my First Amendment right to report crimes by FDA officials to Congress and criminal investigators; crimes that endangered my own life, my child's, as well as the lives of the American public. Thus as an expert in Constitutional law and the First Amendment with an interest in civil rights and the chair of two subcommittees regarding the Constitution I believe that your personal involvement in warranted not only because of the issue of seditious libel but also because of other attacks on Constitutional and civil rights that I believe are criminal in nature. Attacks that I believe include impeachable acts by Federal judges that likely have implications for numerous other whistleblowers. Thus I am also asking for your personal involvement due to the large number of federal employees who are your constituents. However before I discuss these attacks on the Constitution and civil rights, I would first like to provide some background and a brief overview of some of the main safety issues I whistleblew about that endanger the lives of the American public including some that continue to cause deaths on a daily basis.

During the Bush administration there were numerous instances of whistleblowing by FDA reviewers that came to the attention of the public. These included David Graham and Vioxx®, Andy Mosholder and antidepressants inducing suicidality in adolescents and young adults, David Ross and Ketek®, Rosemary Johann-Liang and Avandia®, Susan Wood and Plan B®, Victoria Hampshire and ProHeart 6®, Renée Dufault and mercury in high fructose corn syrup, and the nine device reviewers who wrote President-elect Obama regarding the likelihood of GE's CAT scanner inducing cancers. This of course doesn't include other FDA whistleblowing incidents that have not come to the attention of the public.

In addition to the issue of antidepressants inducing suicidality there were also other whistleblowing cases in the private sector and state government employees involving psychiatric drugs that have resulted in the recovery of multiple billions of dollars due to Medicaid frauds that involved drug companies, academicians, practicing health care providers, and state officials that occurred during the same time period.

During this time I reviewed psychiatric and neurology drugs at the FDA and can attest that corruption involving psychiatric drugs also involved FDA officials. While there are those that will likely say that these

are old issues and that things at the FDA are different now. I have to disagree for a leopard cannot change his spots and many of the same people, including at the most senior levels of the FDA, are still there or have been replaced by their protégées who assisted in harming the American public, while those who stood up to the corruption were eliminated and others were cowed. Consequently there is no reason to trust the FDA and especially with Covid-19 there is a substantial danger that FDA decisions will not be based on science but rather on a desire to gain favor, resulting in decisions that are likely to harm the public and recovery efforts.

Major Safety and Efficacy Issues

The following are the main safety issues that I whistleblew about that I would like to bring to the attention of Congress and the President. Most of these I identified during the last review I performed at FDA in 2008. A review for the approval of the antipsychotic Saphris® (asenapine); where since then as well as since I have otherwise tried to have these issues addressed, I have uncovered additional pertinent information.

- *Lack of Efficacy of Antipsychotics in Mania*

Analyses revealed that approximately the bottom half of patients with mania who are less severely ill (as measured by YMRS scores) do not respond to antipsychotics any differently than to placebo. (See Attachment 1 for plots) This observation was verified by analyses with all antipsychotics where data was available including Zyprexa® and others. Plus around the same time Johnson and Johnson reported to the FDA that they had found the same thing with their antipsychotic Invega® (paliperidone or 9-hydroxy-risperidone), which as the active metabolite of their antipsychotic Risperdal® (risperidone) with equal receptor potencies is claimed by both JNJ and the FDA to have the exact same effects as Risperdal®.

Despite FDA officials knowing this and knowing that antipsychotics cause death and other serious adverse reactions both of which are documented, Ellis Unger the then Associate Director of the Office of Drug Evaluation 1 and others, including Tom Laughren the Director of the Division of Psychopharmacologic Drugs, approved Saphris® for use in all patients with mania despite this being in violation of the Food Drug and Cosmetics Act as well as in violation of labeling regulations that requires a limitation of use for subpopulations such as this where treatment is ineffective; a subpopulation that can be identified prior to treatment.

Dr. Ellis's approval memo uses double talk to justify his actions. In it he claims that the lack of difference from placebo is due to and similar to a ceiling effect seen with ADHD drugs. However there is no ceiling effect with Saphris® nor is there a basement effect with antipsychotics in mania. Plus the only ceiling effect I'm aware of with ADHD drugs is one I discovered, and I assure you it does not apply to the situation with the antipsychotics in mania. Most importantly however is that his justification is essentially trying to explain why there is no difference from placebo with regards to efficacy in these patients. However the reason simply doesn't matter. For if there is no difference from placebo then the drug doesn't work; and it doesn't matter why it doesn't work and so by law the drug can't be approved. Nevertheless he makes a statement to the effect that just because Saphris® doesn't work in these people (and which he knows will harm and even kill many) this is not a reason for him not to approve it.

The total evidence including submissions from Johnson and Johnson where they admitted they found the same thing with their antipsychotic Invega® clearly indicates this is likely a class effect where based on usage and the death rates associated with these drugs (1%) as many as 6,000 people per year may have been killed due to willful poisoning, or 72,000 dead since 2008. With potentially well over 100,000 dead since these drugs were first approved for use in patients with mania. In addition we are likely dealing with fraud and waste in the multiple tens of billions of dollars with a large percentage paid by Medicaid.

I am certain that people will claim that these drugs worked for them, but it should be remembered that based on the evidence they would have gotten better anyway and in my view they should consider themselves lucky that they weren't killed.

- *Lack of Required Metabolite and Toxicology Information, and Infant Deaths*

Thalidomide was stopped due to a lack of mass balance information, i.e. what metabolites it was broken down to and how the drug was being eliminated the body. Due to this the 1962 Kefauver-Harris amendment to the Food Drug and Cosmetics Act was passed and required that information necessary to assess safety must be provided or a drug cannot be approved. This safety information includes mass balance information and toxicologic information on metabolites including human exposures, animal toxicology studies, and pharmacologic effects of metabolites including actions at receptors. The application for Saphris® was missing much of this information. For example FDA policies in effect at the time required that there must be animal toxicology data provided on any metabolite whose exposure in humans is greater than or equal to 10% of the exposure to the parent drug (asenapine) and FDA management even stated in review documents that without this information Saphris® could not be approved. Despite this there were several metabolites from mass balance studies with radiolabeled asenapine (the parent drug in Saphris®) whose exposures exceeded this with one even having exposures of greater than 40% of asenapine's. Despite this, radioactive substances in blood were dismissed as unrelated to asenapine and they and others with significant exposures were not even identified. However the human body does not make radioactive compounds out of thin air and so the only thing these compounds could possibly be are an unidentified metabolite or a contaminant, either of which would require the study to be redone. In addition there is no evidence that the animals used in the toxicology studies even produced these compounds. Plus based on the way the studies were done there was no way to quantify the human exposures of any of the metabolites and thus no way to know if even the metabolites the animals did produce resulted in adequate exposures to assess their toxic potentials including carcinogenic and reproductive risks.

Such animal studies however only provide certain information. So in addition to animal studies the binding of all metabolites to various receptors similar to the ones that asenapine binds to must also be assessed as even small changes to the drug molecule are expected result in effects on similar receptors that otherwise would not be effected. This information including potency must be combined with data on the concentrations these metabolites achieve in humans in order to predict the likelihood of toxic effects. As antipsychotics bind to certain dopamine and serotonin receptors it's thus imperative that <u>all metabolites</u> be assessed for effects <u>at all</u> dopamine and <u>serotonin receptor subtypes</u> and the concentrations at which these effects occur must be assessed. This is especially important for the 5HT2B receptor for metabolites acting on it are responsible for the Pulmonary Arterial Hypertension (PAH) and heart valve problems seen with the diet drug combination fen-phen as well as other drugs that have been removed from the market.

Not only was there a lack of information on Saphris® metabolites and their exposures and if animals were even exposed to certain metabolites, there was also a lack of both binding and effect data for the 5HT2B receptor for most of the nearly 30 or so known metabolites. Thus due to the risk of a fen-phen effect and knowing that PAH in infants is typically misdiagnosed as SIDS, along with the substantial chance that pregnant and breast feeding women with schizophrenia and especially mania (with symptoms that include hypersexuality) are likely to take Saphris® I examined the animal reproductive data which had been hidden and was not included in the toxicologist's NDA review and found animal pups dying due to *in utero* exposures as well as just from breast feeding. Based on this and other information, I requested that human post-marketing safety data for all antipsychotics be examined for these effects (including in infants) and that a public health warning be issued.[1] The other information this request was based on was a communication from a drug company whistleblower that the company did have the information for asenapine and (at least some) metabolites and a number of drug companies knew that antipsychotics had fen-phen like effects on the 5HT2B receptor, things that I communicated to FDA Center Director Janet Woodcock and others in an e-mail. Despite this, evidence in public documents point to Tom Laughren, the Psychiatry Division Director, apparently conspiring with individuals at ScheringPlough (now Merck) to dismiss the lack of metabolite information that precluded approval under the Food Drug and Cosmetics Act. Then at the same time as this was occurring I was removed from the FDA and this issue that could

[1] This was especially important as antipsychotics are often used in combination with antidepressants and there was already a warning for fen-phen like effects with serotonergic antidepressants. Thus combined use could result in a situation exactly like with combined use with fen-phen.

kill both patients and their babies was inappropriately dismissed.[2] While at the same time Janet Woodcock sponsored a seminar on the 5HT2B issue and antipsychotics with an outside 'expert' Bryan Roth, and according to a psychiatry reviewer who was in attendance, FDA staff were told: *"they may not even propose it as a possibility"*.

Several years later I found FDA post-marketing safety data that showed that even at the time I had made my requests to examine the post-marketing safety data in 2008 that several thousand infants had died due to exposure to a variety of serotonergic antipsychotics, where the exposures had to have occurred either during pregnancy or from breast feeding.[3] (See Attachment 2) Where despite this women were being told these drugs were safe and did not pose risks to babies. In addition, I then later found that Otsuka pharmaceuticals admitted that their antipsychotic Abilify®, which is marketed by Bristol-Myers Squibb, had the type of 5HT2B effect that causes PAH that I was warning about and they cited published data from Janet Woodcock's expert.[4] Which by law they were required to have informed the FDA psychiatry division of in their 2003 annual report. Similarly after I was removed from the FDA and before Saphris® was approved, documents released by the FDA for an advisory committee meeting regarding the approval of antipsychotics for use in children show that cases of PAH had been reported to the FDA in children and the FDA was already concerned about cardiac effects known to be related to these effects and the post-marketing division had wanted to issue a warning two years before I raised it as a risk. What's particularly disturbing however is that the 2007 FDA amendments act (FDAAA) passed in the wake of Vioxx® required the FDA to issue a public warning if a new signal was found in the post-marketing data which was required to be examined. A program Janet Woodcock was running at the time. This means either that the FDA violated the 2007 FDA Amendments Act or more likely knew of the infant deaths from the postmarketing surveillance prior to the passage of the FDAAA and my warning, which in either case they chose to suppress.

Not only is the metabolite and 5HT2B issue with the antipsychotics analogous to what occurred with thalidomide, it's actually much worse. This is because the FDA was warned of the risks and even had the data and so was almost certainly aware of the dangers with administering antipsychotics during pregnancy or while breast feeding. While with thalidomide the FDA had no inkling of the risks.

- *Anaphylaxis*

On September 1st 2011 the FDA issued a safety alert warning regarding a risk of anaphylaxis, a severe type of allergic reaction that can cause death that was occurring with Saphris® and the labeling was changed. In addition, the occurrence rate was 1 in 800, which was several fold higher than with penicillins which are the small drug molecules with the previously highest rate of anaphylaxis. Some of these cases of anaphylaxis were even occurring with the very first dose of Saphris® which meant that patients were likely being cross sensitized by other antipsychotics and could die with their first dose of Saphris® after they were switched. Even worse, buried in a different section of labeling than where the anaphylaxis warning was located was information that combined use of Saphris® with epinephrine or dopamine can cause lethal drug interactions of a type that can mimic effects due to anaphylaxis. This is especially

[2] Of course from a scientific and regulatory basis it can't be dismissed without the data I was asking for; data that is required by the FD&CA and had not been provided.

[3] The initial evidence I saw was that over 6% of deaths with Seroquel® reported to the FDA were in infants. This compared to somewhat over 30% of deaths occurring in the elderly where there had been an intensive unlawful off-label marketing campaign despite knowledge that antipsychotics resulted in as many as 25% of elderly to die within weeks of beginning treatment. Due to the low numbers of babies that could be exposed from pregnancy or breast feeding as compared to the usage in the elder the 6% of deaths that were in babies was staggering and based upon the likelihood the FDA was looking at deaths by age due to what occurred with Vioxx® in the elderly, antidepressants and suicides in adolescents and young adults, and antipsychotics in the elderly, and my knowledge of how the FDA monitors postmarketing data I suspect that the FDA was likely aware of this. Plus even after the FDA apparently learned of this later through my reporting to DOJ, the public still hasn't been warned.

[4] Shapiro DA et al. Aripiprazole, a novel atypical antipsychotic drug with a unique and robust pharmacology. Neuropsychopharmacology 28: 1400-1411, 2003. As citied in Hirose T, and Kikuki T. Aripiprazole, a novel antipsychotic agent: Dopamine D2 receptor partial agonist. J Med Invest. Vol 52 Suppl 2005. 284-290. Available at: https://www.jstage.jst.go.jp/article/jmi/52/Supplement/52_Supplement_284/_pdf. Accessed May 21, 2014.

critical as epinephrine and dopamine are the only drugs known to be effective for an acute anaphylactic attack and are what first responders and emergency personnel are going to automatically use without checking labeling, and even if they do check labeling there is virtually no chance they are going to also check the section of labeling this information is found in.

During the review of Saphris® I discovered a death due to anaphylaxis that was falsely attributed to another cause, and information on this death as well as other allergic reactions which indicated the rate of allergic reactions may at least as high and possibly even higher than reported in post-marketing reports are included in my review which is public. Despite this knowledge, the available evidence indicates FDA officials deliberately covered up the true cause of this death and the risks.

- *QT Effect and Sudden Death*

Drugs that prolong the QT interval of the electrocardiogram (ECG) can result in lethal cardiac arrhythmias that suddenly cause the heart to stop pumping blood. Such arrhythmias cause people to suddenly lose consciousness and keel over and die, resulting in what is called sudden cardiac death or sudden death. Drugs that prolong the QT interval by more than 10 milliseconds (mSec)[5] at even a single time point after a dose, that include doses designed to test the effect in patients who achieve the highest drug exposures, are considered to have a significant risk of sudden death. This is considered a significant safety issue with antipsychotic drugs and some have even been removed from the market because of it.

For Saphris® the greatest QT prolongation was 17.1 mSec and there was clinically significant QT prolongation at all four dose levels tested and at 17 of 28 times tested (7 per dose level). This was the second worst of all the antipsychotics and the 17.1 mSec prolongation is approaching the degree of QT prolongation where drugs are typically taken off the market due to being too dangerous.

Despite this clear prolongation and risk of sudden death Saphris's® labeling essentially indicates that there is no clinically significant QT prolongation at all. Thus patients who should avoid Saphris® due to underlying heart problems, which are relatively common in patients treated with antipsychotics, and who should take a different drug, are probably being prescribed a drug that they should be avoiding. This misleading labeling is due to the use of computer modeling to dismiss this clear toxic effect. Modeling which was performed despite it violating several criteria for when such modeling may be used.

- *Direct Cardiac Effects*

In early studies during the development of Saphris® the hearts of healthy volunteers stopped, which in some cases required multiple courses of emergency cardiac drugs to restart the volunteer's heart. A physical examination by a cardiologist for the drug company indicated it was not due to a reflexive bradycardia and he stated that it had to be due to a direct toxic effect on the conducting system of the heart. This was followed by the company itself indicating that it could not be a reflexive bradycardia. It was because of this cardiac effect and liver toxicities that the company kept the dose of Saphris® too low to see any effect for over a decade, which delayed approval and decimated sales and is also why they switched to a sublingual formation and twice daily administration which would minimize the risk of toxicities but also decimated sales. Despite this safety concern, when the New Drug Application was submitted Schering provided a safety summary that indicated that the volunteer fainted simply due to a neurologically mediated reflex bradycardia (NMRB) and this is reflected in labeling; despite my documenting the risks and providing the original cardiologist's letter in my review and in my briefing presentation. Also after I spoke to an FDA cardiologist about these cardiac arrests and asked them why they hadn't examined the original data, the FDA cardiologists provided a consult stating it was simply fainting due to NMRB while at the same time admitting that they hadn't even examined the original reports and were simply going by Schering's clearly misleading summary.

[5] Above the upper limit of the 90% confidence interval

- *Pyridostigmine*

Prior to the 2003 Iraq War the FDA approved pyridostigmine to prevent deaths from the nerve agent soman. Soman and other military nerve agents irreversibly block the enzyme acetylcholinesterase which breaks down the neurotransmitter acetylcholine. The resulting excess acetylcholine causes intense contractions of intestinal and bladder muscles causing people to have GI problems and soil themselves, it also stimulates salivation and respiratory secretions causing breathing problems, effects brain neurotransmitters causing seizures, and most importantly paralyzes muscles including the muscles controlling breathing resulting in suffocation and death within 3-5 minutes. Pyridostigmine is a reversible inhibitor of acetylcholinesterase and it was claimed that blocking a substantial fraction of acetylcholinesterase with pyridostigmine in advance would block soman from binding and after the soman is eliminated from the body the pyridostigmine would then be eliminated and the acetylcholinesterase blocked by pyridostigmine would regenerate and troops would recover and survive. Based on this claim pyridostigmine was approved for use by our troops based on a new regulatory rule (The Animal Rule) that had 5 criteria. However pyridostigmine has an effective half-life of 3 – 3.5 hours and as shown by calculations I've done **it is impossible** for pyridostigmine to work the way it's claimed, as it would take too long for pyridostigmine to be eliminated and so deaths would have already occurred.[6] Thus the only expectation was that pyridostigmine use would result in even more deaths, where the troops who would have survived would instead now die due to the additive effects of pyridostigmine and the similarly acting military nerve agents. In addition, since pyridostigmine does not cross the blood brain barrier these troops would not have seizures and so would be fully awake and aware of their throats and lungs filling up with fluids while otherwise being unable to move and breathe, resulting in truly horrific deaths with expected sensations similar to those experienced due to waterboarding, all while they would be lying in their own filth.

I was brought in to evaluate past non-approvals of pyridostigmine and repeatedly informed my superiors that pyridostigmine couldn't possibly work and would result in an increase in deaths. Instead I was repeatedly pressured to assist with an approval. Ultimately since I wouldn't I was removed from the review of the efficacy and mechanism of action and other criteria under the animal rule, and if you look at the approval documents there is absolutely no review of this, the most critical aspect of the approval criteria. Plus the reviews of other aspects of the animal rule are in my view incorrect and likely willfully misleading. However right before I was removed I informed my superiors that we knew that Saddam Hussein was not using soman and instead was using other nerve agents where the animal data showed that pyridostigmine resulted in increased lethality.[7] Consequently it was unsafe under the conditions of use under which it would be prescribed and so the approval was clearly and explicitly prohibited by the Food Drug and Cosmetics Act.[8]

Among the FDA officials that knew that pyridostigmine could not be approved were Janet Woodcock and Bob Temple, the Director of Medical Policy and of the Office of Drug Evaluation 1 who is the person who signed the approval documents. In fact when I told Dr. Temple that none of the approval criteria had been met, he told me that he wrote the law and when I responded that pyridostigmine still didn't meet the legal requirements whether he wrote the law or not he said: *"The law is what I say it is."* I also told Janet Woodcock that it couldn't be approved and when I pointed out during another meeting that certain claims being invoked for approval under the animal rule were incorrect Dr. Woodcock screamed at me *"Be quiet! I know what's going on. Besides the White House said the President has already looked at it and he isn't going to look at it again."* A statement that was in reference to earlier attempts to get President Bush to waive informed consent so that he would be responsible and not FDA officials; something that I can't see how it was done unless critical information required by law to be provided to the President regarding

[6] Several years later a paper was published that supposedly supports this mechanism however the modeled data that was presented is inconsistent with calculated values based on the known parameters of these drugs.
[7] This was based on Congressional testimony by Christine Gosden I had read about in the Washington Post, but it is also documented in the DoD Chemical and Biological Defense Program March 2000 Annual Report to Congress.
[8] Claiming that it's only to be used against soman is absurd as it has to be administered in advance so you never know which nerve agent will be used, plus even if it's only taken when there are nerve agent attacks we would not be able to determine which ones were being used or would be used, and lastly because we knew Iraq was not using soman and so the approval for use in Iraq simply didn't make sense.

Iraq's use of nerve agents other than soman and their increased lethality in the presence of pyridostigmine was withheld. As for the animal data I believe that studies were likely not done appropriately, were not applicable to the situation they were claimed to be for, and did not support the use of pyridostigmine under the conditions of use that would affect troops.

Not only do I believe that there was a deliberate attempt to poison and kill US troops during war by the people who pressured me to change my opinion who are not among those I have so far identified, but it was also known that the FDA decision would not only impair the combat ability of our troops but would also endanger allied troops, embedded journalists, as well as civilians of a friendly country (Israel) and US citizens in that country.

It should be noted that under both US law and the Geneva Convention war crimes include submitting troops to biological experimentation where there is no expectation of benefit. Yet as part of the approval under the animal rule the effect of pyridostigmine given to troops must be studied. Unfortunately due to the lack of placebo and the varying conditions under combat conditions results of such a study would be uninterpretable which with the expectation that pyridostigmine could only result in more death and harm to troops it's clearly evident that there's no possible benefit.

- Other Issues

In addition to the above issues there are several other safety and efficacy issues with Saphris® that were inappropriately dismissed or downplayed. These included evidence that Saphris® and other antipsychotics acutely induced suicides and suicidality in 1% of patients with mania[9], whereas there was no evidence of suicidality or suicides with placebo. This is in contrast to the well known warning that antidepressants increase suicidality in young adults and adolescents based on data from over 14,000 people none of whom committed suicide. Plus that Saphris® was hepatotoxic and when given to patients with even mild liver failure resulted in substantially increased exposures. Both of which should have caused Saphris® to be contraindicated in these patients. The first because like with alcohol you never want to give someone something that could harm their liver which a person with a normal liver could tolerate but where it could push someone with little functioning liver into a much more precarious position or even kill them. Plus when 1 in 3 people with even mild liver disease can't handle a drug and are getting exposed to dangerous 'levels,' that means that it's not safe to give to anyone with mild disease. Yet both of these were ignored by FDA management and the drug company, and prescribers are not warned and are instead told it's safe to use when it isn't. Each of these and other issues in my view makes the labeling for Saphris® false or misleading, which under the Food Drug and Cosmetics Act means it's misbranded, where under the Food Drug and Cosmetics Act a misbranded drug may not be introduced into interstate commerce. These as well as all of the above otherwise potentially trade-secret or potentially confidential information I've mentioned may be found in public documents released by the FDA[10] or the Justice Department[11] and so there is no prohibition on me discussing them except due to a non-disclosure agreement I was forced to sign against my will that will discuss later.

Termination for Whistleblowing

On December 15th 2008 I was fired by Douglas Throckmorton, the Deputy Director for the FDA's Center for Drugs. Dr. Throckmorton upheld eleven charges or specifications against me. Eight of these are for whistleblowing where each is also for reporting crimes.[12] Now it is illegal to fire government employees who whistleblow (and/or report crimes) unless the government can show by clear and convincing evidence that the employee would have been fired anyway. In addition Federal employees have a clearly

[9] This typically strikes in the late teens or twenties.
[10] See Saphris® and pyridostigmine reviews under the 'Drugs@FDA' website as well as documents related to Saphris® and other drugs on the FDA Advisory Committee website, and other public information on the internet
[11] USA ex rel. Ronald E. Kavanagh v. Merck et al.; US District Court – Massachusetts, Case #: 1:12-cv-12280-GAO
[12] Although not reported at the time I now believe that the crimes I tried to report also constitute hate crimes under 18 USC §249(2)

established civil right to protection from retaliation for whistleblowing and for reporting crimes.[13] Thus I will first discuss the three upheld specifications that are not directly linked by the FDA to whistleblowing and reporting crimes but were nevertheless in my view for purposes of retaliation for reporting crimes, followed by the eight upheld charges/specifications that are directly linked to and involve whistleblowing and reporting crimes.

The first of the three specifications not directly linked by the FDA to whistleblowing was for supposedly discourteous conduct during my Saphris® briefing and for not presenting the appropriate material. As for not presenting the appropriate material I was instructed by the person who issued the termination proposal as to what material I was to present. Then in issuing his decision Dr. Throckmorton claimed he believed the allegations because they were immediately reduced to writing. However the documents he relied on clearly show that they were written two months after the briefing by someone who Dr. Throckmorton knew I had openly reported to Congress and the Inspector General as possibly committing crimes and which is the subject of other specifications for my reporting crimes that the supporting documents used to fire me indicate are the actual beginning of efforts to fire me. Dr. Throckmorton also knew that these written allegations were hearsay which he was advised could not used. In fact use of hearsay evidence for personnel actions is prohibited by statute. (5 USC §2302(b)(2)) In addition my whistleblowing and reports of possible crimes in the other specification were in part based on attempts to interfere with my briefing in order to dismiss the metabolism issues I have described above and where audience members at the briefing clearly did not see any evidence of discourtesy on my part. By law this specification cannot be used to fire me and there is strong evidence that it was included and Dr. Throckmorton upheld it simply to fire me for whistleblowing and reporting crimes to criminal investigators.

The second of the specifications not directly linked to whistleblowing or reporting crimes is an e-mail where I accidentally hit reply-all which sent it to a large number of FDA staff. My e-mail was intended only for a person in IT telling them that a suggested work around for a problem they were notifying us of (i.e. instructions to repeatedly hit a radio-button) did not always work and that (based on past experience) I was afraid that someday it could result in reviews being unable to be timely submitted thereby resulting erroneous decisions on drugs that could result in harm to patients. In fact I didn't even know I had hit the reply-all button until the IT supervisor called me and we discussed it and I explained to him that I had also spoken to the IT person who sent the original e-mail by phone and she agreed with me. Dr. Throckmorton stated that he upheld this specification because he claimed that I had intentionally sent the e-mail out widely and that I had inappropriately criticized internationally agreed upon electronic submission standards agreed to by US, Europe and Japan regulatory agencies. I have already noted that it was sent accidentally and Dr. Throckmorton had no basis to claim it was sent intentionally. It is also self evident from the e-mail itself that it was not about electronic submission standards as the e-mail only dealt with whether FDA computers or software were working properly and thus had nothing to do with the data submission formats. He also claimed that it could not effect finalization of reviews as I stated due to the time we have available to us to do reviews, however this is false as we often find things at the last minute when we are finalizing reviews that need to be checked, which he should know. Thus none of the rationales given for firing me based on this specification are valid and there appears to be intentional falsification of some by Dr. Throckmorton. Plus upholding this specification means that anyone in government can be fired at anytime for accidentally hitting reply-all and sending an e-mail involving non-confidential information to someone it was not intended for, a standard that I am unaware of any other government employee being held to for the numerous e-mails likely sent by the 2 million federal employees excluding contractors.

The third specification not directly linked to whistleblowing was in regards to a meeting with a drug company that occurred after I had whistleblown and reported crimes multiple times, including crimes by Dr. Laughren the Director of the Psychiatry Division which I will discuss later. After the meeting Dr. Laughren claimed I behaved inappropriately toward the company and that he had to calm things down. This is a blatant lie. For nearly an hour the sponsor ignored my telling them that what they wanted to do would not support an NDA approval as it did not fulfill regulatory requirements specified by the Code of Federal Regulations (CFR) (and I believe the Waxman-Hatch Act) and at no point did Dr. Laughren say

[13] 5 USC §2302(b)(8),(9),(12); 5 USC §2301(b)(9); 5a USC §7(c); 45 CFR §73.735–1303

anything. Finally my team leader held the CFR above his head and yelled at the sponsor telling them that I had repeatedly answered their question and to look at the regulations I had repeatedly referred them to. It was only at this point that Dr. Laughren finally said anything, saying we should move on to the critical questions for which there were only minutes left.[14] Then when Dr. Laughren complained about me and my team leader was asked about my behavior he told our management that I was within the normal bounds of behavior and that it was no different from other reviewers and that if I were punished in any way then he definitely should be too. Despite this his yelling at the sponsor was not held against him. Dr. Laughren clearly had motive to lie and retaliate against me for having openly reported to Congress and the Inspector General and others crimes I believed he had committed, including a crime that could have resulted in the death of my own child. Plus Dr. Throckmorton was also informed of documentation of my team leader's response.

As for the other charges/specifications that were directly linked by the specification or supporting documents to my whistleblowing and reporting possible crimes by FDA officials, they began with my indicating on May 29th, 2008 that I would be talking to Congress. (1) This was after I had tried to report possible felonies to my management involving a *"cover-up"* of the death from anaphylaxis, as well as apparent witness tampering by Janet Woodcock in association with others to Commissioner Von Eschenbach, whereupon he also apparently tried to have someone stifle my reporting crimes to criminal investigators. In response my management made a statement in an open e-mail that indicated that I would be fired where I was fairly certain they were aware of what I intended to report to Congress as I had evidence that indicated they were already conspiring with Commissioner Von Eschenbach to retaliate against me. At this point I sent a follow-up e-mail openly whistleblowing to Senator Grassley's office and to the HHS Inspector General reporting a number of possible felonies and where I referred to other issues including the lack of efficacy of the antipsychotics in mania, the metabolism and $5HT_{2B}$ issues and the corrupt obstruction of my review of Saphris® (18 USC §1505) in order to suppress these issues as well as threats that had been made against my children. Plus I reported the apparent witness tampering involving Commissioner Von Eschenbach's office. (2)

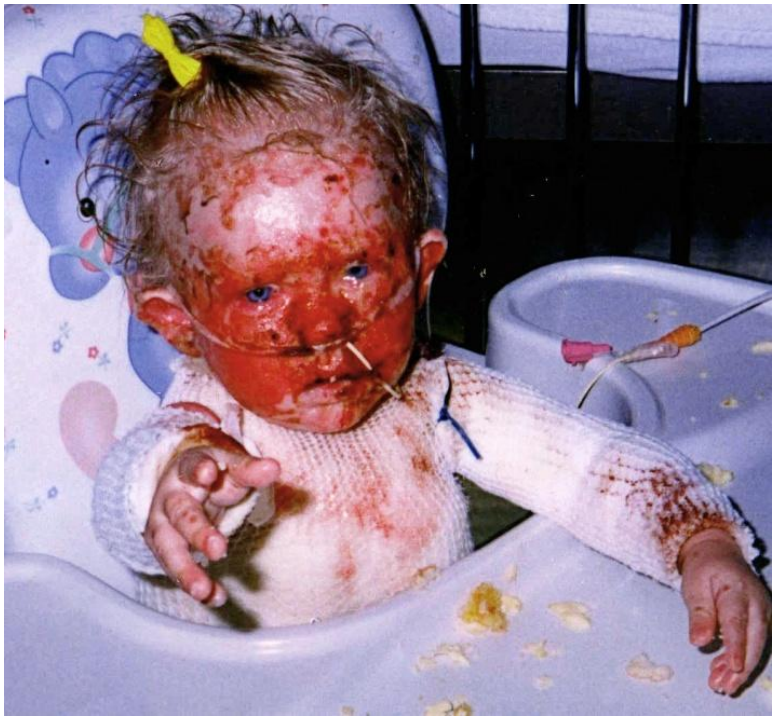
This e-mail that I cced to Congress and the HHS OIG also reported an apparent conspiracy that endangered my own child's life where I had overheard Dr. Laughren telling Dr. Temple that he would *'speak to Wayne and have him drive the discussion and vote'*. A statement that I presumed was about Wayne Goodman the chairman of the psychopharmacologic drugs advisory committee (AC) and an AC meeting the following week regarding the risk of Stevens-Johnson's Syndrome with modafinil, a drug that was under review for treating ADHD in children. Sure enough during the meeting Dr. Goodman appeared to be doing exactly what I had overheard. I had overheard Dr. Laughren as I was walking right by the two of them as he said it and I know he saw me, and because of this and other reasons believe he certainly had to have been aware I was talking about him and Dr. Temple.

Stevens Johnson Syndrome is an autoimmune reaction where the drug attaches to tissues in the body and causes the immune system to attack the person who took the drug. Stevens Johnson Syndrome affects at least 10% of the skin covering the body and begins as a rash. The area then dies and falls off in sheets. The result can be like being napalmed or splashed with acid and is extremely painful. In addition there's involvement of mucus membranes such as the inside of the eyelid, the urethra, the vagina, uterus, fallopian tubes, the inside of the nasal passages, anywhere in the gastrointestinal tract from the mouth to the anus, or the bronchial tree. All of which may also be extremely painful. SJS causes death in 10% of people affected. There is also a milder form but it also has a mortality rate of 10%. When more than 40% of the body is affected it's called Toxic Epidermal Necrosis (TENS) and the mortality rate is over 40% and may be as high as 70%. In some cases SJS can also cause scarring of the cornea and blindness where the only treatment is to surgically implant tiny tubes into the eye which allows people to see a tiny pinprick of what they would normally see.

The following is a picture of Julie who had a severe case of Stevens Johnson Syndrome/TENS. This photo was provided by the Stevens Johnson Syndrome Foundation (sjssupport.org) who graciously

[14] Based on past experiences I believe that this meeting may have been designed in order to make allegations that could be used to fire me.

gave me permission to use it.



Courtesy of the SJS Foundation (sjssupport.org)

Also prior to the AC meeting I also overheard two individuals discussing that FDA management believed that the child likely developed SJS due to a known genetic predisposition as the child was Asian. This genetic predisposition is known to result in SJS in 25% of Southern Chinese given certain drugs and half that rate in Thailand where 50% of the population of Bangkok is of Chinese descent. At the time I had been considering placing my own son on this drug which based on this information meant he would have a 1 in 16 chance of developing SJS and a 1 in 160 chance of dying. Consequently when I whistleblew I mentioned the risk to my own child as this apparent crime effected me personally as well as the safety of other children with ADHD which may affect as many as 14% of boys.

The internet has discussions claiming that SJS with modafinil is rare, however the information is misleading as it's based on adult data and we saw a clear progression of related toxicities as children got younger and younger. Also there was a metabolite, whose structure is similar to other drugs that cause high rates of SJS (5%), and whose average exposure was 16 fold higher in children as compared to adults where SJS is clearly documented. Thus with the available data with a drug that barely worked the advisory committee voted 12-1 against approval, which Glenn Mannheim the reviewer who identified it attributes to my assistance and an *ad hoc* presentation and slides I presented at the advisory committee meeting. There was also a follow-up meeting with Dr. Bixby the Harvard pediatric dermatologic who was invited as a special panelist who voted for approval, where he was shown additional information. After this meeting Dr. Bixby sent a letter to the FDA stating that it was definitely a case of SJS and that if he had seen the additional information during the AC meeting that he would have voted against approval and made the vote unanimous. I strongly believe Congress should look into modafinil and especially the events and chronology regarding this additional information and the ultimate FDA contraindication against use in children that was issued more than 16 months after the advisory committee meeting.

I also mentioned how Dr. Laughren had tried to take administrative action against me when I had complained of discourteous conduct by someone who during an internal meeting had joked about a patient who had died due to an experimental drug causing their brain to swell and crush their brain stem and cerebellum. In response to this statement Dr. Laughren indicated in an e-mail used to fire me that the incident had not occurred. This is another blatant lie! In fact I had stopped the person as he was joking to

Dr. Laughren about this and told him that with antipsychotic drugs being used for depression, mania, and even agitation in children with ADHD, that something like this could kill me or my child. I then also mentioned in the e-mail how Dr. Temple had written in the nonapproval letter for the antipsychotic bifeprunox that it was because it was less effective than other drugs, which I then stated was not the true reason. A statement which I believe is fully supported by FDA documents including documents that are not in the official file such as e-mails and which is why I believe that documents associated with not-approved as well as approved drugs should be made public.[15] I also wrote that he had written the non-approval letter in a way that would allow bifeprunox to be approved and marketed at a later time, a statement which I believe is supported by the evidence. (Discussion of public information about a patient in the bifeprunox study who died is included in Attachment 3.)

In concluding this e-mail that precipitated my firing for whistleblowing and reporting crimes to Congress and the Inspector General, I also said that I was willing to go to jail to fulfill my duty to defend the First Amendment. I said this as the issues not only affected others but also endangered my own life and my child's life and so this e-mail was also First Amendment Speech warning others of the effect of life threatening FDA corruption to them and their families, as well as a petition to Congress and criminal investigators regarding criminal activity. As for being willing to go to prison, in my view this was peaceable civil disobedience to written warnings I had been given indicating that I would be prosecuted under the Trade Secrets Act if I should provide trade secret information to Congress. I was given this warning in writing which was due to communications associated with the bifeprunox review I had with Senator Grassley's office and the House Oversight Committee. Where despite this warning of criminal prosecution the Trade Secret Act has an exemption for communication among government entities and the Lloyd-LaFollette Act allows and protects employee initiated communications to Congress. More importantly the Food Drug and Cosmetics Act explicitly allow FDA employees to provide trade secret information to Congress. Thus I had a clearly established civil right to provide trade secret information to Congress and I had recently informed my management that I had this right and that the threat of prosecution was illegal and that I had been in contact with Congress about this crime against my civil rights. Nevertheless my willingness to go to prison for civil disobedience and for peaceably petitioning and exercising my First Amendment rights to speech in order to protect human life including my own and my child's was cited as an indication of physical violence even though the FDA waited 2.5 months to make this allegation which shows that the FDA did not believe it was a true or imminent threat.

The day after I sent the above e-mails openly whistleblowing I received an e-mail that I believe was likely at the direction of Janet Woodcock who was copied, that stated that I was protected as a whistleblower. Nevertheless there were indications in this e-mail that shortly led me to believe that I was being instructed to violate policies that would allow retaliation on an ostensibly valid basis by the person who later wrote the proposal to terminate my employment. Where later evidence indicates I was correct. I also discovered that one of the people on this e-mail that was apparently sent on orders from Janet Woodcock was also holding a meeting with the subject *"Urgent Meeting: **Allegations** Concerning Asenapine"* that included the aforementioned person who ordered me to violate policy, as well as others who documents clearly show conspired to terminate me for purposes of witness retaliation, and where one of the participants was Bob Temple, who also assisted in my termination for whistleblowing about his actions on bifeprunox. My whistleblowing about these orders to violate policy that I then indicated I believed was attempted witness retaliation was then used as part of another two specifications against me (one upheld (3)) where the documentation provided and written by my accuser clearly did not support the claims being made by him about my behavior in the termination specification and instead indicated he was lying. This was followed by a specification for including in a June 18th, 2008 Saphris® review amendment a request to allow reporting of crimes to criminal investigators including murder and witness tampering, as well as documenting that I had been instructed that I was prohibited from reporting crimes by FDA officials without management approval (i.e. witness tampering). (4) A claim which management then effectively agreed in writing on multiple separate occasions was accurate. As for the charge of murder, at this point there was documentation that the mania efficacy issue was not going to be addressed which I believed exhibited depraved indifference and as a consequence likely well over 100 people had already died from being poisoned since this decision had been made.

[15] I have attached an addendum discussing information about bifeprunox the company has publicly released.

Then in July nearly 6 weeks after I sent the open e-mail to Congress and the Inspector General, the Inspector General's office without contacting me told FDA management that they would not be investigating due to a lack of details. Now I don't understand why they wouldn't investigate or see what additional information was available when I clearly indicated I personally overheard a conspiracy to defraud the government and rig an advisory committee meeting that could harm the public and my own child, as well as other crimes including witness tampering by the Commissioner's office. In my view telling the FDA that they wouldn't investigate essentially told the FDA that they would look the other way to any witness retaliation and that their actions and lack thereof bespeak a violation of my civil right to protection from retaliation for whistleblowing and reporting crimes as specified by statutes and regulations. Once the IG notified FDA management in July that they wouldn't be investigating my reports,[16] the FDA began generating documentation for[17] and writing specifications for prior to my May 29th e-mail to Congress. The first of these earlier specifications was for reporting the 'cover-up' of the death due to anaphylaxis of the patient on Saphris® (that included document falsifications) and indicating I would be speaking to Congress. (5) This was then followed by a specification for my telling the person who threatened me with jail if I should speak to Congress that I had found that I was allowed to provide trade secret information to Congress and that I had spoken to Senator Grassley's office about this and informed them that his threats were illegal, (18 USC §241, 18 USC §242, etc.) (6) Where in response he falsely claimed verbally and then in writing that his warning was regards to communications other than Congress, even though his written warning to me explicitly indicated it was in regards to communications to Senator Grassley's office[18] and where Senator Grassley's office had even been contacted and been falsely told the trade secret information I provided that involved charges of obstruction of the bifeprunox review (18 USC §1505) had been provided illegally and where Senator Grassley's office told me they had destroyed the information in response to this claim.

The last specification chronologically (7) was for me stating that I would be going to the FBI (a meeting that had been initiated by Senator Grassley's office because I had what I believed to be clear and irrefutable documentation (including the case report forms) of the cover-up of the death from anaphylaxis with Saphris®. (18 USC §1505 falsification of documents and 18 USC §371 Conspiracy to Defraud the Government) Where although it was not mentioned in the specification, the previous day I had told the people who are documented as being involved in writing this particular specification that I had e-mails where they had essentially admitted to conspiring with Dr. Laughren against me, evidence of their involvement in multiple racketeering acts that could result in decades in prison, as well as their involvement with the pyridostigmine approval (i.e. attempted murder and possible treason).

The second charge (8) was a essentially a rehash of six of the specifications under charge 1, both ones that were upheld and ones that were not, as well as a claim that I had not followed instructions where the documented evidence clearly shows that this allegation is false. Plus it does not rise to a level justifying firing as I had never been warned of not following instructions and where the only thing that could possibly constitute not following instructions was that I forgot to include someone on an e-mail regarding information I had already told him about verbally and where I had forwarded him the e-mail as soon as I discovered I had forgotten to include him. Thus this charge clearly cannot be upheld, not only for the aforementioned reason but also as it was directly for my whistleblowing and reporting crimes, and as using the same instances for multiple charges/specifications is a form of double jeopardy and thus a violation of due process which Dr. Throckmorton was told and aware of. (Other upheld specifications also involved double jeopardy independent of this charge.)

[16] This is similar to what occurred with the medical device whistleblowers who wrote President-elect Obama's transition team.

[17] This documentation to justify my firing was generated after the fact and after I had reported crimes to criminal investigators and to Congress.

[18] I was also provided a separate document demanding all documents in my possession which I had informed this same individual I was going to turn over to Congress, i.e. the House Oversight and Government Reform Committee. I had also provided this individual with reason to believe I would be meeting with Congress the following day, which I did.

Not only can each of the upheld specifications not be sustained by law, but the words used to justify terminating me are identical or similar to those in the Sedition Acts of 1798 and 1918 including for *"false"*, *"malicious"*, *"slanderous"* (albeit for a written statement)", *"intentional"* and *"defamatory"* statements. As well as for *"disruptive",* inciting, and *"threatening"* speech, and *"disreputable conduct"*. In addition I was also accused of *contumely*. Therefore I was essentially accused of seditious libel for exercising my First Amendment right to speech and for petitioning Congress, the HHS IG, and the FBI to report crimes by FDA officials that could kill me and my family as well as substantial numbers of the public, and for reporting what I believed might possibly be treason and for making truthful and accurate statements regarding possible crimes.

I was also fired for violating the FDA *'violence in the workplace policy'* for multiple *"threats"* which consisted of my reporting crimes with several of the specifications, even though there were no *"true threats"* as defined by the Supreme Court. This is in addition to the claim that my act of civil disobedience to an illegal threat of prosecution for lawfully providing information to Congress also violated this policy and a completely separate claim that I was violent simply based on the fact that I had a history of suffering from severe mental illness. This was based on an e-mail I sent (with cc to Senator Grassley's office) indicating that the things I had whistleblown about endangered my own life and where I raised my fears that my history of mental illness would be used to retaliate against me. Not only that but that I was afraid of then being forcibly medicated against my will for my whistleblowing based on claims that I was violent due to having a history of mental illness, which I based on several attempts by FDA management to make such claims and set up such a situation already and as I had evidence that Dr. Laughren and others including other psychiatrists had lied about me and/or had conspired and attempted to retaliate on several previous occasions.

Of course forced medication under the circumstances would amount to torture[19] similar to what dissidents in the Soviet Union were subjected to, and so I cited passages by Alexander Solzhenitsyn discussing *"special camps"* for scientists who were deemed politically unreliable where he wrote: *"Suddenly all the professors and engineers turned out to be saboteurs — and they believed it? ".*

I specifically included this reference as Solzhenitsyn had just died and it was being widely quoted in the press and as during a meeting of over 100 reviewers that had occurred a few weeks earlier thinly veiled threats were made using imagery of whistleblowers being torn apart and eaten by wild animals where several other reviewers came up to me and stated this was directed at me and my whistleblowing. While also during the meeting other slides were shown and statements were made regarding *"saboteurs"* indicating that they would be fired and that others should take this as a warning and by implication toe the line, not whistleblow, and do whatever management wanted if they didn't want to suffer the same fate. These of course appear to be additional violations of the Lloyd-LaFollette Act.

Sure enough my admission that I suffered from mental illness and so was petitioning to protect my own life was used to claim that I must be violent and in my view demonstrates animus towards the 20% of the US population that experience severe mental illness at some point in their lives. Plus even though this e-mail was not formally included in any individual specification or charge, Dr. Throckmorton still used it to justify firing me even though he should have known that it evidenced unlawful animus. In fact Dr. Throckmorton was even copied on using this e-mail against me even though at the time he presumably had no connection with anything that had occurred. Something that may indicate he was actually involved in the removal effort even before he was named as a supposedly unbiased adjudicator.

As for my fear of being committed for being *'violent'* for peaceably exercising my First Amendment rights and where forcible medication would amount to torture, in 2014 the United Nations Human Rights Council (UNHRC) issued a report stating that in many cases forcible medication does indeed does amount to torture. In addition being unlawfully committed as a consequence would under Federal law also result in a loss of my Second Amendment rights, and if anyone doesn't believe there is a real danger of the government abusing this and illegally taking away Second Amendment rights of non-violent citizens for

[19] As there would be no legitimate medical purpose and as the drugs that would be used profoundly disrupt personality. (18 USC §2340)

exercising their First Amendment rights then they should read the book *'The Zyprexa Files'* which shows how unlawful commitment and forced medication of non-violent people with mental illness is easy to effect by the government and commonly occurs in Alaska, a jurisdiction where Second Amendment rights are highly regarded.

Besides Dr. Throckmorton attacking my First Amendment rights, firing me for reporting crimes,[20] and his violations of my due process rights that I have already discussed, Dr. Throckmorton was also informed that we were given less than 72 hours to respond to the proposal to fire me from the time my attorney was given the materials that were relied on.[21] Something that is another violation of due process under 5 USC §7513(b)(2) and 5 CFR §752.404(c)(1) which require a reasonable time to respond and no less than seven days after providing the materials relied upon (to me). Nevertheless Dr. Throckmorton just summarily dismissed this violation. In contrast he took just three months to issue his decision. A time where I was effectively under house arrest during the day and prohibited from coming to work in violation of the law, where as a consequence I was not allowed to attend the annual large pharmaceutical science and clinical meetings where I could have tried to find a new job. This is despite due process requirements that the decision be provided at the earliest practicable date. (5 USC §7513(b)(4))

All told, in addition to the violations of due process, there are a total of 45 lines of evidence that indicate that Dr. Throckmorton was biased. Plus documentary evidence that at least 4 different individuals including Dr. Throckmorton lied or falsified documents so as to fire me for reporting crimes.

In conclusion I believe Dr. Throckmorton deprived me of civil and Constitutional rights under color of law in violation of 18 USC §242 and that people have died as a result. I also believe that based on the evidence it can be inferred that he was a co-conspirator in a well documented conspiracy against my Constitutional and civil rights in violation of 18 USC §241.

Post Termination

Shortly after my termination FDA device whistleblowers wrote to the Obama transition team and this was in the news for years with letters requesting criminal prosecution for crimes by FDA officials, and revelations of spying, and inadequate investigations by the Inspector General's office. I also experienced issues with my computer and my office when I returned from leave that I suspected was electronic and other forms of spying on me. Plus similar to the device whistleblowers the Inspector General's office also refused to investigate my case and so let people be killed. Plus I later met several of these FDA device whistleblowers at a whistleblowing conference and they had also been called on the same day I had been by a very senior FDA official where I believe my documentation of the conversation evidences witness tampering, and where I reported this tampering in the e-mail to Congress and the HHS IG for which I was fired.

After I was fired I was also denied my Constitutional right to speak and petition on two other occasions. The first time was during President Obama's FDA transparency meeting in June 2009 where I was denied the right to discuss certain things under the claim that they did not fall under the approved topics for the meeting, when in fact my proposed comments were completely consistent with the approved topics. I was then also denied my First Amendment right to speak and petition at an FDA psychopharmacologic drug advisory committee meeting on the approval of Saphris®. Where if I had been allowed to speak I believe that the FDA would have been unable to approve Saphris® for the patients who it didn't work in, or even at all because it would have been clear that the metabolism issue that Dr. Laughren said precluded approval had not been resolved and that approval was therefore prohibited under the Food Drug and Cosmetics Act. I believe I was unlawfully denied my right to speak and petition as I applied to be a public speaker minutes after the meeting was announced and was denied, whereas I had my wife apply several weeks later and per the FDA she was the only other speaker request and was approved. In addition, I again

[20] While I can appreciate that First Amendment rights must be balanced against governmental control of the workplace, surely this cannot outweigh the reporting of crimes, including but not limited to mass murder and possible treason) that can kill the petitioner, his child, and others. All of which there is also a duty to report.
[21] I was only provided 48 hours.

applied at the meeting where there were only me and two other members of the public in attendance and I knew neither of them applied at the meeting. Nevertheless I saw the notebook with my request to speak brought up to the dais and showed to Dr. Laughren who then spoke to Dr. Unger and with others, whereupon security was called in and an announcement was made that if any member of the audience tried to speak openly or with individual members of the committee during breaks that they would be physically removed. Consequently I believe Drs. Laughren, Unger, and others conspired to deprive me of my Constitutional First Amendment Right to petition (18 USC §241) and that people died as a result.

Witness/Whistleblower Retaliation and Intent

Witness retaliation (18 USC §1513) requires that there be an intention to retaliate. While the evidence from just the termination may be sufficient to demonstrate this, in my view this intent is irrefutable when things from the period prior to the period encompassing the termination specifications and from the period after I was physically removed from the FDA and even after a settlement was signed are considered.

Evidence of Retaliation during Period prior to Termination Charges

With regards to the earlier period, in January 2007 I whistleblew about what I believed was an abuse of authority by John Jenkins, Sandra Kweder, and Bob Temple in intimidating around 100 reviewers and telling them not question drug companies and to let them do whatever they want, and to not raise complaints about review timelines under the Prescription Drug User Fee, which many reviewers were complaining were unreasonable and a danger to the public. Subsequent to this whistleblowing there were indications including from e-mails that I was being overworked in order to exacerbate my mental illness and justify retaliation. Also approximately 24 hours after I told management that I was prepared to go outside the agency to whistleblow about discrimination, Commissioner Von Eschenbach made a public statement at a pharmaceutical industry luncheon that whistleblowers who go outside the agency would not be tolerated. In a Congressional hearing held in response to this Dr. Von Eschenbach denied that he was talking about whistleblowers, however audio recordings of the meeting demonstrate that his denial was untrue. An attempt was then made to force me to have a psychiatric evaluation due to a comment I made suggesting that scientists with mental illness such as I should have training opportunities to update skills and reenter the workforce similar to training available to female scientists who take time to have children. Whereupon when I suggested to the person who transmitted this to me that such a recommendation by his superiors, even though likely not made with any malice, was nevertheless inappropriate and asked him to relay this to his superiors, in response he said that when I make allegations against him that he would lie to protect himself that it would be his word and his assistant's word against mine. He then opened the door to his office and started yelling, in front of his assistant, that I was physically threatening him. I was so shaken that I immediately documented what had occurred in an e-mail I sent to the Union. Then two days later because of a lack of sleep due to the stress that this episode caused me I became agitated during a meeting (but in no manner threatening or violent), where I then excused myself to calm down and came back with the Union VP and we suggested in front of witnesses that I take off the rest of the day off to get some sleep and re-equilibrate. Despite agreeing to this the same person (who later prepared the termination proposal) then lied in documents claiming that he had suggested I take time off and he notified security to be ready to remove me for being violent upon my return.

Several weeks later when this manager was afraid I might make an EEO complaint against him for the attempt to force me to have a psychiatric exam I was told by another manager that he had stated that he didn't want to hurt me but that I should think of my children, (4 and 7 years old). At the time and for years after I truly believed this was a threat of physical violence against my children. This was followed by several psychiatrist/medical reviewers warning me of an conspiracy against me involving him and Dr. Laughren that had been overheard, and their warning me to immediately take sick leave and to be evaluated by a forensic psychiatric in order to protect myself and to counter any false allegations that might be made against me. Where I now believe their advice about the forensic psychiatrist was because they were concerned I would falsely be accused of being violent due to my mental illness. This was followed by an attempt by Dr. Laughren to retaliate against me based on not finishing work on time, where one of the managers previously discussed accidentally admitted in an e-mail that she had held

back my work on purpose and that Dr. Laughren was aware of it. At which point I became scared and took leave, met with a forensic psychiatrist, and filed an EEO complaint. Then when I returned to work and was under a deadline to finish the bifeprunox review there were multiple attempts to obstruct my review, harassment to goad me so that I would show emotional responses so that they could be held against me, was physically struck by a foreigner who was involved in the aforementioned harassment and goading, then suspended without pay and threatened with jail for whistleblowing about obstruction of the bifeprunox review (18 USC §1505) and providing information on bifeprunox to Congress including both Senator Grassley's office and the House Oversight Committee. It was during this time that I found evidence suggesting that my computer was being monitored, plus my office appeared to have been broken into, and few months later I learned that others had been given orders to spy on me for clearly retaliatory purposes. All of which was during the same time period that the FDA device whistleblowers who wrote President Elect Obama were being spied upon.

There were then further attacks and harassment and denials of reasonable accommodations that occurred on multiple occasions from September 2007 to April 2008 as well as attempts to make sure that I could not respond to charges being leveled against me for my whistleblowing as well as FDA Commissioner Von Eschenbach sending an e-mail to the FDA staff the day before I was to return from being suspended without pay for whistleblowing to Congress where he told staff to call security if they felt threatened by anyone (this was after I had whistleblown about his actions in response to my EEO case). As well as an attempt in April 2008 to completely remove me from review work after I was scheduled to complete the Saphris® review, which the Union said was likely designed to eventually eliminate me from the agency. Plus numerous other retaliatory acts that are described in detail in my full complaint and petition to Congress.

Not only is there evidence that there was a conspiracy to retaliate against me for whistleblowing by claiming I was violent due to my history of mental illness that extended back possibly as early as January 2007, 19 months before I was eventually removed from the FDA. It was also widely known that the guard in our building was potentially dangerous as he would immediately go for his gun whenever anyone coming into the building, including employees he saw every day, would object to his unreasonable demands. Such as when I saw him going for his gun when the regular snack chip delivery driver objected to demands that he open every single box of snacks being delivered to the cafeteria when even the White House did not demand that of him when he made deliveries there. Consequently when Dr. Von Eschenbach sent his e-mail regarding the FDA violence policy (that surreptitiously included behavior that is not covered by this policy) to call security the day before I was to return from a suspension for whistleblowing, and which was later used to justify my firing. I became afraid that I was being set up for a situation where I could be shot and killed, especially as I knew that the person who I later learned was pushing the violence angle against me had seen the guard pull his gun, and as I learned he was having me surreptitiously monitored for anything he could use to claim I was emotionally unstable. Plus based on my past history of being hospitalized for being suicidal, FDA management, which included people familiar with psychiatric illnesses, surely knew that the stress and retaliation they were subjecting me to could easily result in my taking my own life, similar to what appears to have occurred with other Federal whistleblowers including Chris Kirkpatrick and Philip Haney.

Evidence of Retaliation after Removal from the FDA
(Including post-termination and post-settlement)

As for retaliation that I was subjected to after I was removed from the FDA. The first instance was termination of my health insurance 3 days before Dr. Throckmorton issued his termination decision with no opportunity given to me to extend it under COBRA which prohibited its termination for another 42 days. An attempt was then made to deny me unemployment benefits by claiming I had been fired due to being violent, which the State of Maryland rejected based on the fact that the evidence provided by the FDA did not support their claims that I was violent. Then upon telling me that I had to claim my personal belongings, I notified the agency that there might be review materials in my filing cabinet among my personal collection of scientific papers and I suggested that we go through the materials together to extract anything I wasn't entitled to. Whereupon all but two of approximately 10 boxes of my personal belongings I had been told had been boxed up and were waiting for me were seized in violation of the

Fourth Amendment and claimed to be government property. These personal belongings included a file cabinet full of scientific papers and several boxes containing numerous medical and scientific text books costing hundreds of dollars apiece that I would need to earn a living in a new job, plus personal photos, prayer books, a coffee maker, food for when I would work late and for hypoglycemia, a change of clothes, medicines and diabetic supplies, etc.. Eventually I was able to obtain most of my belongings after contacting my Senator and obtaining legal assistance, but the FDA still refused to return some personal papers that they admittedly kept for government use without compensation in violation of the Fifth Amendment.

Then in drafting a settlement the FDA attempted to short me several thousand dollars of the agreed upon compensation of 4 months of salary. This was clearly done by calculating the amount based on as if I were paid on a semi-monthly basis rather than the actual biweekly basis Federal employees are paid, (i.e. they tried to pay me the equivalent of 8 paychecks rather than the equivalent of the 8.7 paychecks I was entitled to, something that had to have been done purposefully. The FDA then violated the settlement immediately upon signing by not changing the documents with the reason I had been terminated in my personnel file and sealing them, and then violating the confidentiality provisions in order to sabotage my obtaining other compensation that had been agreed to and then falsifying documents and forms (including by clearly whiting out and changing things), which were clearly designed to sabotage my obtaining the agreed upon compensation. Where based upon the way the settlement was written where I would have no recourse if this sabotage were successful, it's evident that the FDA had not negotiated in good faith. All told there were possibly as many as 15 separate retaliatory acts for my reporting crimes after I was removed from the FDA with some occurring even after a settlement had been signed when there would be no possible reason for the FDA to take such actions except in order to retaliate.

Unlawful Settlement

As for the settlement I only signed it because when I told one of the lawyers on my case that I did not want to settle and instead wanted to fight she started screaming at me and threatened to sabotage my case in order to cause me to lose, bankrupt me by running up my bills, and also sabotage any attempt I might make to find another lawyer. This cowed me into signing due to the fragile emotional state I was in due to what I had been subjected to over the past 32 months. In addition my lawyers misled me about the legality of the terms of the settlement.

Shortly after signing I learned that any contract that stifles prosecution of crimes is unlawful. Consequently I filed a petition for review with the Merit Systems Protection Board as the settlement required me to *"withdraw all… charges… filed with any administrative agency"*, where it was absolutely and clearly understood by both sides that charges referred to criminal charges and where the FDA had in firing me used the word charges in describing my allegations of crimes. Then despite having raised the unlawfulness of this contract term as the very first reason I gave in the petition for review of the settlement, and its unlawfulness being raised and discussed separate six times in the petition and in the appeal to the Court of Appeals for the Federal Circuit. As well as despite a government attorney in court filings clearly stating that this contract term was unambiguous, was in reference to reports of criminal activity, and that I had tried to renegotiate this term (i.e. change it to exclude criminal charges such as by changing the wording to administrative charges which the government refused to do.) Plus despite the Court being referred to and provided with various documents clearing demonstrating my reporting of crimes by FDA officials including from my June 18th review memo that included charges of murder and witness tampering, as well as the complete termination proposal and decision that clearly fired me for this, and that also clearly demonstrated I was fired for seditious libel in retaliation for exercising my First Amendment Rights and reporting crimes by FDA officials including to the FBI. As well as the settlement contract itself, which among other things prohibited me from bringing civil suits against FDA officials in their personal capacity, which is only possible when a government official has violated a clearly established Constitutional or civil right[22] which should have been a tip off. The Court of Appeals nevertheless completely ignored the unambiguous settlement term and my arguments regarding it, and instead focused exclusively on a separate term that they labeled ambiguous.

[22] Little v. Barreme, 6 U.S. 170 (1804)

As for the clearly illegal unambiguous term that mandated witness tampering and stifled prosecution, Judges Bryson, Schall, and Prost of the Court of Appeals for the Federal Circuit simply said: *"We have reviewed Mr. Kavanagh's other arguments and consider them unpersuasive."* With absolutely no discussion of the evidence that they relied on in making this determination regarding the contract term that stifled prosecution.[23] This of course is a violation of my right to due process as required by the Supreme Court with regards to a statement as to the evidence relied upon in reaching their decision.[24] Plus they also denied my petition to a public hearing, which I believe was done purposefully so that I could not introduce this evidence into the public record.

As the criminal charges remained withdrawn, in my view Judges Bryson, Schall, and Prost facilitated witness tampering. In addition by upholding this illegal settlement they denied me of my First Amendment right to warn the public which resulted in as many as 60,000 deaths due to poisoning. As it was a unanimous opinion Judges Bryson, Schall, and Prost were clearly in agreement. Thus I believe they have conspired to and have denied me my civil and Constitutional rights under color of law, which in my view are crimes that carry the death penalty as they have resulted in deaths. (18 USC §241 and §242) These are not allegations that I make lightly or without evidence, for it would be absolutely foolish to make such accusations knowing that I could potentially face judgment by their colleagues in the future.

False Claims Act Filing

The Court of Appeals however did allow me to report things that I had not reported yet. Consequently with the assistance of a new attorney, Mark Schlein, we filed a false claim case with the Department of Justice in 2012. I did this not for the money but rather because it was the only way that I could legally get information in front of the Justice Department where they were required to look into things. Mark was the former head of the Florida Medicaid Fraud Control Unit (MFCU) and so was someone experienced in the False Claims Act and had credibility with the Justice Department. Plus the firm he was with had been prominently involved in large class action suits including those involving suicides from antidepressants in adolescents. Consequently they had the expertise with psychiatric drugs and the resources to pursue a case. In addition we were assisted by Stephen Sheller, the attorney who brought the original fen-phen case, where such fen-phen cases ultimately resulted in a $20 billion settlement. Plus Stephen was the most successful false claims act attorney in the country having brought cases that resulted in over $6.25 billion in false claim *(qui tam)* recoveries from drug companies primarily for Medicaid fraud with psychiatric drugs. In fact I was told that Stephen said I had the best evidence he had ever seen. We also had at the Justice Department's request reports from a high powered biostatistician who supported my conclusions.

Despite everything the Justice Department declined to intervene claiming that *'the FDA disagreed with me'*. Of course they were going to disagree with me! People in the FDA who participated in these frauds, and who were in my opinion committing mass murder and witness retaliation, were not going to agree with me and open themselves up to prosecution. In my view we made a mistake in focusing solely on the drug companies and not bringing up the FDA's involvement and evidence of their involvement in a conspiracy, although I know that a number of other major false claim act attorneys I approached had when they declined my case told me that the FDA was the government's client and so they would never help with a case against the FDA. So discussing the FDA's involvement was likely not considered advisable by my attorneys. Plus the case could have been turned down by higher ups in Washington DC where if these higher ups approved DOJ joining the case it could have revealed their own past suppression of it when I was initially removed from the FDA and Senator Grassley's office had contacted them to have them speak to me.

With the Justice Department failing to join my cases things were then effectively ended via the courts. For as a former FDA employee who learned of things via my job I was then prohibited by FDA regulations from pursuing the cases on my own without the Justice Department. Whereas if my cases had been taken up by the Justice Department then it's likely that multiple billions of dollars could have been

[23] Kavanagh v HHS, No. 2010-3133 (Fed. Cir. 2010); (Google Kavanagh v. HHS)
[24] Goldberg v. Kelly, 397 U.S. 254 (1970)

recovered and tens of billions in waste and fraud could have been prevented and tens of thousands of deaths could have been prevented.

Consequences of Termination

After I was removed from the FDA, the FDA issued a letter to ScheringPlough, the company sponsoring Saphris®, which essentially indicated that Saphris® would be approved. Right after this became public it was also disclosed that Merck would be buying Schering. It was stated that the purchase was in part due to the *"late stage compounds"* that Schering had of which Saphris® was expected to result in 80% of the anticipated resulting income. The sale then went through a few weeks after Saphris® came to market. In order to pay for the sale 50,000 highly paid employees were fired. This was equal to the entire workforce of Schering and Organon, the company Schering had bought to obtain Saphris® and the other late stage compounds. As a consequence of this sale Fred Hassan the CEO of Schering earned a quarter of a billion dollars and four other top executives combined earned another quarter of a billion dollars. Fred Hassan had previously made other fortunes as CEO of several drug companies that he sold to other larger companies after the company he had headed had purchased smaller companies with late stage or newly approved drugs that often had safety problems but were nevertheless marketed very successfully. This is similar to the situation with Organon and Saphris®. An Organon/Schering VP even told me that Schering had bought Organon specifically because of Saphris®.

Even though many people would have been laid off due to the sale of Schering even if Saphris® hadn't been approved, the illegal approval by the FDA in my opinion likely resulted in many more people losing their jobs due to this sale during the last recession as a consequence of a higher sale price than would have otherwise would have been obtained.

Presidential Petitions, the Press, and Plans to go Public

After the government failed to join my False Claims Act filing I spent a year in preparation and then petitioned President Obama in September 2015, also providing a copy of this petition to a number of Congressional committees. After waiting and not hearing and also seeing new activity with regards to pyridostigmine, I followed this with additional smaller follow-up petitions including to the Army Inspector General regarding what I had now come to believe was treason involving the pyridostigmine and its approval. Although later I learned that treason likely requires a treasonable intent which I could not be certain existed, and so I no longer believe that it constitutes treason. None of these petitions however really focused on or fully addressed the retaliation I suffered from or my case. I then tried to go to the news media but only for the safety issues. I even wrote up a series of small articles on each safety issue that would be of a size (1500 – 1800 words) that the press could publish or more likely use as a basis for their own articles. Although this was risky for me I could point to the information being in public documents. Unfortunately except for an interview discussing the FDA in a general way in a documentary I haven't seen and two interviews in Truthout, one that was published during the false claim filing and so didn't address any of the issues with Saphris® or the other antipsychotics, and one that addressed pyridostigmine; both of which may be found by googling Kavanagh and Truthout. I couldn't get anything into the press despite speaking with a number of major news outlets. Consequently around the time of the 2016 election I began writing a book for self publication and as an open petition to the incoming President and Congress.

This book includes the following sections among others and totals around 875 pages.

- Drug Development, the FDA, Mental Illness, Psychiatric Drugs, and Mental Illness and the Pharmaceutical Industry
- Safety and Efficacy Issues Regarding Saphris® and Pyridostigmine
- Detailed chronology of my whistleblowing and what happened at the FDA
- The Termination Proposal and Decision
- The Appeal of the Unlawful Settlement
- Other FDA Issues

- Psychiatric Disabilities and Discrimination and my experiences
- Thoughts on Whistleblowing, Civil and Constitutional Rights, Defamation, e**tc...**
- Petitions to the President and Congress with specific requests

Parts of the book are geared to the lay reader and others are geared towards lawyers and criminal and congressional investigators. I plan on submitting several sections of it as it will outline the available documents evidencing criminal activity in the FDA. Although some original evidence extracted from public documents is included in the book, by necessity this is limited and the remaining documents containing evidence will still need to be obtained. Even so there are hundreds of documents consisting of thousands of pages that will need to be obtained and you will need me to guide you through them and show you how they connect with each other. As well as to help you understand the science and medical issues that only experts in very narrow scientific disciplines would understand. I am more than prepared to help with this in order to save lives and bring criminals to justice but can only do so if the President grants my personal petitions.

During editing of the book after it was largely completed I looked into laws regarding defamation and realized that no matter what I did that lower level government employees even if not cited by name could potentially be identified or others might be misidentified which could open me to libel suits as much of the book describes what I believe to be possible criminal acts. Since this might open me to years and years of court battles where even if I should win, which I realized would be unlikely, I would have my family's and my lives destroyed and so I decided that I could not publish. Thus I decided to file petitions with Congress and the President that would include the detailed information and petitions from the book. In addition I am providing information to DOJ Inspector General Michael E. Horowitz regarding the abuses of authority by Justice Department officials and the abuses of authority and crimes I believe have been committed by government employees in a variety of agencies and branches including the Justice Department. Consequently if there are any actions by any part of government that adversely affect me in any manner, including by the Office of Personnel Management, the IRS, or other government entities I believe that they should be treated as witness retaliation.

This includes any attacks on my consideration for violating the settlement because even though unlawful settlements may not be enforced it is well settled law that "*where the parties are not in equal fault as to the illegal element of the contract, or, to use the phrase of the maxim, are not in pari delicto, and where there are elements of public policy more outraged by the conduct of one than of the other, then relief in equity may be granted to the less guilty."* Massachusetts Supreme Court: Berman v. Coakley [243 Mass. 348 (Mass. 1923)]

As for the sections on psychiatric disabilities and discrimination I discuss my experiences with mental illness and the discrimination I've suffered from. People with severe psychiatric disabilities, including people like me with repeated severe depressions where the unemployment rate is seventy percent, are considered to be a targeted affirmative action group for government employment. Despite this and the FDA being one of the most important agencies in the government with regards to such individuals and where such individuals should be employed in order to access our knowledge and experiences and to help the public, which is part of the intent behind affirmative action. The FDA was instead the worst agency in the entire government in terms of affirmative action and equal opportunity goals. Where at the time I was undergoing active harassment based on my disability I was the only person in this targeted group in the Center for Drugs and possibly in the entire FDA. However the FDA was not the first place I suffered discrimination. One university where I applied for a position brought up episodes of illness that occurred a dozen years before on the other side of the country, that they shouldn't have had any knowledge of. Another wrote a white paper after I applied declaring that universities shouldn't have to abide by affirmative action for people with psychiatric disabilities because there were simply no candidates available. Plus it's not only the FDA where there are problems in government. Prior to President Bush's 2004 reelection campaign the annual participation rate statistics for 2003 were delayed and withheld from the public. Later when they were released after the election they showed that thousands of individuals with mental illness in the VA system, which is the largest government employer of people with mental illness, had lost their jobs and this was certainly due to outsourcing that was going on at the time. In addition I was also subjected to harassment and retaliation for requesting reasonable

accommodations. Plus I was also subjected to harassment and a hostile work environment based on my religious practices.

We also know that outsourcing of Federal jobs generally increases costs and that workers actually earn less under outsourcing, but in the aforementioned case with the VA we also have added indirect costs for people previously doing these jobs as government employees who may then need to go on social security disability or other forms of aid because of problems with obtaining jobs due to their disability, as well as the costs of increased use of mental health services as a consequence of being let go.

As for the FDA, my area was 95% foreign immigrants where as a native born US citizen I found that my race, country of origin, and disability were held against me. In fact much less qualified white foreign born, males were preferentially promoted and I was told outright by FDA management that I was being discriminated against. There was also clear and blatant discrimination against Blacks in my office and discrimination against Orientals in biostatistics. I also saw special hiring authorities for hiring foreign Ph.D. level scientists in areas with shortages instead being used to hire foreign born immigrants for secretarial positions rather than better qualified native born Americans from affirmative action groups. Plus I saw a number of exceptionally well qualified native born as well as some our best foreign born scientists and reviewers leave due to harassment and discrimination by FDA management, and poorly qualified and even incompetent foreign immigrants being used as goons to harass them and to help promote the pharmaceutical industry's agendas, and then be rewarded with promotions.[25] The medical reviewers even referred to these individuals as the Indian mafia due to the overwhelming numbers of Indians involved although there were some Orientals as well as some native and foreign born Whites involved, and in my Office they were referred to as the brown shirts. I even had a new employee, who was likely replacing me, tell me two weeks before I was removed from the agency that the US as a Western country was aligned with imperialism and that he was glad to be in a position to help send US jobs overseas. Plus the FDA had been training foreigners in new advanced skills, while not allowing US citizens to maintain skills, where the foreign nationals would then move home to places like China or India and work for the large US pharmaceutical firms and do jobs there that could have been done in the US by US nationals. This is not to say that all foreign nationals were like this, as many of the foreign born reviewers I worked with were good people and dedicated to the United States, unfortunately FDA management would attack them too.

Then when I lost my position and thought of trying to go into business I found that there were no set government asides for businesses for people like me who are in the most highly unemployed group in the country, whereas my wife who is a foreign immigrant and Asian could easily qualify. Underemployment and discrimination against those of us with severe mental illness is a severe problem. Women complain about only earning 70 cents on the dollar. I wish I earned that much, as I figure I will earn less than 30 cents on the dollar during my life compared to equally qualified people, and even if I had retained my position maybe 40-50 cents on the dollar.

While I understand that the allegations I have made would appear to be outrageous let me assure you that there is documentary evidence that can be obtained that will back up nearly 100% of what I claim. As for the little that is not backed up by documents it is based on personal knowledge that I am more than willing to testify to under oath and which in many cases should be able to be corroborated by others if they haven't forgotten due to the length of time.

Petitions

My detailed petitions in the book include personal petitions to President Trump, and Petitions to Congress covering FDA Reforms, Criminal Statutes, Whistleblowing and Whistleblowers, False Claims, Disability Rights and Protection of the Disabled, Impeachments, and Immigration, as well as petitions to the Judiciary and others. All told there are eleven chapters of petitions with specific requests totaling over 70 pages.

[25] I even saw one of these individuals harass a medical reviewer and tell him that they couldn't allow him to write scientifically valid reviews.

Some of the most important petition requests to the President and Congress follow:

Petition Requests to President Trump:

Major petition requests to President Trump include:

- Hold people accountable by firing, criminal prosecution, and requiring repayment of any money unlawfully obtained under the Lloyd-La Follette Act Anti-gag rider. As well as by denaturalization for concealment of material facts regarding criminal acts, and/or for moral turpitude and endangering the lives of Americans.

  My full complaint includes details and a twelve page appendix of laws violated (including criminal laws), and identifies around 50 people who I believe were involved in violating laws including criminal laws and it also notes where there are likely other unidentified individuals. I also believe that individuals in the DOJ and FBI, and the Inspectors General Offices of HHS and the Army should be looked into and individuals held accountable.

  Holding accountable government lawyers is particularly important for they like all government employees work for the American people and not those employed by the government, and it's government lawyers who corruptly provided the cover to attack congressional oversight, engage in witness tampering and retaliation, attack the Constitution, and helped to kill the very people they are supposed to be serving.

  As part of this request I ask that individuals who may have committed crimes be immediately placed on leave without pay. I also ask that anyone who has committed a crime of moral turpitude and/or violated professional standards be disbarred, lose their professional licenses, and be denaturalized as appropriate.

- Fulfill his constitutionally mandated duty to defend the Constitution by defending my First, Second, Fourth, Fifth and Fourteenth Amendment Rights by immediately reinstating me, reversing the effects of discrimination, and making me whole, and by doing so fulfill his primary duty to defend the lives of US citizens.

- As well as assuring my family's and my protection.

Petition Requests to Congress:

Major petition requests to Congress in include:

Part 1 - FDA Reforms

My full petition should be referred to for details on the following and for a number of other requests necessary to protect the public.

- Replace PDUFA and other FDA User Fee Programs

  PDUFA has effectively eliminated the ability of Congress to do adequate oversight and has resulted in undue influence of drug companies over the FDA. (He who pays the piper calls the tune.) Consequently PDUFA fees should be replaced with either a flat tax or proportional tax on each prescription filled with the proceeds designated exclusively for the FDA and with Congress having the ability to prevent transfer to the FDA (although not going into the

general fund). This will completely fund all FDA programs, maintain Congressional oversight abilities, and will decrease improper drug company influence.[26]

- Statutorily require that reviews and submitted safety and efficacy information be made public

  Previously most parts of reviews associated with new drug approvals were made public, and it's only through publicly available information that the issues with antipsychotics and pyridostigmine are open for public knowledge. Otherwise they would likely have been buried forever. Yet in the last few months the FDA has changed policy so that only management summaries are made public. Such summaries will hide fraud and as shown with Saphris® and pyridostigmine may even hide mass murder and so will endanger the public health. Consequently I request that the Food Drug and Cosmetics Act be amended to mandate that all review information including for supplemental approvals as well as for drugs not approved be made public, with details included in my full petition.

- Allow adequate time for reviews (including by extending PDUFA deadlines) and prevent overriding of reviewers in order to help drug companies and approve drugs in violation of the Food Drug and Cosmetics Act and over reviewer objections

- Protect and improve the review process

  Prevent corrupt overriding of reviewers and also allow reviewers to consult with colleagues.

- Mandate certain submission, review, and approval standards

  Mandate that certain information needed to adequately assess safety, efficacy, quality, and labeling be provided and standards adhered to.

- Hold drug companies and executives personally responsible

Part 2 - Criminal Statutes

- Modify civil right and hate crime laws to include disabilities and the disabled

- Amend statutes regarding conspiracies and individual acts to include the other type

- Amend obstruction of justice statutes to include harassment and intimidation

- Require investigation by criminal investigators of any truthful report by government employees of possible crimes by government officials, employees, and others and mandate that prosecution shall be required

- Criminalize retroactive classification of information and abuse of classification and set objective standards for classification

[26] As of 03/29/2018 the FDA claims that the CDER Budget is over $1 billion. The total FDA 2019 budget was $5.5 billion with a request of $6.1 billion for 2020. According to IQVIA total net medicine spending in the United States was $344 billion in 2018 and 5.77 billion prescriptions were filled. Consequently the CDER budget is equal to about 0.29% of drug spending in this country or just under 1 cent for every $3 spent on drugs and this would be the minimum proportional tax rate to maintain current levels of support and with slightly more the current inadequate monitoring of offshore manufacturing plants could be enhanced. A flat tax that would produce a similar amount of revenue would be on average about $0.17 per prescription

Part 3 - Protect Whistleblowers

There are numerous requests I have in this area many of which are important. However the most important are:

- Criminalize retaliation and interference with communications with Congress (including staff), Inspectors General, or other intra- and extra-governmental whistleblowing channels and have a zero tolerance policy

- Provide for jury trials for government whistleblowers

  I was fired for reporting mass murder, witness tampering and retaliation, attempted mass murder and possible treason, and other crimes including health care fraud. I was also fired for seditious libel for exercising my First Amendment rights as a private citizen to petition Congress and criminal investigators, and to warn others of government corruption that endangered me, my child, our troops, my coworkers, and the public. Corruption that has resulted in myriads of deaths including the deaths of some of the most vulnerable members of society, including those with severe disabilities and babies who the government was tasked with protecting; plus I was also fired for fulfilling my legally mandated duty to report corruption and for fulfilling my oath of office to defend the Constitution.

  The Sixth and Seventh Amendments respectively provide for jury trials in criminal and civil cases. Although the firing of a whistleblower by the government is typically a civil case, government whistleblowers do not have access to jury trials.

  As with other Constitutional rights, the right to a jury trial in civil cases was intended to protect us from abuses by the government. This is shown in various writings of the founding fathers including a July 1789 letter from Thomas Jefferson to Thomas Paine outlining what is needed in a constitution where he stated with respect to civil trials:

  > *"I consider that* (i.e. trial by jury*) as the only anchor ever yet imagined by man, by which a government can be held to the principles of its constitution."*

  Plus the Supreme Court has stated:

  > *"The dominant purpose of the First Amendment was to prohibit the widespread practice of governmental suppression of embarrassing information. It is common knowledge that the First Amendment was adopted against the widespread use of the common law of seditious libel to punish the dissemination of material that is embarrassing to the powers-that-be."*[27]

  Thomas Paine's trial for seditious libel is often invoked in discussions of the First Amendment's guarantee of free speech. Consequently it might be thought that the First Amendment was a response to the charges of seditious libel levied against Paine. However the Bill of Rights was transmitted to the States on September 25th, 1789, and it wasn't ratified until December 15th, 1791. However publication of the second part of the Rights of Man which he was prosecuted for didn't occur until February 1792 and his trial was not until December 18th, 1792, a year after ratification. In contrast a lawsuit for criminal libel against the sailors from the Navy ship Warren for whistleblowing to the Continental Congress occurred in 1778 more than 11 years prior to the transmission of the Bill of Rights to the States. Where the Continental Congress; despite the costs and the potential effect on the war effort and despite the danger to their own lives voted to provide funds for a lawyer and to release documents needed for a defense. Thus it's likely that the basis for the First Amendment's rights to

[27] Supreme Court Justice William O. Douglas; New York Times Co. v. United States, 403 U.S. 713 (1971)

speech and petition are directly related to concerns of seditious libel being used against government whistleblowers.

In addition jury trials are a form of due process where the Supreme Court has stated:

> *"Due process, unlike some legal rules, is not a technical conception with a fixed content unrelated to time, place and circumstances. Due process is flexible and calls for such procedural protections as the particular situation demands."*[28]

Consequently, jury trials are clearly necessary for government whistleblowers where abuses of the judicial system by the government is of particular concern, and where seditious libel is in essence what every case of retaliation of a government whistleblower is about. Especially as it's clear that the original intent of the founding fathers was that there be jury trials for charges of seditious libel (which is distinct from criminal libel), and particularly for government employee whistleblowers.[29] Along with all the attendant protections including the right to cross examine hostile witnesses who have motive to lie, the right to obtain exculpatory evidence, and supporting witnesses, and especially public scrutiny. For as Supreme Court Justice Louis D. Brandeis said:

> *"Publicity is justly commended as a remedy for social and industrial diseases. Sunlight is said to be the best of disinfectants."*

The Supreme Court has also said that government employees, unlike at will employees, have property rights in their jobs. Where suspensions can cost us hundreds of dollars a day and termination millions of dollars, and where the Seventh Amendment states:

> *"In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved"*

Thus when the government attempts to deny whistleblowers our property rights we are similarly entitled under the Constitution to jury trials regardless of First Amendment issues, for the Seventh Amendment does not say *'except for government employees'*.

Therefore Representative Raskin I ask you and the House to contact and work with Senator Grassley and the Senate to guarantee that Federal whistleblowers have the right to jury trials to protect our First Amendment right to petition and speak, as well as our duty to report corruption in order to protect the American people for whom we work.

For as General Washington said to and about his troops (i.e. government employees):

> *"For if Men are to be precluded from offering their sentiments on a matter, which may involve the most serious and alarming consequences, that can invite the consideration of Mankind; reason is of no use to us—the freedom of Speech may be taken away—and, dumb & silent we may be led, like sheep, to the Slaughter."*

- Protect whistleblowers from defamation suits by <u>any</u> government employee

Currently only truthful speech not made with *'actual malice'* against high ranking *'public officials'* is considered protected First Amendment speech. However government corruption that harms the public typically involves lower level officials and employees who may even be used by high ranking *'public officials'* to violate the law, including criminal laws such as murder, fraud, etcetera. I therefore ask that truthful whistleblowing about <u>both</u> *'public officials'* and lower level officials and employees be statutorily protected <u>and preempted</u> from defamation.

[28] Mathews v. Eldridge, 424 U.S. 319, 96 S. Ct. 893 (1976)
[29] i.e. Sailors from the Navy ship Warren.

- Allow for presentation of a jury nullification argument during trials[30]

  The founding fathers also clearly intended that there be jury trials with jury nullification for attacks by the government on our liberties. For example Thomas Jefferson wrote:

  > *"If the question relate to any point of public liberty, or if it be one of those in which the judges may be suspected of bias, the jury undertake to decide both law and fact."*[31]

  Where despite this, judges often prohibit juries being informed of this right or allow it to be raised in any manner, and may even give instructions to juries that are likely to be interpreted so that they believe they don't have this right.

  Whistleblower laws unanimously passed by Congress in response to abuses by the Merit Systems Protection Board and the Court of Appeals for the Federal Circuit indicate Congress believes these courts are biased and exercise a devotion to the executive branch. This as Thomas Jefferson indicated in a 1789 Letter to M. L'Abbé Arnold, is the reason the right to jury nullification is absolutely necessary in all types of trials, writing:

  > *"In the form of juries, therefore, they determine all matters of fact, leaving to the permanent judges to decide the law resulting from those facts. But we all know that permanent judges acquire an Esprit de corps; that being known they are liable to be tempted by bribery; that they are mislead by favor, by devotion to the executive or legislative power; that it is better to leave a cause to the decision of cross and pile than to that of a judge biased to one side; and that the opinion of twelve honest jurymen gives still a better hope of right, than cross and pile does. It is in the power, therefore, of the juries, if they think permanent judges are under any bias whatever, in any cause, to take on themselves to judge the law as well as the fact. They never exercise this power but when they suspect partiality in the judges; and by the exercise of this power they have been the firmest bulwarks of English liberty."*

  Consequently I believe that there needs to be a statutorily protected right to present the option of jury nullification in defense.

- Allow for a public interest defense especially in cases of national security

- Protect non-government whistleblowers for revealing dangers to the public health, safety, and from frauds

- Prohibit sealing of evidence that harms the public

- Increase funding for the Merit Systems Protection Board to eliminate the backlog, and limit the time for nomination and confirmation of members of the board, for a lack of judges blocks access to Courts and is a form of denial of due process.

Part 4 – Enhance the False Claims Act

- Most important in this regard is to explicitly allow members of the military and other government employees to pursue False Act Claims

[30] Even the Sedition Act of 1798 explicitly provided the right to jury nullification stating, *"And the jury who shall try the cause, shall have a right to determine the law and the fact"*.
[31] Thomas Jefferson, Notes on Virginia, 1782

Part 5 - Protect the Disabled and Disability Rights

- Require equal opportunity and affirmative action for those with targeted disabilities in government, government contracts, and in academia which relies on government grants and where it's been demonstrated that the unemployment rate for scientists with disabilities is through the roof while foreign immigrants are often hired instead.

- Zero tolerance policy for discrimination in government programs

- Include individuals with targeted disabilities and especially severe psychiatric disabilities in government contract set asides and in small business start-up programs.

- Hold accountable individuals from the HHS and FDA Equal Opportunity Offices

Part 6 – Impeachment, Immigration Reforms, etc.

- Impeach Judges of the Court of Appeals for the Federal Circuit and the Merit Systems Protection Board (MSPB)

  In issuing a unanimous opinion, Judges Bryson, Schall, and Prost of the Court of Appeals for the Federal Circuit are clearly in agreement and thus appear to have in the words of Cooper v. Aaron *'warred against the Constitution'* by willfully conspiring to deprive me of my Constitutional right to due process as enunciated by the Supreme Court in Goldberg v. Kelly[32] in violation of 18 USC § 241 (Conspiracy against rights). Plus they have also apparently conspired to deny me my First Amendment right to warn the public as well as deprived me of other civil rights that I was unlawfully forced to give up by the unlawful settlement under color of law. (18 USC § 241 and 18 USC §242 Deprivation of rights under color of law) In addition they appear to be accessories to witness tampering (18 USC §3 and 18 USC §1512).

  In doing this they have demonstrated a devotion to executive power in enforcing punishments for seditious libel. As a result of their actions potentially upwards of sixty thousand people including babies have been poisoned and died. Consequently I believe they are liable for the death penalty under the aforementioned laws.

  I ask thus Congress to impeach the Judges who have ruled on my petition for review of the unlawful settlement I was forced to sign due to their apparent criminal acts in violation of the public trust and I also ask for their subsequent criminal prosecution.

  In my view any member of Congress who does not vote for impeachment is essentially voting to abrogate the Constitution and for the killing of their own constituents.

- Allow retrial of cases involving the biased judges from my case

  In addition to the evidence Congress was already aware of regarding the MSPB's and Court of Appeal's attitude toward whistleblowers.[33] Through my case certain of these judges

[32] See Cooper v. Aaron, 358 U.S. 1 (1958) and Goldberg v. Kelly, 397 U.S. 254 (1970)

[33] In 2012 Congress unanimously passed the Whistleblower Protection Enforcement Act (WPEA) due to the Court's rulings gutting the WPA in order to reassert Congressional intent. Prior to this the Court of Appeals had ruled against whistleblowers on the merits 226 times in 229 appeals from October 1994 to May 2012. Where one of the 3 cases decided in favor of whistleblowers was the case of Robert McLean a Federal Air Marshall who went to the press to report policy changes that exposed the flying public to terrorist attacks. In other words a case that was so well known and so clear cut that it would have been inconceivable for the Court of Appeals to rule otherwise. Plus to counter the court's other precedential decisions Congress also had to clearly reiterate in the 2012 WPEA that when they said any disclosure in the 1989 Whistleblower Protection Act, that they meant any disclosure. Plus they had to clarify and strengthen other provisions of the 1989 act that the Court of Appeals had eviscerated so as to make it virtually impossible in most cases for a whistleblower to prevail.

demonstrated clear bias against whistleblowers.[34] Consequently I request that any whistleblower who has had a case where any of these judges have been an adjudicator be allowed to have their case retried.

- Reform immigration laws for highly skilled workers to ensure that qualified US citizens and especially those who are members of targeted groups for affirmative action are not discriminated against and replaced.

  This includes setting up databases where US citizens can see available jobs and required qualifications where foreign immigrants are being considered and to apply and challenge qualifications that they believe are design for hiring specific individuals over US citizens.

  It also includes limiting foreign nationals in academic training programs and post-docs due to the secondary effects on US citizens, US competitiveness, and national security.

Miscellaneous Requests

- Appoint a Special Counsel for Investigations and Prosecutions

  Regardless of the fact that I have no complaints against the current administration, as there are potentially individuals in the FBI and Justice Department, as well in HHS, and the Defense Department who may have committed crimes or abused their authority, any investigations by the Justice Department or involving investigators or officials in other agencies could be tainted due to friendships or due to other longer term political considerations. Consequently, I believe that a special counsel is absolutely necessary for conducting investigations into the charges I will be forwarding and to prosecute them.

- Toll statutes of limitations

  While certain conspiracies as well as certain crimes that have resulted in deaths do not have a statute of limitation, others do. Due to the failures to investigate and the witness tampering I was subjected to, I request that the statute of limitations on all crimes with statutes of limitations be tolled. Including crimes I reported, attempted to report, or would have reported during investigations, or even crimes I was not aware of at the time but that would have become evident if proper investigations had been performed.

- Request certain Senators and others to resign

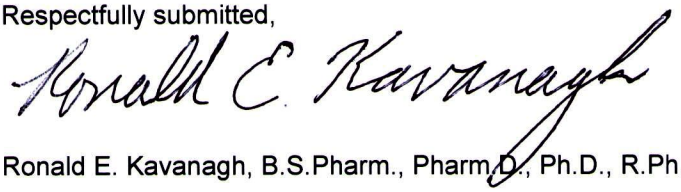
  I request that Senator Van Hollen (D-MD) be asked to resign and allow someone else take his place as I know that he was personally aware of issues I'm reporting, including with pyridostigmine, and instead only offered to do something after I went public thereby placing me, our troops, and others including US citizens in Israel in danger, where he would then be able to afterwards claim he took action.

  I also ask that Senator Cardin be asked to fire certain members of his staff for refusing to accept my petition which has resulted in the deaths of tens of thousands and the endangerment of US troops and citizens in Israel.

  Similarly I request that Senator Ron Johnson (R-WI) be asked to step down due to his actions which I will discuss in more detail in a petition I will be submitting to President Trump via Senator Grassley (R-IA).

[34] My case was one of the over 300 where whistleblowers were ruled against.

Respectfully submitted,



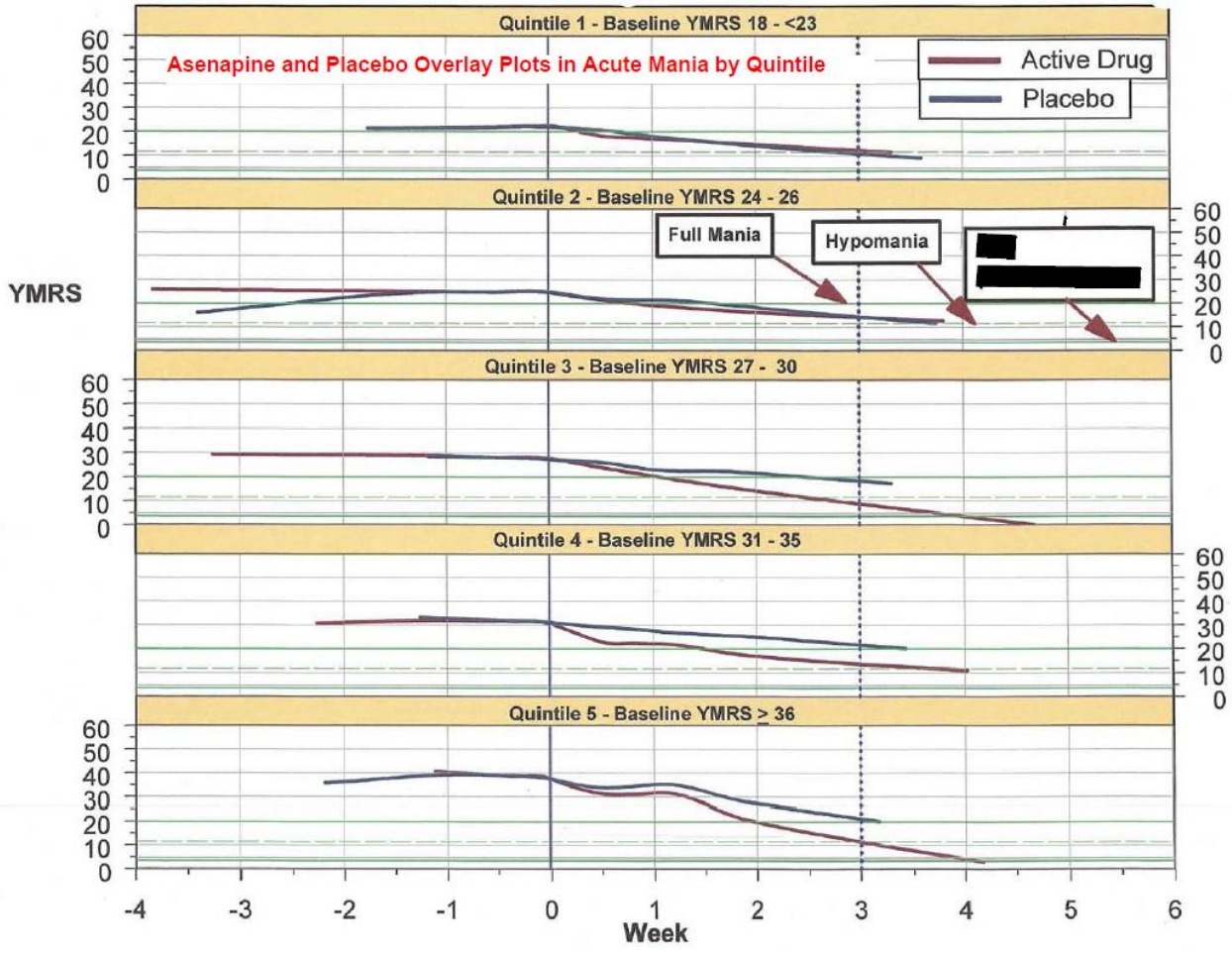
Ronald E. Kavanagh, B.S.Pharm., Pharm.D., Ph.D., R.Ph.

cc:

The House Oversight and Government Reform Committee
Senator Charles Grassley
DOJ Inspectors General Office / Inspector General Michael E. Horowitz

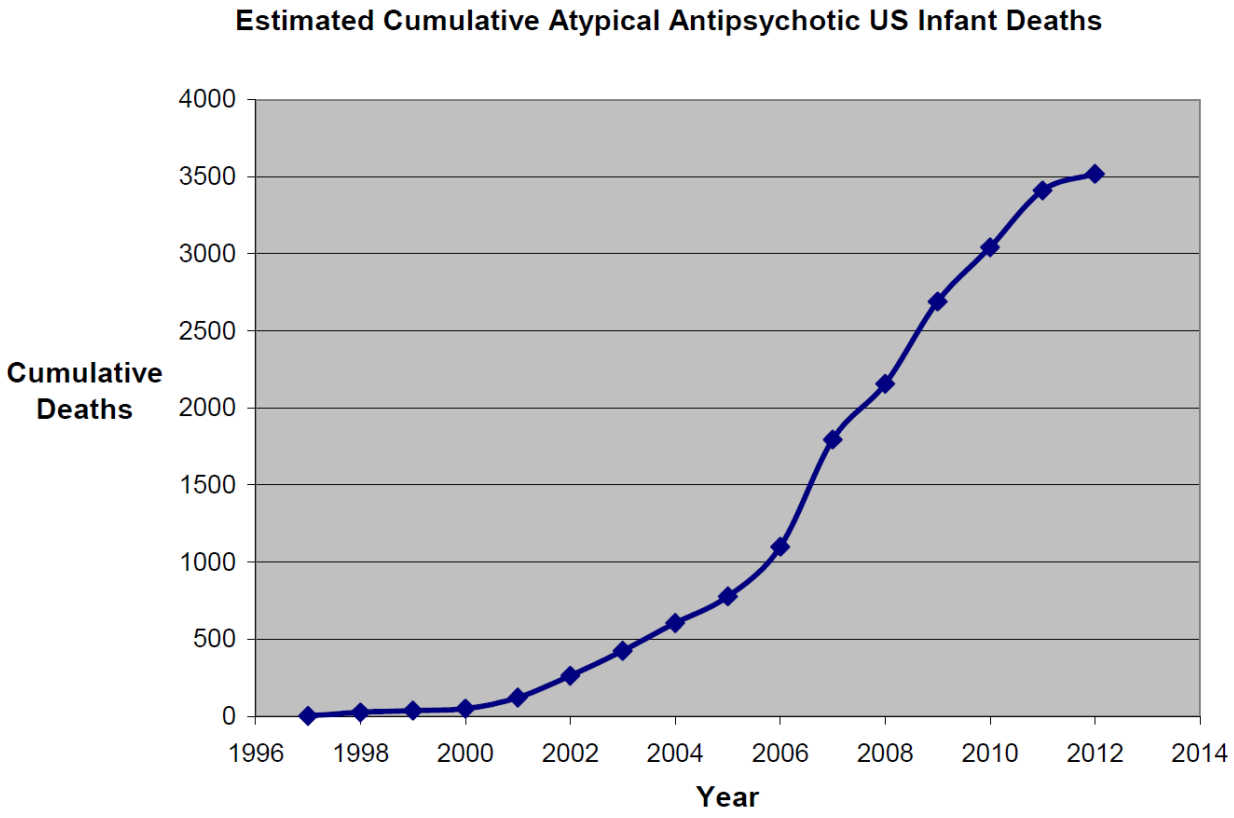
Attachment 1 – Plots Showing Saphris's Lack of Efficacy in Less Severely Ill Patients with Mania

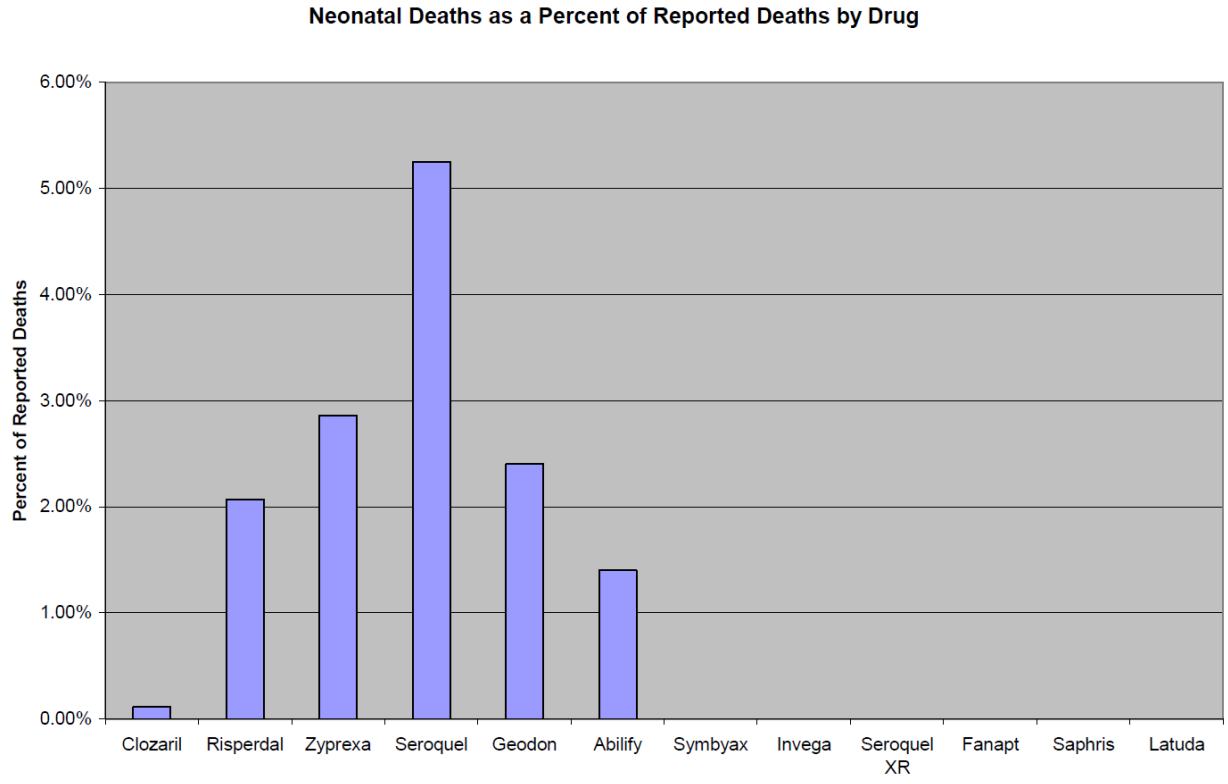
Figure 1 Overlay Plots of Young's Mania Rating Score by Quintile for Saphris® and Placebo[35,36]



[35] A quintile is 20% of the patients.
[36] Although this figure is not included in the FDA reviews it includes the exact same plots as in the publicly released FDA reviews but overlaid with the individual data points removed. In addition, easily obtained software available for 30 years or more allows extraction of the raw data from the plots published by the FDA which would then allow the independent generation of the above figure in less than an hour.

Attachment 2 – Antipsychotic Infant Deaths from FDA Post-Marketing Reports





Attachment 3 – Discussion of Public Information regarding Bifeprunox's Safety and Efficacy

In 2016 I found that Solvay Pharmaceuticals had released information from a report that included autopsy findings from the patient who died that was mentioned in the FDA's nonapproval letter for bifeprunox[37] and it may be found by googling: '*bifeprunox Mad in America'.* This report clearly shows that the patient did not die from hepatorenal failure as is often suggested but rather that death was due to "*inclination of the cerebellar tonsils and subsequent paralysis of vital cerebral centers"*, which is simply a fancy way of saying that he died due to swelling of the brain that crushed the parts of his brain that control the ability to breath and the heart to beat.

The report also shows that on Day 7 of treatment he became *"agitated"*, developed *"frequent and severe choreoathetoid movements"* on Day 8 and then became stuporous and comatose before dying on Day 9. Autopsy findings included *"heavy steatosis of the liver, parenchymal dystrophy of the kidneys and lung emphysema."* The report also states: *"In view of the history, it seems most likely that the microvesicular steatosis associated with aminotransferase elevations and severe metabolic abnormalities (metabolic acidosis, hypoglycemia) as well as renal dysfunction and coma represent a toxic reaction to the investigational drug' probably due to mitochondrial toxicity."*

After I heard in June 2007 that there was concern that bifeprunox wasn't working as well as other drugs I sent an e-mail to the medical reviewer stating that since we assess average measures of efficacy, if there were significant numbers of individuals who got worse on bifeprunox then this might cause it to be less efficacious on average. In response the medical reviewer got defensive and asked me why I was telling her this. Also even though I asked the pharmacometrics group for the raw data in order to look into this they instead repeatedly prevented me from seeing the data, eventually causing me to whistleblow to Senator Grassley's office about this obstruction. The medical reviewer also got upset at me for simply looking for additional indications of liver toxicity in the clinical pharmacology studies (which is my area of responsibility) and came to my office to intimidate me and prevent me from I doing so and she also prevented me from obtaining the autopsy report of this patient, which I had been dealing with due to my concerns of metabolites potentially being responsible for the hepatotoxicity since 2005, when interference in my review of the IND prompted me to talk with Senator Grassley's staff.

As for the public report it's notable for the agitation and other CNS findings which could cause the measures we use for assessing efficacy against psychosis to worsen. In addition severe choreoathetosis associated with psychosis due to mitochondrial effects is seen with Huntington's Chorea which any psychiatrist would be aware of. Plus these types of symptoms are also seen with Pediatric Acute Neuropsychiatric Syndrome (PANS) and the microvesicular steatosis is reminiscent of Reye's Syndrome, both of which are associated with mitochondrial effects. In addition in the FDA neuropsychiatric and psychiatry drug divisions we commonly dealt with the anticonvulsant/anti-manic agent valproate which is also known to cause this sort of hepatic steatosis due to mitochondrial toxicities as well as brain swelling (aka intracranial hypertension or pseudotumor cerebri). Plus they're also seen with tetracycline (most commonly in infants) where I had taken care of a teenage girl with brain swelling and changes in mental status due to tetracycline when I was in practice. In contrast to this case with bifeprunox where the choreoathetosis was severe and developed rapidly, mild choreoathetoid movements with other antipsychotics typically take years to develop and are believed to be associated with other mechanisms and not mitochondrial toxicity.

The two articles about bifeprunox in Mad in America also discuss another patient in a bifeprunox study at the University of Minnesota who developed headaches so severe that he had to go to the emergency room three times, once by ambulance, and where other news articles show these headaches were associated with vision problems. Severe headaches associated with vision problems are hallmarks of brain swelling and this can easily be confirmed by simply looking through the pupils of the eyes for swelling of the optic disk. Such an exam should have been done and a positive finding should have resulted in the patient immediately being taken off bifeprunox as well as other measures. Instead the

[37] Solvay has claimed that this death was not a reason for the non-approval of bifeprunox but that the FDA was asking for additional information.

patient was sent home and the psychiatrist running the bifeprunox study at the University, Stephen Olson, told the patient that it was psychosomatic. This psychiatrist is the same person who was responsible for Dan Markingson a patient who killed himself during another drug study by trying to take his own head off with a razor blade, a case that has been the subject of extensive discussion and response including by the Governor of Minnesota.

Based on the above case with bifeprunox and what is known about the type of mitochondrial effects seen the obvious thing for the FDA to have done would have been to…

Attachment 4 – Summary of Basis for Termination of Employment for Whistleblowing

- I was fired for reporting mass murder
- I was fired for trying to stop the poisoning and killing of babies
- I was fired so that FDA officials could facilitate tens of billions of dollars of fraud and waste that I tried to prevent
- I was fired for reporting the attempted murder and slaughter of US troops with the nerve agent pyridostigmine during the 2003 war in Iraq and trying to stop our troops and others from being killed in the future (i.e. reporting possible treason)
- I was fired for seditious libel for exercising my First Amendment right to petition Congress and criminal investigators regarding crimes that endangered my own life and the lives of others
- I was fired for seditious libel for exercising my First Amendment right to petition Congress and criminal investigators to report a crime that could kill my own child and other children with ADHD that would cause them to be maimed and even killed by an adverse drug reaction that would result in an effect that would be similar to being napalmed or doused with acid
- I was fired for reporting these and other felonies by FDA officials (including racketeering) to the FBI