

Ron Kavanagh

From: Ron Kavanagh
Sent: Wednesday, May 20, 2020 8:09 AM
To: 'Jamie.Raskin@mail.house.gov'
Cc: i@mail.house.gov'
Subject: FDA Whistleblower Disclosure and Petition

Dear Representative Raskin,

I am a former FDA reviewer, FDA whistleblower, and a constituent. I have recently completed a detailed write-up that I promised to provide your office and have attached a document summarizing the most important points for your review and for the House Oversight Committee and others.

Among the major safety issues that I would like to bring to your attention are the following:

- Approval by Ellis Unger in association with Tom Laughren and others of the antipsychotic Saphris® for the treatment of mania despite knowledge and an admission that it (and other antipsychotics) did not work in about half of patients who could be identified prior to treatment and despite knowledge that it would kill about 1% of patients it would be given to. Plus it was known that this was almost certainly a class effect. Consequently potentially over 100,000 Americans with serious psychiatric disorders have been killed by poisoning from ineffective drugs with tens of billions of dollars in associated fraud and waste.
- Approval of Saphris® despite knowledge that safety information required by the Food Drug and Cosmetics Act had not been provided and knowledge that there could be toxic metabolites with Saphris® and with other antipsychotics that would result in fen-phen like toxicities that could kill infants exposed *in utero* and via breast feeding. Where FDA post-marketing data shows that several thousand infants have indeed been killed due to women taking antipsychotics, including almost certainly for mania where the drugs are ineffective, and where Janet Woodcock is personally involved in this issue.
- A cover-up by FDA officials of a death due to anaphylaxis with Saphris® where the FDA later had to issue a safety warning regarding allergic reactions that indicated Saphris® was the most dangerous small molecule drug with regards to causing allergic reactions (including anaphylaxis and death) and could even cause them with the very first dose. Plus the FDA effectively buried information that the only known effective treatments for anaphylaxis, epinephrine and dopamine, could cause a lethal interaction that would mimic certain causes of death from anaphylaxis.
- Manipulation of computer analyses to claim that Saphris® did not prolong the ECG QT interval and so didn't have an increased risk of sudden cardiac death when in fact Saphris® had the second worst QT prolongation effect among antipsychotics so that patients with cardiac problems should not receive it. Consequently patients who are at increased risk are likely to receive Saphris® rather than safer antipsychotics.
- FDA dismissal (including by Norm Stockbridge the cardiology division director) of cardiac arrests due to Saphris® that required antiarrhythmic drugs for resuscitation by claiming it was instead fainting due to Neurologically Mediated Reflex Bradycardia (NMRB) based on misleading claims and summaries prepared by the company without examining the original data and despite the psychiatry division director Tom Laughren knowing that the company's own original assessments stated that it couldn't possibly be NMRB and was instead a direct effect on the conducting system of the heart.
- The unlawful approval of pyridostigmine to prevent death from the nerve agent soman during the Iraq war based on a claim that use of a reversible nerve agent (pyridostigmine) would prevent the binding of the irreversible nerve agent (soman) which would allow elimination of soman followed by the elimination of pyridostigmine and regeneration of 'protected' enzyme thus allowing soldiers to recover. This is despite knowledge that there would be an additive effect with the use of both types of nerve agents, and with pyridostigmine's effective half-life of 3.5 hours the amount of enzyme inhibition could not recover to be as low as with soman alone in the 3-5 minutes that it takes for death to occur. Thus instead increasing the number of US troops as well as embedded journalists and potentially even US citizens in Israel who would be killed (i.e. apparent attempted mass murder of US troops during war). Plus we also had data that lethality was increased in the presence of other nerve agents such as

sarin, where it's documented that we knew that Saddam Hussein was not using soman but was instead using these other nerve agents.

For reporting these crimes as well as others to Congress and to criminal investigators including the FBI as well as via other appropriate channels and for explicitly exercising my First Amendment rights in order to protect my own life, my child's life, and the lives of others I was fired by Douglas Throckmorton, the Deputy Director for the Center for Drugs. Dr. Throckmorton upheld eleven charges/specifications against me, eight of which were directly linked to whistleblowing and reporting felonies by FDA officials, (including but not limited to witness tampering and conspiracies for fraud, as well as mass murder, and attempted mass murder and possible treason). And where the three other charges/specifications not directly linked to whistleblowing clearly could not be upheld under law. Plus Dr. Throckmorton willfully violated my rights to due process, including statutorily mandated due process rights that have resulted in the poisoning deaths of potentially myriads of individuals.

I was also fired for seditious libel for explicitly exercising my First Amendment rights and for reporting crimes by FDA officials where allegations against me are identical to charges in the Sedition Acts of 1798 and 1918, including allegations of contumely. Plus I was fired for violating the FDA violence in the workplace policy based on allegations that my reporting crimes by FDA officials constituted "threats", and for being violent for my stated willingness to go to prison for exercising my First Amendment rights and peaceably petitioning Congress as an act of civil disobedience, where civil disobedience by definition is peaceful, when I had been previously threatened with prison if I should provide trade secret information to Congress. Despite having the explicit civil right to do so under the Food Drug and Cosmetics Act, as well as under the Lloyd-LaFollette Act, and the Trade Secrets Act. Plus my firing was based on illegal animus and claims that I must be violent simply due to having a history of serious mental illness that included severe depressions. In contrast the Maryland state unemployment office rejected the FDA's claims that I was violent due to the inability of the FDA to provide any supporting evidence.¹

Subsequent to this I was intimidated into signing a settlement agreement against my will that mandated witness tampering through a clause that required me to "withdraw all... charges... filed with any administrative agency", where it was clearly understood by both sides that charges referred to criminal charges and where the FDA had even 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 a petition for review of the settlement, and its unlawfulness being raised and discussed separate six times in the petition and the appeal to the Court of Appeals for the Federal Circuit. As well as despite an HHS 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) and 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 report in my June 18th review, and other reports of crimes including to Congress and the HHS Inspector General that I was fired for. Nevertheless Judges Bryson, Schall, and Prost of the Court of Appeals for the Federal Circuit completely ignored the unambiguous settlement term and my arguments regarding it in their decision, and 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. [See Kavanagh v HHS, No. 2010-3133 (Fed. Cir. 2010); (Google - Kavanagh v. HHS)] something that appears to make them accessories to witness tampering.

This of course is also 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. Consequently I believe that these judges (as well as MSPB judges) conspired to violate my rights under color of law resulting in the unlawful suppression of my First Amendment right to warn the public which as a consequence resulted in the poisoning deaths of potentially upwards of 60,000 people. Something that under 18 USC §§241 and 242 appears to carry the death penalty.

It doesn't take a constitutional scholar to appreciate the implications of these attacks on my Constitutional rights, for in essence not having First Amendment rights to report crimes that can result in your own death or the death of your child means we don't have the right to live.

As I mentioned I have attached a more detailed summary and have also made a number of petition requests in it.

Among the most significant of petition requests are:

- Requiring investigation by criminal investigators of truthful reports by government employees involving possible crimes by government officials, employees and others and mandating that prosecution shall be required

- Protect whistleblowers by criminalizing 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 for retaliation
- Amending obstruction of justice statutes to criminalize harassment and intimidationⁱⁱ
- Appointment of a Special Counsel
- Tolling statutes of limitations
- Working with Senator Grassley to provide for jury trials for government whistleblowers as all retaliation of government whistleblowers is essentially for seditious libel and as some retaliation can constitute attacks on property rights that the seventh amendment guarantees the right to jury trials for
- Providing for jury nullification, a public interest defense, and prohibiting the abuse of sealing of evidence that harms the public
- Numerous FDA reforms including replacing PDUFA and other FDA User Fee programs, mandating that drug review information be made public, adequate time for reviews and protecting and improving the review process, mandating standards, preventing abuse of authority and overriding of reviewers, and holding drug company executives personally responsible
- Protecting the disabled and disability rights and full inclusion of the disabled in affirmative action, government contract set asides, and in hate crime laws
- Impeach and criminally prosecute judges of the Court of Appeals for the Federal Circuit and the Merit Systems Protection Board (MSPB) and allow retrials of cases involving these judges

In addition I will be petitioning President Trump for the following requests among others and I ask the President and everyone in Congress for bipartisan and bicameral support in order to protect the lives of the American people.

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

In total there are more than 50 individuals including Janet Woodcock and in multiple agencies including the FDA, Army, and Justice Department who I believe have either committed crimes or should otherwise be held accountable.

- 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 thus also fulfill his primary duty to defend the lives of US citizens.
- Assuring my family's and my protection.

In addition to the attached disclosure summary I anticipate in the future also be providing a complete detailed account as well as additional petition requests including what is needed to protect the public from FDA corruption and whistleblower protections also needed to protect the lives of the public. This full detailed account includes discussion of the available evidence including original documents that likely number in the hundreds and total thousands of pages. Please note that only a few examples from select original documents are included even in the full disclosure and the rest will need to be obtained. The full disclosure is intended to provide a guide as to relevant documents. Regardless my expertise will still be needed to assist in understanding some of them, either as to how they relate to other documents that are months or years apart or because they require a particular scientific expertise.

As your staff knows, I have been also been trying to obtain contact information to submit the summary document I am attaching to the House Oversight Committee. In fact initially your staff didn't want me to petition you and instead directed me to the Oversight Committee. Whereas when pushed I was advised to set up a meeting with you. However your schedulers have ignored me and the House Oversight Committee staff are now making it difficult if not impossible for me to submit the aforementioned document and petition to the Committee. Consequently I ask that you provide the

Committee with a copy of this e-mail and the summary document and make sure that I can provide my full disclosure and petition, and that hearings are held. Especially as many of the issues I raise (but not all) involve criminal violations of the First Amendment and other Constitutional rights, where some carry the death penalty, and thus are specifically dealt with by the subcommittee you chair.

I look forward to assisting in any way that I can to fulfill my duty to defend the Constitution, protect the lives of the American public, protect our troops, and bring people to justice.

Respectfully submitted,

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

¹ If I had been fired for being violent then I would not have been eligible for unemployment benefits.

¹ Where intimidation does not necessarily imply violence or a fear of violence, but may include other adverse consequences



Petition Letter to
Rep. Raskin...

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