

Exhibit A

*Dr. Anthony Semone, Affidavit in Support of the Testimony
of Joshua G. Prince, Esq.*

**AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
CHIEF COUNSEL
CIVIL RIGHTS DEFENSE FIRM, PC
BECHTELSVILLE, PA**

**THE SENATE JUDICIARY SUBCOMMITTEE HEARINGS
24 and 25 September 2019
Harrisburg, PA**

**MENTAL AND BEHAVIORAL HEALTH, SECOND AMENDMENT and
OTHER GUN RELATED ISSUES**

On this date 11 September 2019, being first duly sworn, your Affiant, H. Anthony Semone, PhD, hereby testifies that:

1. My name is H. Anthony Semone, PhD. I have a private practice office at 1 Bala Ave., Suite 125, Bala Cynwyd, PA 19004. I have been continuously licensed as a Psychologist from 1969 through 1975 in Florida, and from 1976 to the present in Pennsylvania (PS002249L).
2. I hold an earned doctorate from Kent State University (1968) with a major in Clinical Psychology and a minor in Operant Behavior; a Master of Arts in Psychology from Kent State (1967); a Master of Rehabilitation Counseling from the University of Florida (1963); and a Bachelor of Arts in Psychology, from the University of Florida (1962).
3. My Kent State University doctoral program included a two-year, split internship from (then) Summit County Receiving Hospital in Cuyahoga Falls, OH (1966-1968), and that internship afforded me working with disturbing individuals in two contexts:
 - a. Involuntarily committed persons whose behavior was sufficiently troubling to family, friends or community that it led to their involuntary hospitalization for the reported behavior.
 - b. And with persons in a walk-in setting whose lives were in sufficient disarray that, while not requiring involuntary commitment, provided for them the available presence of skilled, collaborative, problem-solvers who served as problem-solving resources.
4. On the basis of my education, both academic as well as specialized, I aver that I have the requisite knowledge to offer my opinions to Attorney within a reasonable degree of psychological certainty.¹
5. For the purpose(s) of Attorney Prince's testimony before the Senate Judiciary Subcommittee Hearing referenced above, he has asked me to address three topics as they relate to that topic as described.

¹ I have attached copies of my CV and Specialized Use of Force credentials to support my assertions.

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

6. In addition, Attorney Prince offered me the opportunity to comment upon an area of special interest to me in which, as in the other, I have specialized expertise. I have accepted his offer. This affidavit is provided without expectation of recompense.

7. Attorney Prince has asked me to provide my professional opinion as to the following questions:

- a. Has the “breakdown in the family unit...led to a breakdown in morals and ethics.”
- b. (Does) “the use of psychotropic/SSRI drugs and the fact that every school shooter was on some SSRI drug and the pharmaceutical industry has refused to disclose studies relating to SSRI drugs effect on the juvenile brain (which I believe is different than the adult brain).”
- c. (Is there) “stigmatization of mental health treatment.”

8. Attorney Prince also offered to me the opportunity to provide my commentary on an issue that my credentials afford me the requisite expertise upon which to offer them. Therefore, I shall provide my appraisal of the variables that compromise the validity of the verbal reports of risk offered by complainants seeking so-called Extreme Risk Protection Orders.

9. In the contexts of ERPO’s, I will address the following:

- a. The inherent unreliability and invalidity of verbal reports particularly as to the predictive probabilities associated with false positive and false negative incidences.
- b. Unreliability and invalidity of verbal reports in contexts specifically having to do with allegations as to future dangerousness.
- c. The presence of already existing protocols for arriving at reasonable decisions as to protective steps to increase the probability of minimizing erroneous decisions, both as to false positives and false negatives.

10. On the basis of my education, both academic as well as specialized, I aver that I have the requisite knowledge to offer my opinions within a reasonable degree of psychological certainty.²

Breakdown in the Family Unit.

11. Has the “breakdown in the family unit...(led)...to a resultant break down in morals and ethics?”

12. Yes, and that “breakdown” has created a context for the emergence of violent youth and young adults and supported them engaging in that behavior.³

² I have attached copies of my CV and Specialized Use of Force credentials to support my assertions.

³ My description of the many factors involved in explicating family dynamics is based upon my formal training in Structural Family Therapy in Philadelphia, PA; in direct treatment and training services I conducted at the Abraxas Foundation in PA and WV; the Youth in Transition programs in York, PA and Baltimore, MD; and, the Child and Adolescent Unit, York PA; as well as in private, independent practice in Clarion, PA; Pittsburgh, PA; York, PA; and Philadelphia, PA.

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

13. Families in which its children grow up having no more than the ordinary problems of living and who comport themselves as law-abiding systems, are characterized, first and foremost, by a clearly defined leadership structure. It is one comprised of one or more adults who exercise authoritative leadership over the family membership. In other words, one or more adults are “in charge.”

14. Being “in charge” entails that the leader(s) “lead” the family with firm yet compassionate behavior as to its membership. In doing so, the leader(s) hold themselves as accountable, thereby generating credibility amongst its members, that is, they lead by example; they “walk the walk.”

15. An additional dynamic in life-giving families is the presence of clear boundaries that are firm yet pliable as befits the daily demands of the family experience. Boundaries lend strong support to creating unique family roles played that respective family members can develop.

16. Families that work well have communication patterns that allow its members to negotiate the inevitable clash of goals, needs, wants and conflicts that attend the various developmental stages. Those patterns enable each of the family members to have a unique voice to resolve conflict, negotiate impasses, and arrive at resolutions to interpersonal conflict.⁴ The net effect is to create a family whose needs for “growth” are met: physiological, safety, intimacy, esteem, thereby creating the context for its members to achieve their full potential.⁵ In families that are disconnected, disrupted, and destructive, first and foremost, there is no one in charge, or, if in charge, serve only as role-models for illegal, violent and other anti-social behavior.

17. Such ostensible “family” leader(s) are absent or disconnected. They show no consistency in their behavior toward its members. Those leader(s) model behaviors which is punitive, violative, addictive, and criminal; and, they act abusively, verbally, physically and/or sexually toward its membership, especially its vulnerable youth.

18. The children who grow up in such families, especially at early developmental stages, become the unwitting recipients of trauma induced structural and physiological changes to the brain,⁶ the consequences of which predispose those children to extreme problems with living productive, responsible lives.

19. In disrupted families with only destructive values modeled or demonstrated by its leadership, or whose modeled values demonstrate illegal behavioral, vulnerable youth do attach to those whom they respect because of the power those “leaders” show.

⁴ <https://www.psychotherapy.net/data/uploads/5113e45715ce5.pdf> Structural Family Therapy - Minuchin/Lappin

⁵ <https://www.britannica.com/biography/Abraham-H-Maslow>

⁶ <https://conscioused.org/books/the-body-keeps-the-score-bessel-van-der-kolk-review-summary> - B. van der Kolk

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

20. Since that power is reflected in the violent subculture of “the Hood and the Corner,”⁷ it is unsurprising then to see those vulnerable youth engage in the precise behavior that is modeled for them by criminals acting as parental surrogates. That modeling is seen principally in the culture of the sale and distribution of illegal commodities, principally drugs. Rape, aggravated assault, robbery, violations of countless firearms laws, and homicidal behavior are natural outgrowths of that decay.

Psychotropic Medication Effects⁸

21. Do psychotropic medications have dangerous effects on the brain-behavior relationships?

22. Yes. There is evidence-based support as to the dangerous effects of psychotropic medications on brain behavior relationships and with associated increased risk, especially among adolescents for homicide and/or suicide.

23. As reported in *Children & Society* volume 28, (2014) pp. 231-241, Peter R. Breggin, MD has provided such evidence. E.g., he explicates the impact of neurotropic medications on the brain by addressing the “Effects of the ADHD diagnosis and stimulant drugs.” (P. 231) For example, Breggin reports:

24. “ADHD is not a valid diagnostic category that meets the criteria for a medical syndrome (Baughman and Hovey, 2006; Breggin, 2008a; Whitely, 2010). Like all other psychiatric disorders, there is no evidence that it is has a biological cause (Moncrieff, 2007a).” (p 231). And further as to ADHD:

25. “Stimulants are the most commonly prescribed drugs for ADHD. Most are either amphetamines (e.g. Adderall or Dexedrine) or methylphenidate (e.g. Ritalin or Concerta). **Atomoxetine** has been promoted by manufacturer Eli Lilly & Co. as a ‘non-stimulant’ treatment for ADHD, but it has been shown to cause dangerously stimulating symptoms in one-third of children (Henderson and Hartman, 2004) and carries a **Black Box Warning about causing suicidality in children (Strattera, 2011)**. Black box warnings are labels placed on pharmaceuticals in the USA, required by the Food and Drug Administration, when there is sufficient scientific

⁷ The HBO Series of the 90’s entitled “The Wire” is uniquely representative of the impact on the youthful members of what remains of families. I worked with the Youth in Transition program in precisely the neighborhoods depicted in that Series. Any reader of this Affidavit, who wants to experience the reality of the “combat zones” and its effects on youth, neighborhoods, etc., and also to learn that one of the primary corrupters of the Life-Giving attributes of the youth of those neighborhoods is political and law enforcement corruption would do well to view that entire series.

⁸ As a clinical neuropsychologist I am formally trained in the evaluation of the effects on the brain of injurious events. While I offer no medical opinions, I am required ethically and professionally to be proficient in understanding the various causes of brain injury.

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

25.(cont'd). evidence for causality with regard to serious adverse or life-threatening effects.” (p. 232. Emphasis added). And Breggin continues:

26. “Amphetamine and methylphenidate produce persistent biochemical abnormalities in the brain (Breggin, 2008a). Children treated with stimulants often develop atrophy of the brain. At the NIH Consensus Development Conference on ADHD, Swanson (Swanson and Castellanos, 1998) reviewed available studies purporting to show biological bases for ADHD including brain atrophy (e.g. Castellanos and others, 1996; Giedd and others, 1994). My presentation at the same conference concluded that these brain scans were ‘almost certainly measuring pathology caused by psychostimulants’ (Breggin, 1998: 109). Proal and others (2011) found widespread brain atrophy in grown adults who had been diagnosed and treated for ADHD as children. Furthermore, there is evidence that these stimulants lead to growth suppression in children. A large-scaled federally funded study (the MTA) involving multiple centres reconfirmed that stimulants suppress growth (Swanson and others, 2007a,b). These stimulant-induced losses in growth are due to a disruption in growth hormone cycles (Aarskog and others, 1977) that could adversely affect other organs of the body.” (p.232).

27. Breggin adds further:

“No long-term benefit for children of any kind has ever been demonstrated for any stimulant drug — no improved behaviour, no improved socialisation skills, no improved academic skills and no improvement in learning (McDonagh and Peterson, 2006; Regier and Leshner, 1992; Despite six decades of research, the FDA-approved labels for stimulants remain required to state, ‘Long-term effects of amphetamines in children have not been well established’ (Adderall, 2013; Section 8.4 ‘Pediatric Use’). **Even the pro-medication Multi-Modal Treatment Study (MTA) found at 36 months that medication treatment strategies were no better than any other behavioural and educational approaches, including a stay at a summer camp (Swanson and others, 2007b).** (p. 233) Emphasis added.

28. And as to the effects of bipolar diagnosis and antipsychotic drugs, the efficacy effects are not salutary. As Breggin reports, (ibid) “bipolar diagnoses in children, (yes, CHILDREN) has increased 40-fold since 2007 (Moreno)⁹ Moreover, these (newer – sic) drugs are documented to produce serious movement disorders, one in particular – tardive akathisia – that is described as “**a variant of TD (Tardive Dyskinesia), (that) causes a torture-like inner sensation that can drive patients into despair, psychosis, violence and suicide (American Psychiatric Association, 2000: 803).**” (ibid. p233 Emphasis added).

⁹ Moreno C, Laje G, Blanco C, Jiang H, Schmidt A, Olfson M. 2007. National trends in the outpatient diagnosis and treatment of bipolar disorder in youth. Archives of General Psychiatry, 64: 1032–1039.

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

29. “Rational Principles of Psychopharmacology for Therapists, Healthcare Providers and Clients.”

30. “The Myth of the Biochemical Imbalance.”

“Many professionals and the public have been falsely convinced that biochemical imbalances in the brain drive mental suffering, such as the serotonin theory of depression or the dopamine theory of so-called schizophrenia. Yet the evidence for any biological basis for “psychiatric disorders” is utterly lacking (Glenmullen 2000; Healy 2015; Kirsch 2010; Lacasse and Leo 2005; Moncrieff 2007a, b, 2013; also, Breggin 1983, 1991, 2008a).” [Breggin. P. 2, *ibid.*]

31. “Three Basic Rational Principles of Psychopharmacology.”

“These principles apply to all psychoactive agents, but are especially important in respect to psychiatric drugs, which are the object of so much false marketing by drug- company sponsored experts in the field.” [Breggin. *Ibid.*]

32. “The First Basic Principle: The Brain-Disabling Principle of Psychopharmacology.”

“All drugs that impact on the brain and mind “work” by partially disabling the brain and mind. No psychoactive substance corrects biochemical imbalances or any other real and presumed defects, deficits or disorders of the brain and mind, and none improve the function of the brain or mind. The so-called therapeutic effect is always a disability (Breggin 2007, 2008a, b, 2013).” [Breggin. *Ibid.*] (Emphasis added.)

“All psychoactive drugs specifically impair the frontal lobes because they are among the most vulnerable areas in the brain and because the widespread disruption of neurotransmitters inevitably has a negative impact on them. As we examine the remaining categories of psychiatric drugs, keep in mind that all of them over time will impair frontal lobe function and produce a degree of apathy and indifference, with a related loss in quality of life.”(Breggin. P.3, *Ibid*

33. “The Second Basic Principle: Intoxication Anosognosia (Medication Spellbinding).”

“Intoxication anosognosia or medication spellbinding occurs when a psychoactive drug prevents the recipients from fully knowing or grasping that they are experiencing adverse drug effects upon their brain and mind (Breggin 2007, 2008a, b, 2013).”¹⁰ Secondary to this form of agnosognosia, persons so afflicted are unable to detect the adverse reactions of the drug and their impact upon behavior. Breggin writes: “Individuals drunk on alcohol often fail to appreciate the

¹⁰ I have neuropsychologically test results acquired in the course of examining and treating head-injured persons of damage to sensory receptive systems of the right cerebral hemisphere of brain, coupled with verbal expressive damage to left cerebral hemisphere systems, likely secondary to damage to interhemispheric transfer systems of the brain. In these cases, the individuals were unable to know that they didn't know.

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

33. (cont'd). degree of their intoxication and impairment, even when their conduct becomes offensive at a social gathering or when they commit crimes such as domestic violence or vehicular homicide.”¹¹

34. The Third Basic Principle: Chronic Brain Impairment (CBI).

“The continued use of psychoactive substances leads to chronic brain impairment and in worst cases to irreversible mental deficits, shortened lifespan, and dementia (Breggin 1983, 1990, 1991, 2008a, 2011, 2013).

35. Yet it is not only Breggin who report on the adverse behavioral effects of the use of psychotropic medication. In an article entitled:

36. “Prescription Drugs Associated with Reports of Violence Towards Others”¹² The authors of this study conclude “Acts of violence towards others are a genuine and serious adverse drug event associated with a relatively small group of drugs. Varenicline which increases the availability of dopamine, and antidepressants with serotonergic effects were the most strongly and consistently implicated drugs. Prospective studies to evaluate systematically this side effect are needed to establish the incidence, confirm differences among drugs and identify additional common features. “In the above study, Varenicline’s brand name is “Chantix,” a prescribed drug for smoking-cessation.

37. In addition, “We identified 1527 cases of violence disproportionately reported for 31 drugs. Primary suspect drugs included varenicline (an aid to smoking cessation), 11 antidepressants, 6 sedative/hypnotics and 3 drugs for attention deficit hyperactivity disorder. The evidence of an association was weaker and mixed for antipsychotic drugs and absent for all but 1 anticonvulsant/mood stabilizer. Two or fewer violence cases were reported for 435/484 (84.7%) of all evaluable drugs suggesting that an association with this adverse event is unlikely for these drugs.”

38. The authors conclude: “These data provide new evidence that acts of violence towards others are a genuine and serious adverse drug event that is associated with a relatively small group of drugs. Varenicline, which increases the availability of dopamine, and serotonin reuptake inhibitors were the most strongly and consistently implicated drugs. Prospective studies to evaluate

¹¹ http://breggin.com/wp-content/uploads/2008/06/Breggin2016_RationalPrinciples.pdf p.3

¹² Moore TJ, Glenmullen J, Furberg CD (2010) Prescription Drugs Associated with Reports of Violence Towards Others. PLoS ONE 5(12): e15337. <https://doi.org/10.1371/journal.pone.0015337>

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

38. (cont'd). systematically this side effect are needed to establish the incidence, confirm differences among drugs and identify additional common features.

39. In evaluating the objectivity of this article, it is important to note: “**Competing interests:** Mr. Moore has received consulting fees from litigators in cases involving paroxetine and was an expert witness in a criminal case involving varenicline. Dr. Glenmullen has been retained as an expert witness in cases involving varenicline and psychiatric drugs including antidepressants, antipsychotics, benzodiazepines, mood stabilizers, and ADHD drugs. Dr. Furberg has received consulting fees from litigators in cases involving gabapentin. This does not alter the authors' adherence to the PLoS ONE policies on sharing data and materials.” [ibid]

40. Scientific American has published an article on the relationship between antidepressants and harm entitled:

41. “The Hidden Harm of Antidepressants” published 23 February 2016 and purports to be “An in-depth analysis of clinical trials reveals widespread underreporting of negative side effects, including suicide attempts and aggressive behavior.”¹³ This report concludes in its closing section “Time to reassess?”, continues:

42. “Because many prior studies found increased suicidal ideation with antidepressant use, in 2004 the FDA gave these drugs a black box warning—a label reserved for the most serious hazards—and the EMA issued similar alerts. There are no labels about risks for aggression, however. Although hints about hostile behavior existed in the past, including in published case studies, last week’s *BMJ* study was the first large-scale work to document an increase in aggressive behavior in children and adolescents. “This is obviously important in the debate about school shootings in the States and in other places where the perpetrators are frequently taking antidepressants,” Moncrieff says.”

43. “Taken together with other research that raises questions about the pros and cons of this class of drugs—including studies that suggest antidepressants are only marginally better than placebos—some experts say it is time to reevaluate. “My view is that we really don't have good enough evidence that antidepressants are effective, and we have increasing evidence that they can be harmful,” Moncrieff says. “So, we need to go into reverse and stop this increasing trend of prescribing [them].”

44. Similarly, “thebmj” (sic) in its research division, published 27 January 2016 reports on “Suicidality and aggression during antidepressant treatment: systematic review and meta-analyses based on clinical study reports.”¹⁴ This study concludes:

¹³<https://www.scientificamerican.com/article/the-hidden-harm-of-antidepressants/>

¹⁴ <https://doi.org/10.1136/bmj.165>

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

44. (cont'd). *“What is already known on this topic*

Important information on harms is often missing in published trial report

Clinical study reports should therefore be the preferred source for systematic reviews of drugs

Antidepressants can increase the risk of suicide in children and adolescents

What this study adds

Despite all the limitations we identified in the trials and in the clinical study reports, we found an increase in events of aggression with antidepressants (lost in adults alone), with a doubling of both suicidality and aggression in children and adolescents

Selective reporting of relevant harms across the different sections of the clinical study reports meant that patient narratives, tables with individual patient listings (often found in appendices), and case report forms are needed for complete information.

Online summary reports of trials available from Eli Lilly’s website are inadequate as source documents for identifying harms data”

45. Most dramatically is the finding reported in this most recent article,¹⁵ one which purports to be “the first review that implicates certain drugs as a cause of due to pharmacogenetic polymorphisms and neurotransmitter disruption.”

46. Pharmacogenetics can be defined as “the branch of pharmacology concerned with the effect of genetic factors on reactions to drugs, and a genetic polymorphism refers to the occurrence of two or more genetically determined phenotypes in a certain population... .”

47. More simply put: Multiple Forms of a Single Gene. In certain circumstances there exist the potential for such a factor adversely to influence the effects of “Antidepressant and Neuroleptic Psychiatric Drugs”

48. For examples, as are seen in the following article entitled: “Treatment Emergent Violence to Self and Others; A Literature Review of Neuropsychiatric Adverse Reactions for Antidepressant and Neuroleptic Psychiatric Drugs and General Medications by Clarke C, Evans J, Brogan K.

¹⁵ **Treatment Emergent Violence to Self and Others; A literature Review of Neuropsychiatric Adverse Reactions for Antidepressant and Neuroleptic Psychiatric Drugs and General Medications. By Clarke C, Evans J, Brogan K in *Advances in Mind-Body Medicine* 2019 Winter;33(1)4-21.**

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

49. This paper reviews the literature linking physical violence, directed towards self or others, to serotonergic and dopaminergic psychiatric drugs and general medications. It notes that “ it is established genetic polymorphisms in the CYP450 and serotonergic metabolizing system cause higher drug blood levels which are associated with neuropsychiatric adverse conditions (ADRs), such as akathisia.”

50. If not recognized, akathisia, which often precedes violence, suicidality, homicide, mania and psychosis, may be mistaken for new or emergent mental illness and (be) treat(ed) with further ineffective, counter-productive psychiatric drugs.

51. To repeat, the authors of this article conclude that: **This paper is the first review that implicates certain drugs AS A CAUSE OF VIOLENCE due to pharmacogenetic polymorphisms and neurotransmitter disruption.** (All emphases added).

52. The practical implications of that finding speak to the critical necessity of “Safer prescribing...and could be achieved by individual genotype testing, which would identify persons with genetic polymorphisms, who are unable to metabolize drugs. ...”

53. Yet there is further evidence and referenced below¹⁶ as to the specific issues of the relationship between drugs and violence, summarizing as follows:

“The information in this report is not to excuse violent crimes and make the perpetrator blameless, but to demonstrate why there may be a much different type of violent behavior that police and the community face today compared to 50 years ago. All psychotropic drugs are called that because they are mind-altering or mind-turning. For some of those taking them, the consequences can be serious. For the community, where the psychiatric drug consumer acts wittingly or unwittingly due to the drug’s adverse effects and kills, the results are tragic and catastrophic.

“Doctors Charles Gant and Greg Lewis wrote: “The area in which we need much more restrictive laws” is “against allowing psychotropic chemicals to get into the brains of children 21 years of age and younger, during which time their brains are developing and very vulnerable. The war against drugs needs to begin with eliminating prescription psychotropic drug availability to and used by our children. Gun control laws or the lack thereof, had nothing to do with the Newtown massacre. Adam Lanza was denied a permit to purchase a gun, but that didn’t prevent him from committing a gun crime. In the meantime, and for a long time to come, there are going to be great quantities of ‘legal’ psychotropic drugs out there, not least because ‘psych meds’ are still going to be prescribed to children as if they were candy.” (Emphasis added).

¹⁶ “Psychiatric Drugs Create Violence and Suicide.” From the Psychotropic Drug Series. Published by the Citizens Commission on Human Rights. March 2018. (Appended hereto).

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

54. And yet, these data were known as far back as March 2010 as shown in an earlier article also published¹⁷ in Psychotropic Drug Series by Citizens Commission on Human Rights and shown in the following excerpt taken therefrom:

“The amount of violence in today’s society is truly astounding—and the sheer number of theories attempting to explain it can leave the average person shaking his head in confusion.

“One cause is known: the astonishing rise in psychiatric drug-related crime.

“In fact, Harvard University’s Dr. Joseph Glenmullen warns that antidepressants could explain the rash of school shootings and mass suicides over the last decade. People taking them “feel like jumping out of their skin. The irritability and impulsivity can make people suicidal or homicidal.”¹⁸

“A study of 950 acts of violence committed by people taking antidepressants found 362 murders, 13 school shootings, 5 bomb threats or bombings, 24 acts of arson, 21 robberies, 3 pilots who crashed their planes and more than 350 suicides and suicide attempts.

“Medical studies show that patients with no history of violence, develop “violent urges to assault” while under the effects of psychiatric drugs.

“At Columbine High School, on April 20, 1999, teens Eric Harris and Dylan Klebold shot dead 12 students and a teacher and wounded 23 others before shooting and killing themselves. Harris was taking Luvox, an antidepressant known to cause mania and violence.

“Following the Columbine incident, Colorado State Rep. Penn Pfiffner chaired a hearing on the potential connection between violent behavior and psychotropic drugs, stating: “There is enough coincidence and enough professional opinion from legitimate scientists to cause us to raise the issue and to ask further questions.”

55. In view of the data from these studies it appears that the good Colorado State Representative has been ignored as to his recommendations. It is my hope that this Committee will not prove equally indifferent and obviously ineffectual.

¹⁷ Psychiatric Drugs Create Violence and Suicide. Published by Citizens Commission on Human Rights 2010. (Appended hereto).

¹⁸ Dr. Glenmullen’s study appears to be cited as Fn#2 in the article I just cited as having been written by Elizabeth Showgren, “FDA reviews labels on antidepressants,” The Seattle Times, 21 Mar. 2004.

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

Is there Stigmatization of Mental Health Treatment?

56. Addressing my response to this question requires a clearer and more precise exposition of it. The phrase “mental health” is nothing more than a euphemism and it shares that characteristic with its more recently enacted version “behavioral health.”

57. Of course one could argue that either of the above “euphemisms” is a better alternative than the still current, although reserved for more extremely “ill” persons, “mentally ill.” Thomas Szasz, MD has written eloquently as to the “Myth of Mental Illness.” As seen in earlier parts of this Affidavit, Peter Breggin, MD shares a similar orientation, eschewing the concept of “mental illness.”

58. What are we talking about when we use these terms? Fortunately, Sir William of Ockham has afforded us a ‘razor’ for clarifying the issue in simpler form: In ordinary life, we are talking about the behavior of some person or some system that is troubling, frightening, inexplicable, ineffable, to someone observer, or to the person him or herself. When anyone or more of those behaviors rises to a level, either in frequency, intensity, duration, or finality, either the person or others decides “there’s something wrong with so and so.”

59. So, from my perspective, the most powerful explanation as to explicating “mental health” is that we are talking about behavior, either external to a person or internal to that person AND the status of the observer(s) as to their level of ability to accept, understand, tolerate that behavior, or, to be frightened, put off, in fear of death or grave bodily harm, etc.

60. Judgments as to displays of troubling behavior are ALWAYS an interactional dynamic. One can NEVER evaluate an individual without a clear understanding of context. Context is most centrally the concurrent evaluation of the other person who is making the judgment about the allegations made by the “other person(s).”

61. Nevertheless, there can be no question that great effort has been exerted by medical professionals to establish that “Mental illness is like any other medical illness,” notwithstanding the absence of any evidence-based data to support that identity. Suffering the loss of child to violence is NOT depression – it is grief. Escaping the confines of a crashed vehicle does NOT necessarily cause PTSD. And even if it did, PTSD is NOT a disease. Surviving the experience of multiple combat engagements produces combat stress, and, in some cases, persistent combat trauma experiences. Yet, neither of these events inherently produces PTSD.

62. Based upon my 51 years of professional practice, the “ill” and “illness” language emerged from the following sources: first, from the development of so-called psychotropic medications and their reputed efficacy in “treating” disturbing behavior; two, from the power of professional psychiatric organizations whose efforts created a welcoming context for those interventions; third, the hope that authoritatively defining as equivalent so-called “mental illness” with any “other form of medical illness” would increase the referral response, generate income, certainly

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

62. (cont'd),pleasing to the drug companies, and, perhaps, reduce the stigma associated with troubling individuals as they seek out "treatment."

63. In a paradoxical twist, if you will, diagnosing someone as "mentally ill" or "behaviorally unhealthy," perhaps in the service of reducing resistance to "treatment," has reduced the frequency of referrals rather than increasing it. Persons do not present themselves for "treatment" when characterized as "ill." The person knows full well that he/she has no temperature, no broken bones.

64. Yet there are other, less polemic and ideological, reasons that create a "stigma" for reaching out to assistive individuals for help, certainly one prominent one of which is the cost associated with paying for the service.

65. Associated with the cost is the experience and competence level of the person assisting the troubled individual(s). Insurance payments will not cover the cost of highly trained and experienced individuals. While that in itself doesn't create a context for stigmatization, it does decrease the likelihood that someone will present themselves for assistance from the most able providers.

66. And where there no longer exist the Community Mental Health (sic) Centers facilities that were prominent "back in the day" and where Federal and State funds supported payment, however named, the absence of such facilities now virtually guarantees that professional staff, although trained to meet licensing standards, are often compensated at levels well below their educational and training experience.

67. HIPAA notwithstanding, privacy of communication content between the one asking for and the one providing the service cannot be guaranteed. And that failure of privacy is particularly apparent in those matters where potential violence is at issue and some (many?) providers have no experience whatever with issues of violence and are thus prone to not accepting such referrals.

68. In addition, some states (most notably NYS)¹⁹ are now mandating that anyone who presents to a licensed professional where the issue is potential violence and such individual is thought by the provider to present a "reasonable danger" that professional MUST report that individual to law enforcement.

69. And I am not talking about issues that fall within the context of mandated reporting laws, but rather those which, given the naivete of far too many, present day service providers, simply "scare the provider." "Bare fear" does not rise to any level of evidentiary value. NONE.

70. So the last person to whom I would refer a person, say, for "anger management issues," would be to someone, with respect to whom I had prior knowledge, employed a "bare fear"

¹⁹ https://www.nyspsych.org/index.php?option=com_content&view=article&id=73:the-safe-act--guidelines-for-complying&catid=41:safe-act&Itemid=140 URL describes reporting requirements under its SAFE Act of 2013.

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

70. (cont'd). standard for violating confidentiality on the one hand, or, on the other hand, would be forced by Federal or State law to report what would amount to be the service provider's BARE FEAR.

71. In those kinds of matters, stigma is the least of the concerns at issue. Persons who desire assistance, especially as to those involving allegations of risk, will simply refuse to seek out assistance where governmentally mandated reporting is required. Tarasoff/Emerich (and its recently expanded version) and other such laws that follow from mandated reporting acts as to suspected child abuse are the only legal justifications authorizing breach of privilege in PA.

SUPPLEMENTARY DECLARATION

The Inadmissibility of Reports as to Extreme Risk Protection Orders (ERPOs).

72. The goals of ERPOs are irrelevant to the issues involved in the deprivation to an otherwise innocent victim of his/her rights to due process. I will not, however, make an argument on Constitutional grounds, since I am not a Constitutional lawyer.

73. Instead, I will make my declaration based upon more than 50 years of experience as a clinical and forensic psychologist and a police psychologist with 100's of hours of task-specific training in use of force, including deadly force, together with more than several 100's of hours of active, armed, on duty patrol with LE partners in both rural as well as large city departments. In addition, I am certified by two nationally recognized instructors in the law of self-defense and deadly force instructor. My Specialized Training Summary attached hereto will reflect that background.

74. Presumably, an individual who makes a report to LE as to his/her perception of danger that justifies immediate relief under proposed ERPO legislation presumably has some ground on the basis of which to make a verbal assertion claiming that he or she is in immediate need of protection.

75. Indeed, under Petition for order. Para 62B02 (b) Contents of petition. –A petition shall: (1) Allege that the respondent poses a significant danger of causing personal injury to self or others by having in the respondent's custody or control, purchasing, possessing or receiving a firearm and be accompanied by an affidavit made under oath stating the specific statements, actions or facts that give rise to a reasonable belief of future dangerous acts by the respondent.

76. The creators of this legislation apparently have no clue as to the reliability and validity of self-reports by a person whose interest in securing the order is entirely self-serving. Verbal reports by an involved witness as to the intentions or meanings of utterances by another person against whom the complainant is requesting the issuance of such an order are simple hearsay, absent any corresponding, independent validation by an uninvolved observer.

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

77. Especially in the context of high-conflict relationships such as those seen in custody disputes, spousal accusations as to infidelity, intimate partners involved in drug abuse/drug trade, the likelihood is high that any such reports made by the Complainant are, shall I say, false at worst or misleading at best. The Court has no way to know which to apply, given the inherent invalidity of self-reports and no credible, evidentiary grounds available to assist the Court.

78. And the Court has no credentialed grounds on the basis of which to make a credible assessment as to "future dangerousness," absent an immediate hearing at which time Complainant can be cross-examined as to the credibility and veracity of Complainant's allegations.

79. I have been involved in numerous threat assessment evaluations as part of my forensic psychologist experience. I have used the USSS Safe Schools Initiative, to assess the "future dangerousness" of students who were reported to have made threats of imminent danger or grave bodily harm to students and/or faculty, a high-risk assessment even though I am well trained to do them.

80. Even so, I would have engaged in malpractice of the first order had I sought to make that judgment without having first included an "immediate hearing" with both the alleged perpetrator of the threat and the recipient of the threat. And as well, to ensure that there was concurrent validity and reliability to my ultimate judgments, to include family members and faculty.

81. For as skilled as Judges are, they are NOT trained Threat Assessment professionals. Threat Assessment is a specialized art/science and no competent, ethical professional would ever rely entirely and only upon the unsubstantiated, likely self-serving claim, of an adversarial complainant.

82. And it is ludicrous to admit as "evidence" the purchase of a firearm (knife; baseball bat)? within the prior 12 months of the allegation as to Respondent's dangerousness absent an evidentiary hearing in which cross-examination is conducted to establish the validity of that kind of allegation.

83. In my professional opinion, so-called ERPO legislation **ALREADY EXISTS**. That is so because under PA Code Title 50, Chapter 15. Mental Health Procedures, Articles II and III, there are already protocols for voluntary and involuntary hospitalization (7201 et seq. and 7301 et seq) for admitting allegedly dangerous persons to secure facilities. Of course, real evidence needs to be presented because, first it is tested law, and second, it is a "due process" intervention, and thus has built in protection as to both Complainant and Respondent.

84. When I first began to learn about the justifiable use of deadly force, I learned that the presence of "bare fear" never met any level of proof that would justify the use of deadly force. "Bare Fear" is speculation, fantasy, and/or imagination. It emerges from an interactional dynamic between (at least) two individuals, and never justifies the use of any force whatever. It embodies no standard of proof.

AFFIDAVIT IN SUPPORT OF THE TESTIMONY of JOSHUA G. PRINCE, ESQ.
(cont'd).

85. "Bare fear" NEVER justifies the use of deadly force in a person to person conflict, and therefore, in my professional opinion, it can never subject an otherwise innocent citizen to the equivalent of Constitutional death.

FURTHER THIS AFFIANT SAITH NAUGHT.

/s/ H. Anthony Semone, PhD

H. ANTHONY SEMONE, PhD

Police and Forensic Psychologist

9/13/2019

DATE

Sworn to and subscribed before me
this 13th day of Sept 2019

Margaret M. Angeloni

COMMONWEALTH OF PENNSYLVANIA

NOTARIAL SEAL
MARGARET M. ANGELONI, Notary Public
City of Philadelphia, Phila. County
My Commission Expires May 26, 2020

VITAE

H. ANTHONY SEMONE, PhD
Licensed Psychologist (PS002249L)
1 Bala Ave., Suite 125.
Bala Cynwyd, PA 19004

Tel #: 215-327-1887
copdocster@gmail.com

PRIMARY AREAS OF PROFESSIONAL PRACTICE

Providing clinical psychological treatment and assessment services for First Responders and Family members, to include Critical Incident Stress Debriefing, Extended Debriefing, and such other treatment interventions as are appropriate to the referring issues and within the range of my professional competencies. Those interventions would include evidence-based methods to enhance the integration into a Responder's life their exposure to life-threatening events, persistent, daily stressors, and/or the effects of those events on family members.

Providing suitably qualified, private citizens with protocols by which to evaluate the legal requirements, under PA law, as to the Justification Defense, to include expositions of black-letter law, case law, and jury instructions. While not legal advice, educating such individuals in the legal requirements of use of force enhances their ability to know when and to what extent a use of force is justifiable; and, also to choose legal counsel in the event of need for such expertise. These educational protocols also include explication of the neuropsychological correlates of use of force in defense of self, others and property so as to understand better the extent to which those phenomena associate with the use of force prior to, during and post-use of force.

Providing a retaining entity with evidence-based opinion(s) as to the neuropsychological, behavioral, and emotional complexities of a person's, whether private citizen, law enforcement and/or military, use of force in defense of self, others, or property, within the legal context of the defense of self-defense, as well as, providing a retaining entity with evidence-based opinions as to the danger posed by a given individual to self-and/or others within especially suicidal, domestic violence, and/or extreme risk protection contexts.

ACADEMIC EDUCATION

Kent State University

PhD - Clinical Psychology	03/1967 - 07/1968
Internship – Clinical Psychology	09/1966 - 06/1968
MA - Psychology	09/1964 - 03/1967

University of Florida

Master of Rehabilitation Counseling	09/1962 - 07/1963
-------------------------------------	-------------------

Bachelor of Arts, Psychology

09/1959 - 06/1962 ¹

09/1956 - 06/1957

SPECIALIZED PROFESSIONAL PSYCHOLOGY TRAINING²

CLINICAL PSYCHOLOGY

Externship in Family Therapy
Family Therapy Training Center
Philadelphia Child Guidance Clinic
Philadelphia, PA
Director – Bernice Rosman, PhD

09/1985 – 05/1986

Critical Incident Stress Debriefing
International Critical Incident Stress Foundation
Pittsburgh, PA
George Everly, PhD Jeffrey Mitchell, PhD Directors

12/2000

CLINICAL NEUROPSYCHOLOGY

Halstead-Reitan Neuropsychological Test Batteries
Reitan Neuropsychology Laboratory
Coronado, CA
Ralph M. Reitan, PhD, and Associates

12/1973

Halstead-Reitan Neuropsychological Test Batteries
Certification in Administration of Test Batteries
Reitan Neuropsychological Laboratory
Tucson, AZ
Ralph M. Reitan, PhD and Deborah Wolfson, PhD

10/1989

Integrative Neurosciences
Medical College University of Pennsylvania
Philadelphia, PA
Peter Sterling, PhD, Director

09/1992 – 05/1993

PROFESSIONAL PSYCHOLOGIST EMPLOYMENT³

Independent Practice of Police, Forensic Psychology and
Clinical Neuropsychology
Private Practice

¹ Discontinuity in time attributable to Dr. Semone's active duty service with USMC 07/57 to 04/59 and summer employment that followed prior to start of the forthcoming school year.

² For brevity, specialized training is not inclusive of all training taken within the context of 51 years of professional practice.

³ Employment dates are not consecutive secondary to working concurrently in multiple locations.

⁴ Concurrently practicing in this specialty area secondary to certification by examination in the specialty area of high intensity, controlled momentum physical exercise.

Philadelphia, PA	05/2016 - Present
Independent Practice of Police Psychology, Forensic Psychology, Clinical and Clinical Neuropsychology Private Practice Wyndmoor, PA	05/1995 - 05/2016
PROFESSIONAL PSYCHOLOGIST EMPLOYMENT (cont'd)	
Clinical, Health and Exercise Psychology ⁴ Slow Works, LLC, Flourtown, PA	10/2004 - 10/2010
GKSW/Crystal Group Associates Limited Practice of Clinical Psychology Wyndmoor, PA	06/2001 - 02/2003
Independent Practice of Clinical Psychology, Clinical Neuropsychology, and Forensic Psychology Private Practice York, PA	01/1992 – 04/1995
Director of Clinical Services and Neuropsychology Neuro Unit, Bancroft Rehabilitation Services Haddonfield, NJ	03/1991 - 08/1992
Internal Consultant The Abraxas Foundation Pittsburgh, PA	08/1990 - 02/1991
Staff Clinical Neuropsychologist The Rehabilitation Hospital of York York, PA	06/1987 - 08/1990
Clinical Psychologist and Family Therapist The Child and Adolescent Psychiatric Unit York Hospital, York, PA	02/1986 – 05/1987
Independent Practice of Clinical Psychology, Clinical Neuropsychology and Forensic Psychology Private Practice York, PA	06/1986 – 08/1990
Associate Professor of Psychology Independent Practice of Clinical and Forensic Psychology Clarion State College (now Clarion University of Pennsylvania) Clarion, PA	09/1975 - 05/1986

Externship in Forensic Psychology⁵
Mental Health Associates
Tallahassee, FL

09/1977 - 06/1978

PROFESSIONAL PSYCHOLOGIST EMPLOYMENT (cont'd)

Independent Practice of Clinical Psychology, Clinical
Neuropsychology, and Forensic Psychology
Private Practice
Pensacola, FL

06/1971 - 08/1975

Adjunct Professor Psychology⁶
University of West Florida
Pensacola, FL

01/1969 - 05/1975

Staff Psychologist
Escambia County Community Mental Health Center
Pensacola, FL

08/1968 - 06/1971

Vocational Rehabilitation Counselor
Cardiovascular Surgical Unit
Medical Hospital of Charleston
Charleston, SC

08/1963 – 07/1964

AREAS OF PRACTICE

Clinical Psychology. Given his extensive history in evaluating and treating violent individuals, Dr. Semone is well-qualified to provide comprehensive assessments⁷ of persons alleged to present a high risk for engaging in violent behavior, either Self or Other directed, or both. Those individuals would include persons alleged to place intimate partners at extreme risk as well as ones regarded as posing threats to fellow students and/or teachers. Dr. Semone's assessments are systemic in nature, that is, they are carried out by involving as integral parts of the evaluation those persons who have made the referral for the assessment, and also, where willing, or Court-ordered to do so, those person(s) who represent the complainants. Dr. Semone actively seeks out law enforcement participation in that process.

The assessment instruments used by Dr. Semone in these evaluations consist of those materials that are behaviorally specific to the issue in question, validated, and representative of those used by other professionals engaged in the assessment of high-risk behavior toward others, toward self, or both. In Dr. Semone's professional judgment, violent threatening of persons also requires evaluating the alleged or con-

⁵ On educational leave from Clarion State College during the noted time period to carry out the externship.

⁶ Adjunct position concurrent with employment at Escambia County Mental Health Center and with subsequent private practice.

⁷ All assessments carried out by Dr. Semone contain either embedded measures, external measures, or both, designed to assess the validity of the results produced by the examinee.

victed perpetrator for level of suicidality. The history of the ultimate demise of active shooters cannot be ignored in any proactive assessment.

Of central importance in any assessment, clinical or forensic, but especially those conducted as to the evaluation of high-risk individuals, is the need to incorporate within the overall test battery those tests that are specifically designed to measure the extent to which, if any, that the test-taker is giving either less than full effort and/or intentionally biasing his or her answers, thereby compromising the validity of the results. Dr. Semone's approach to the production of insufficient effort by the examinee is to consider the results invalid, offer normative data as to how

Clinical Psychology (cont'd)

"poor effort" or "invalid data" effect the validity of other obtained test scores, present that information to the relevant entities, so that the entity can make an appropriate decision as to further judicial proceedings. All examinees and counsel are apprised of my use of such validity measures and are free to refuse to go forward with the examination.

Clinical Neuropsychology. Using the Halstead-Reitan Neuropsychological Test Batteries, Dr. Semone has evaluated scores of individuals across a wide range of brain-related conditions, to include in specific cases, stroke, head injury, tumors, aneurysms, arterio-venous malformations, anoxic encephalopathy, toxic exposure, post-concussive syndrome and developmental delays, among others. He has offered testimony in both State and Federal courts on the effects of an individual's exposure to childhood trauma and the impact thereof on lowering defendant's threshold for the commission of violent behavior toward others.

Within the Use of Force specific context of Dr. Semone's clinical neuropsychological training and practice, as well as his professional exposure to high intensity, potentially harmful force events, he has become familiar with the extent to which the brain, as the primary organ responsible for adaptive human behavior, is involved in the orchestration of a person's behavior from initial exposure, during, as well as after having been faced with those experiences.⁸

As a clinical neuropsychologist, it is within his domain of expertise to offer this testimony, and, hence, has been court-qualified in several jurisdictions across the country, where data acquired in his evaluation has met Frye or Daubert standards, as to the neuropsychological and neurophysiological effects on the behavior of the defender in his or her use of force. Those brain-related effects are seen in many such confrontations noteworthy of which are in instances of alleged or adjudicated partner violence. They are also prominently displayed in private citizens and law enforcement officers across the temporal and behavioral sequence associated with the use of deadly force.

Police Psychology.⁹ Dr. Semone has acquired over 1300 hours of training, both didactic and experiential, in courses designed to identify and respond to the behavioral and psychological characteristics of lethal confrontations. He has provided training and consultation to members of police departments on such issues as post-shooting trauma, post-violent event trauma, domestic violence, sexual offending, interventions in threatened suicide, and officer selection. He has also provided consultation to a state police

⁸ Recent, peer reviewed research, in which Dr. Semone has had formal training, has shown that neurological and cardiovascular responses are intimately interwoven.

⁹ See Attached summary of specialized training in the use of force.

firearms' training unit and a major county police department firearms' training unit on the role played by neuro/cardiovascular factors attendant to deadly force encounters.

Dr. Semone also has evaluated and intervened on behalf of law enforcement officers suffering from the persistent effects of post-shooting trauma and post-traumatic stress disorder. He has provided pro-bono testimony in a Federal sentencing hearing as to mitigation in the sentencing phase in the case of a former police officer who had been shot in the line of duty and almost killed in the encounter. In that case, Dr. Semone was qualified as an expert in post-shooting trauma and post-traumatic stress disorder secondary to his qualification as a clinical psychologist.

Secondary to his role as a departmental psychologist for two police departments, Dr. Semone has acquired over 300 hours of patrol experience. While not commissioned, he was authorized to accompany officers to provide

operational support; to assist in providing after-contact reviews; and, to provide them with the opportunity to discuss personal matters of importance with the assurance of privilege and confidentiality. Each department had

Police Psychology (cont'd)

endorsed his role in supporting the officers' ability to "keep their head in the game." Pursuant to his direct participation in the daily experience of officers on so-called "routine" patrol, Dr. Semone knows directly the stressor-impact on officers, as well as specialized unit members (SWAT; Narcotics) of seemingly innocuous calls for service that, upon arrival and contact, turn out to be quite different, with life threatening potential.

And in the context of life-harming events, potential as well as actual, Dr. Semone, in his many years of consultation to law enforcement entities, has been called upon to provide numerous Critical Incident Stress Debriefings of Officers and Deputies, to include their family members, secondary to those personnel having been either directly or vicariously involved in episodes where deadly force had been threatened and/or used.

Forensic Psychology. Though no longer practicing in the civil arena, Dr. Semone has been retained in numerous civil injury cases and has testified in hearings and trials in several of those cases. He has also been involved as

a court-qualified expert in custody cases in which the Court was seeking to secure his assistance to increase the Court's ability to provide for non-adversarial based decisions.

In criminal matters, Dr. Semone has served as a trial consultant for cases in both state and federal courts. He has evaluated persons on referral from private attorneys as to the effects of traumatic brain injuries on their client's post-use of force behavior. He has also provided affidavits in cases involving criminal homicide and has been retained and court-qualified in both state and federal courts as an expert in clinical neuropsychology and provided testimony in several cases in which the death penalty had either already been rendered or was being sought. Dr. Semone has been retained on behalf of the defense in over 60 cases across the United States where criminal homicide had been charged and a death penalty either was being sought or had been already applied.

Dr. Semone has also provided testimony in support of the defense of not guilty by reason of insanity. He has testified on behalf of the prosecution in a case in opposition to release from a mental hospital following a verdict of not guilty by reason of insanity. He has also testified for the prosecution on behalf of a po-

lice officer murdered by a defendant in a retrial of a case overturned by that state's Supreme Court. Though not testifying, Dr. Semone was retained by defense counsel to provide continuing consultation to the defense team in a case involving alleged mass murder and terrorism.

Use of Force. Dr. Semone's academic use of force training encompasses the rules of engagement for both private citizens as well as law enforcement personnel. His didactic training in the legal principles of use of force, especially as to the critical role played by case law and jury instructions, while not credentialing him as an attorney at law, nevertheless has provided him with the framework within which to estimate for a given individual whether or not a potential use of force may or may not comport itself with the jurisdiction's legal requirements for it.

More specifically, that legal course work includes instruction not in only the elements required for a justification defense as in innocence (freedom from fault); imminence; proportionality; avoidance; and, reasonableness. It also covers the issues of who bears the respective burdens of proof and persuasion. It covers both statutory and case law with respect to Castle Doctrine, curtilage, highly defensible property, legal presumption of reasonable fear, self-defense immunity, and other such state specific matters. For law enforcement officers, that training also includes, among others, the US Supreme Court Rulings as found in *Graham v. Conner*, *Garner v. TN* and the reasonableness, necessity and proportionality parameters in use of force.

As well, Dr. Semone's use of force training has provided him with the means by which to assist persons, law enforcement, military and private citizens, with the knowledge by which to gauge the efficacy of potential legal

Use of Force (cont'd)

counsel in cases involving use of force. It has enabled him to structure for a private citizen what is essentially the law enforcement equivalent of a use of force policy. That policy addresses the critical elements of how the defender should consider responding to a deadly threat; how, when and what to say in initial contact with 911; how to respond and what to say to arriving officers; what to understand about the psychological factors involved in the investigation, arrest, booking, jailing.

In one such case, Dr. Semone was court-qualified as an expert in the post-shooting psychological impact of a deadly force encounter as to an attorney's client charged with the murder of a neighbor. The issue at hand addressed the dissociative impact of the use of deadly force and the extent to which the appearance of post-shooting event normalcy does not preclude the presence of bona fide neurophysiological sequelae sufficient to account for the post-shooting behavior.

In yet a second case, the presence of body alarm reactions precluded the defendant from recognizing the cessation of the perpetrator's attack and defendant's failure to terminate his defensive response. The judge ruled in that case that the continuation of his defensive response was disproportionate because the attacker no longer posed an imminent threat of grave bodily harm or death.

Current as of 19 Aug 2019

(References upon request)

**H. ANTHONY SEMONE, PhD
Licensed Psychologist (PS002249L)
1 Bala Ave., Suite 125.
Bala Cynwyd, PA 19004**

**Tel#: 215-327-1887
copdocster@gmail.com**

SPECIALIZED TRAINING IN THE USE OF FORCE

LEGAL PRINCIPLES TRAINING

Judicious Use of Lethal Force for the Private Citizen Lethal Force Institute Concord, NH Massad Ayoob, Director	1992, 1994
Certified Advanced Instructor in Police Use of Force and Risk Management Smith and Wesson Academy Springfield, MA Tom Aveni, MA and Steve Avery, Directors	1999
Judicious Use of Lethal Force for the Private Citizen Harrisburg, PA Massad Ayoob, Director	2014
Judicious Use of Lethal Force for the Private Citizen Harrisburg, PA Massad Ayoob, Director	2015
Graduate, Instructor Graduate Program Law of Self Defense Academy Certification by Written Examination Andrew Branca, Esquire On-line Academy	2017
State Specific Training as to Laws of Self-Defense PA, CT, MA, NJ, NC, FL Law of Self Defense Academy Andrew Branca, Esq. On-Line Academy	2017/2018
Continuing Education Laws of Self-Defense On-line Webinars Andrew Branca, Esq.	2019

LEGAL PRINCIPLES TRAINING (cont.)

**Deadly Force Instructor
Certification by Written Examination
And Mock Trial Performance
Massad Ayoob Group
Giddings, TX**

02/2018

LETHAL WEAPONS TRAINING

Firearms Instructor Certifications

**Certified Stressfire Instructor Combat Pistol and Combat Shotgun*
Firearms Academy of Seattle/Lethal Force Institute
Onalaska, WA
Marty Hayes and Massad Ayoob, Lead Instructors** **1996**

**NRA Certified Law Enforcement/Security Firearms
Instructor (#BWF6337J)*
Chapman Academy
Columbia, MO
Clive Shepherd, Lead Instructor** **1996**

**PA State Police Certified Firearms Instructor (LW#7023)
Found qualified, secondary to review of credentials
PA State Police Lethal Weapons Act 235
/s/ P. Evancho, Col. PASP** **1996**

**Certified Reduced Light Training Instructor*
Smith and Wesson Academy
Springfield, MA
Tom Aveni, MA Lead Instructor** **1999**

Prevailing in Low Light Instructor Certification*
Strategos International
West Palm Beach, FL
Mark Warren, Ken Good, Lead Instructors** **2002**

Law Enforcement Response to the Active Shooter*
Instructor Certification, Strategos International
Mark Warren, Ken Good Lead Instructors, St. Cloud, FL** **2004**

LESS THAN LETHAL WEAPONS TRAINING

Less than Lethal Instructor Certifications

**Experimental, Advanced Course in Threat Management
NLETC & LFI Certification as Police Instructor in Weapon Retention***

LESS THAN LETHAL WEAPONS TRAINING (cont'd)

Less than Lethal Instructor Certifications (cont.)

Lethal Force Institute Concord, NH Massad Ayoob Director	1995
LFI and PRO-Systems Certification as Police Instructor in Kubotan/Persuader Baton* Lethal Force Institute Concord, NH Massad Ayoob, Director	1995
Physical Conflict Resolution Instructor Certification** Strategos International Reedsburg, WI Ken Good, Lead Instructor	2002

WEAPONS-SPECIFIC TRAINING

Advanced Weapons Training – Sidearm

United States Marine Corps Marine Corps Recruit Depot Parris Island, SC Colt 1911A1 .45 Cal. Qualified Marksman	07/57 -10/57
Advanced Pistol Course Chapman Academy – Graduate* Columbia, MO Ray Chapman, Director	1993
Farnum Method of Defensive Handgunning Defense Training International Pittsburgh, PA John Farnum, Director	1995
Tactical Handgun for the Protection Specialist** Smith and Wesson Academy Springfield, MA Bert DuVernay, Lead Instructor	1995
Distinguished Graduate – Taylor Method* Defense Associates of CT Blue Trail Range Wallingford, CT Chuck Taylor, Lead Instructor	1996

WEAPONS-SPECIFIC TRAINING (cont.)

Advanced Weapons Training (cont.)

Defensive Handgun 2 – Graduate*
Thunder Ranch #1,
Camp Wood, TX (present name)
Clint Smith, Lead Instructor 1996

Close Quarters Battle Pistol*
Smith and Wesson Academy
Springfield, MA
Bob Taubert, Lead Instructor 2000

Urban Tactical Handgun Seminar*
Defense Associates of CT
Blue Trail Range
Wallingford, CT
Chuck Taylor, Lead Instructor 2001

Officer Survival Training Program
Presenter and Participant
Firearms Training Unit
Baltimore County (MD) PD
Baltimore, MD
Sgt. Todd Rossa, Lead Instructor 2001

Active Shooter Training Program***
Firearms Training Unit
Baltimore County (MD) PD
Baltimore, MD
Sgt. Todd Rossa, Lead Instructor 2002

Advanced Weapons Training – Rifle

United States Marine Corps
Marine Corps Recruit Depot
Parris Island, SC
Springfield Garand M-1 30-06 cal. Expert
G/Sgt John J. Dugan III CDI 07/57 – 10/57

Close Precision Rifle Engagement
Qualified Advanced FBI Sniper Protocol
Hart .308 cal. Rifle Horus Vision scope
Storm Mountain Training Center
Elk Garden, WV

Rod Ryan, Director and Lead Instructor 2005

WEAPONS-SPECIFIC TRAINING (cont.)

Advanced Weapons Training - Rifle

Long Range Precision Rifle I
Qualified .308 Cal. 175 gr. BH HPBT to 800 yards
Central Virginia Tactical
Louisa, VA
Vern Harrison, Director and Instructor 2005

Long Range Precision Rifle II
Qualified .308 Cal. 175 gr. BH HPBT to 1000 yards
Central Virginia Tactical
Louisa, VA
Vern Harrison, Director and Instructor 2006

Introduction to the Combat Carbine**
Basic skill acquisition with M4 5.56 platform
Met Qualification Standards
Black Hat Tactical Training Group
Frank Wissing, Lead Instructor 2011

Force on Force, Scenario-Based Training

Prevailing in Low Light Instructor Certification***
Strategos International
West Palm Beach, FL
Mark Warren, Ken Good, Lead Instructors 2002

Law Enforcement Response to the Active Shooter***
Instructor Certification, Strategos International
Mark Warren, Ken Good Lead Instructors, St. Cloud, FL 2004

Tactical Entry - Ensnoced Subject Training***
Hazleton City (PA) Police Department SWAT
Butler Township Facility
Butler, PA
Det. Lt. Jason Zola, Lead Instructor 2018

Massachusetts State Police Firearms Training Unit 2000

Baltimore County (MD) Police Department
Firearms Training Unit 2001

Strategos International 2003

Berks County Sheriff's Department	2009
Baltimore County (MD) Police Recruit Academy	2011
PROFESSIONAL CONSULTATION TO LAW ENFORCEMENT ENTITIES (cont.)	
Indiana SWAT Officers Association	2011
Multiple Police Departments in the Northern Tier of PA to include: Butler Township, Hazelton City PD, Sugarloaf Township PD, Rush Township PD, West Hazleton PD, Freeland Borough PD, Berwick Borough PD, Mahanoy City Borough PD. Sheriff's Department, Reading, PA High Risk Warrant Unit.	2006 – 2019

Court Appearances Involving Law Enforcement Officers.

Appeared in York County, York, PA on behalf of juvenile defendant's attorney in a case of alleged excessive use of force as to the Officer against the juvenile and juvenile's alleged retaliation.

Appeared in State Court on behalf of a murdered Law Enforcement Officer in the resentencing of the defendant following that State's rescinding of its death penalty.

Appeared in Federal Court, Pittsburgh, PA on behalf of Officer's attorney in a hearing as to sentencing mitigation of an Officer suffering from post-shooting trauma and post-traumatic stress disorder.

Appeared in Federal Court, Baltimore, MD on behalf of the Officer's attorney's in a matter involving an Officer accused of Aggravated Assault and Terroristic Threats by Communications as to a government official.

In each of the above cases, Dr. Semone was qualified by the Court to render an expert opinion as to the issues at hand. There has never been an occasion in Dr. Semone's professional history where he has been disallowed from offering an expert opinion.

PUBLICATIONS

Dr. Semone is the contributor of a chapter in the book entitled: "Straight Talk on Armed Defense" Edited by Massad Ayoob. Published by Gun Digest Books 2017. His chapter is entitled:

"Psychological Aftermath of a Citizen's Use of Lethal Force."

Dr. Semone has also contributed to an article authored by Gila Hayes and published in the June 2010 - edition of the eJournal of the Armed Citizens' Legal Defense Network entitled:

"Defending Self-Defense: Psychology's Role"
http://www.armedcitizensnetwork.org/images/stories/journal/2010/Network_2010-06.pdf

Dr. Semone also authored the article:

“Physical Conflict Resolution – An Analysis”
<http://www.progressivecombat.com/pdfs/PCR-Analysis.pdf>

REFERENCES UPON REQUEST
(Current as of 08/19/2019)

Exhibit B

Curriculum Vitae of Joshua G. Prince, Esq.

Joshua Prince, Esq.

Civil Rights Defense Firm, P.C.
646 Lenape Rd
Bechtelsville, Pa 19505
888-202-9297 ext 81114
610-400-8439 (fax)
Joshua@CivilRightsDefenseFirm.com

BAR ADMISSIONS

State Admissions

Pennsylvania Supreme Court – October 13, 2009
Maryland Court of Appeals – June 12, 2017

Federal Admissions

U.S. Supreme Court – January 22, 2013
U.S. Court of Appeals for the D.C. Circuit – February 15, 2019
U.S. Court of Appeals for the 3rd Circuit – April 11, 2012
U.S. Court of Appeals for the 6th Circuit – July 17, 2017
U.S. District Court, Eastern District of Pennsylvania – March 19, 2010
U.S. District Court, Middle District of Pennsylvania – February 10, 2012
U.S. District Court, Western District of Pennsylvania – December 20, 2012
U.S. District Court, District of Columbia – August 6, 2018 (Bar No. PA0081)
U.S. District Court, District of Colorado – June 16, 2011

EDUCATION

McGill University, Montreal, Canada

- **Double Major in Political Science and World Religions**
- **Graduated Cum Laude**

Widener University of Law, Harrisburg, PA

2006 - 2009

- **Top 10% of class**
- **Member of the Widener Law Journal**
- **Graduated Cum Laude**

EMPLOYMENT

Prince Law Offices, P.C., Bechtelsville, PA

2009 - present

- Handling legal matters, including, but not limited to:
 - Civil Rights deprivations at the state and federal level, including unlawful seizure, failure to provide procedural and substantive due process, and violations of equal rights;

- Class Actions;
- Mental Health Commitments under Pennsylvania’s Mental Health and Procedures Act;
- Criminal Law;
- School Law, including requirements to provide students with due process and the appointment of school law enforcement officers; and,
- Estate Planning and Administration.

Civil Rights Defense Firm, P.C., Bechtelsville, PA 2016 - present

- Handling legal matters, including, but not limited to:
 - All firearms law and Second Amendment issues at the state and federal level;
 - Civil Rights deprivations at the state and federal level, including unlawful seizure, failure to provide procedural and substantive due process, and violations of equal rights; and,
 - Class Actions.

MAJOR CASES

- *Alton Franklin v. Sessions, et al.*, 291 F.Supp.3d 705 (W.D. Pa. 2017) – Establishing that a 302 evaluation under Pennsylvania’s Mental Health and Procedures Act does not trigger a federal prohibition under 18 U.S.C. § 922(g)(4), due to the lack of due process provided.
- *Commonwealth v. Goslin*, 2017 PA Super 38 (*en banc*) – Establishing that an individual is entitled to the defense found within 18 Pa.C.S. § 912(c), if he/she is in lawful possession of a weapon on school grounds, provided that it is possessed for a lawful purpose.
- *Michael Keyes, et al., v. Lynch, et al.*, 195 F.Supp.3d 702 (M.D. Pa. 2016) and 282 F.Supp.3d 858 (M.D. Pa. 2017) – Establishing a right to relief under a Second Amendment *as-applied* challenge to a single-isolated involuntary mental health commitment. The court held that 18 U.S.C. § 922(g)(4)’s prohibition, in perpetuity, was unconstitutional as applied.
- *John Doe, et al. v. Franklin County, et al.*, 139 A.3d 296 (Cmwlth. Ct. 2016) – Establishing that pursuant to 18 Pa.C.S. § 6111(i) that all license to carry firearms applicant information is confidential and not subject to disclosure, including through the use of un-enveloped postcards.
- *Andrew Dissinger v. Manheim Township School District*, 72 A.3d 723 (Pa. Cmwlth. 2013) – Represented Mr. Dissinger in an action regarding violations of his due process rights, which the Commonwealth Court confirmed. Thereafter, represented Mr. Dissinger in a federal civil rights deprivation action, 5:14-cv-2741 in the Eastern District of Pennsylvania, which resulted in a settlement.

- *Justin Dillon v. City of Erie*, 1038 C.D. 2013 (Pa. Cmwlth. 2013) – Establishing that state preemption precludes the City of Erie’s ordinance criminalizing the possession of firearms in city parks.
- *John Doe, et al. v. City of Philadelphia, et al.*, Docket No. 121203785, (Philadelphia County Court of Common Pleas, 2012)– Class action lawsuit against the City of Philadelphia and several other defendants relating to their publication of statutorily confidential information, which resulted in a \$1.425 million dollar settlement.
- *Barbara Hensch, et al., v. Perry County Sheriff Carl Nace*, Docket No. 2014-454 (Perry County Court of Common Pleas, 2014) – Successfully represented Sheriff Nace, *pro-bono*, in an action by the Perry County Auditors to force him to disclose statutorily confidential information.
- *Caba v. Weaknecht*, 64 A.3d 39 (Pa. Cmwlth. 2012) – Before the Commonwealth Court, successfully established both a liberty and property interest, for procedural due process purposes, in an issued license.

PUBLICATIONS

Law Journal Publications

- Joshua G. Prince and Allen Thompson, *The Inalienable Right to Stand Your Ground*, St. Thomas Law Journal, 27 St. Thomas. L. Rev. 32 (2015)
- Joshua G. Prince, *Fee Disputes in Workers' Compensation Cases: The Hendricks/Weidner Headache*, Widener Law Journal, Vol. 18, No. 2 (2009)
- Joshua G. Prince, *Violating Due Process: Convictions Based on the National Firearms Registration and Transfer Record when its "Files are Missing"*, Article awaiting publication in a Law Journal, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2752028

Legal Publications

- Joshua G. Prince, *Weapons on School Grounds: The En Banc Goslin Decision* (PA BAR ASSOC. AT ISSUE, Spring 2017) available at <http://www.pabar.org/public/yld/pubs/atissue/At%20Issue%20Spring2017.pdf>.

- Joshua G. Prince, *Grandpop's Machine Gun in the Chest: Part II of II* (PA BAR ASSOC. AT ISSUE, Spring 2013) available at <http://www.pabar.org/public/yld/pubs/atissue/AtIssueSpring13.pdf>.
- Joshua G. Prince, *Grandpop's Machine Gun in the Chest: Part I of II* (PA BAR ASSOC. AT ISSUE, Fall 2012) available at <http://www.pabar.org/public/yld/pubs/atissue/AtIssue%20Fall%202012.pdf>.
- Joshua G. Prince, *Firearms Law 101: Knowing When Your Client Loses His/Her Second Amendment Rights*, (PA BAR ASSOC. AT ISSUE, Spring 2012) available at <http://www.pabar.org/public/yld/pubs/atissue/AISpring2012.pdf>.
- Joshua G. Prince, *I Bequeath My Machine Gun to...* (PA BAR ASSOC. NEWSLETTER, REAL PROPERTY, PROBATE AND TRUST LAW, Issue No. 64), Fall 2007 at 18-19.

LEGAL SEMINARS TAUGHT

- **Pennsylvania License to Carry Firearms Overview** – 96th Annual Pennsylvania Sheriffs' Association Conference – July 11, 2018
- **The 4473 and You** – Penn State Law School – April 5, 2018
- **Understanding the Second Amendment, Mental Health Prohibitors and Federal Firearms Right Restoration** – USCCA Expo – April 8, 2017.
- **Gun Law: Advanced Issues** – National Business Institute (NBI) – January 31, 2017
- **My Estate Has Firearms, Now What?** – 15th Annual Estate & Elder Law Symposium, PBI – Feb 12, 2014 and Feb. 20, 2014 and 20th Annual Estate Law Conference, PBI – November 14, 2013
- **Firearms and Real Estate in Estates** – Estate Planning Council of Lehigh Valley – February 13, 2013
- **2012 Firearms Law & The Second Amendment Symposium** – View from the Street: Firearms Law in Pennsylvania and New Jersey – NRA – October 13, 2012
- **Firearms Law for Every Practitioner** – Berks Bar Assc. – July 11, 2012
- **When the Primer Ignites No More** – 18th Annual Estate Law Conference, PBI – November 18, 2011

- **Pennsylvania Gun Crimes and Sentencing** – Montgomery Bar Assc. – Sept. 9, 2011
- **Firearms & Estates** – PBI – Apr. 7, 2011
- **Firearms Law 101 – What Every Practitioner Need to Know about Firearms Law** – Berks Bar Assc. – Aug. 18, 2011
- **Firearms in Estates and Trusts** – Berks, Cumberland, and Dauphin Bar Assc. 2008-2009.

Exhibit C

*Declaration of Peter R. Breggin, M.D. in Shirley Lacuzong,
et al., v. Smithkline Beecham Pharmaceuticals, et al., Case
No. 773623*

Vince D. Nguyen, Esq. (SBN 171768)
Law Offices of Vince D. Nguyen
2858 Stevens Creek Blvd., Ste 102
San Jose, CA 95128
ph (408) 296-1881/Fax (408) 296-0474

In Association:
Donald J. Farber, Esq. (SBN 168837)
c/o Law Office of Donald J. Farber
1907 Las Gallinas Ave.
San Rafael, California 94903
Ph (415) 491-0674/Fax (415) 491-0829

Attorneys for Plaintiff

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SANTA CLARA**

SHIRLEY LACUZONG, individually, and as successor-in-
interest of Reynaldo Lacuzong, Rechele Lacuzong and
Reniel Lacuzong,

Plaintiffs

vs

JESSICA DAVIDSON, MILPITAS ACUTECARE &
GENERAL MEDICINE, SMITHKLINE BEECHAM
PHARMACEUTICALS, LONGS DRUG STORES
CALIFORNIA, INC.,
and DOES 1 through 20,

Defendants

Case No.: CV 773623

**DECLARATION OF PETER R.
BREGGIN, MD.**

Judicial Arbitration Hearing:

Date: August 14, 2001

Time: 10.00 a.m.

Arbitrator: Timothy J. Schmal

Trial Date: None

Complaint filed: April 28, 1998

IT IS HEREBY DECLARED UNER PENALTY OF PERJURY

1. My name is Peter R. Breggin, M.D. On October 3, 1999, I was retained as a consultant and expert witness by the plaintiff's attorney in this action. In this declaration I opine on the professional conduct and the standard of care given by defendant SmithKline Beecham Corporation, and on the inadequacy of safety warnings given to the physician on the drug Paxil by that defendant. I further opine on issue of causation, specifically that Paxil induced Reynaldo Lacuzong to commit the destructive acts in question.

2. I am licensed to practice medicine in Maryland, Virginia, Washington DC, and New York. I have been in the private practice of psychiatry since 1968 and I am identified in the State of Maryland as a specialist in psychiatry. I am the founder and International Director of the International Center for the Study of Psychiatry and Psychology (ICSPP), in Bethesda, Maryland, a professional organization with more than 1,500 members. I am the Founder and Co-Editor of the peer review journal, Ethical Human Sciences and Services and hold the position of editor on several other peer review journals. I have written more than two dozen peer review scientific articles and more than 15 professional books. My additional qualifications to testify as an expert are attached. I incorporate to this declaration, and declare to be truthful the attached appendices: (a) Summary and Annotated Resume of Peter R. Breggin, M.D., (b) Bibliography of Peter R. Breggin, M.D., and (c) Peter Breggin, M.D., Trial Testimony Accepted in Court.

3. In this declaration and in the expression of my opinions, I rely upon the totality of my professional career, including all of my writings listed in the appendices and the materials cited therein. In addition, I have reviewed and relied upon the written materials provided by plaintiff's attorney. They are substantial, and include 46 pages of medical charts of Reynaldo Lacuzong taken from 1995 to his death, the San Jose police report, and depositions of Shirley Lacuzong, Bert Ducusin, Jessica Davidson (two depositions), SmithKline's Ian Hudson, and David Wheadon. My opinions have also been formed as the result of extensive review of SmithKline Beecham and Food & Drug Administration ("FDA") documents on Paxil. They include Paxil's prescribing information as found in the label for Paxil as reproduced in the Physicians' Desk Reference and as produced by SmithKline, including those proposed to the FDA by SmithKline in 1992 and those in effect in 1996 and 1997. I joined plaintiff's counsel for 3 days of a Paxil document review at SmithKline facilities in Collegeville, Pennsylvania, in February 2000. We reviewed Paxil documents and files continuously for those 3 days, and received custody of approximately 1050 pages of documents. My notes for that period are extensive. The documentation reviewed included adverse events reported on Paxil patients during the clinical trials for depression, and correspondence between SmithKline and the FDA. In addition I requested from the FDA and received from them in the neighborhood of 1,000 pages of Paxil documents and microfiche via Freedom of Information procedures. I reviewed the 150 page transcript recorded during the FDA committee hearing held on 10.5.92 that cleared Paxil for the U.S. market.

Preliminary Report in Regard to Product Liability

At the beginning of this report it is important to affirm that SKB remains responsible for its behavior even though it must get FDA approval for its final label and its right to market the drug. FDA regulations always allow a company to upgrade its adverse reactions (to strengthen its warnings) without prior approval. In addition, the FDA can only respond to data that has been generated by the company, and SKB, as this report will document, repeatedly found ways to hide or simply not to generate data about adverse effects.

This is a preliminary report. I expect to elaborate and develop a number of issues in more depth, including areas pertaining to advertising and promotion, as well as documentation of the scientific evidence that Paxil and SSRIs in general can cause suicide and violence.

Part A will examine data generated from discovery. Part B will examine the label for Paxil. Part C will relate Part A and B to the Lacuzong case. Part D will present my conclusions.

Part A. An Analysis of Data from Discovery

I. FDA Criticism Relating to SmithKline Beecham (SKB) in Regard to Paxil Promotional Claims

The material in this section illustrates the tendency by SKB to make Paxil look safer than it is, and safer than other antidepressant medications. Material like this increased the likelihood that Mr. Lacuzong would be prescribed Paxil. Furthermore, SKB minimized the stimulating effects of Paxil, including agitation, anxiety, irritability, and insomnia, as well as akathisia. Indeed, SKB tried to promote Paxil as especially effective for anxiety associated with depression.

(1) 1.6.93 Letter from FDA's Janet L. Rose to SKB

In a 1.6.93 letter from Janet L. Rose, Division of Marketing, to Thomas Donnelly, (00000265), the FDA criticized many parts of their "Launching Sales Aid" (475-P2-158-01), including the following. The FDA challenged the basis for SKB's claim "The most extensively studied anti-depressant to be introduced" (p. 3 of SKB document). The FDA required the phrase "unsurpassed control" (p. 5) to be "deleted" because it is "not known how Paxil will ultimately compare with other SSRIs." The FDA challenged the term "fewer concerns" in emphasizing the safety of Paxil (p.5). The FDA observed that this general statement needed to emphasize that there were fewer concerns in regard to tricyclic antidepressants but not in regard to other SSRIs.

In addition, the FDA noted that the claim "improves sleep quality" (p. 9) is incorrect because Paxil causes insomnia in 13% of patients.

The FDA was also concerned about a potentially dangerous and unfounded claim that "In the elderly, Paxil significantly improves symptoms of depression" (p. 10). The FDA declared that "general conclusions about the efficacy of Paxil in the elderly" must be "disallowed" because they were based on studies with no placebo control. The FDA concluded (p. 2 of their letter), "While a purely factual description of relevant studies and results of those studies may be acceptable, generalizations from study data must avoid pseudoscientific claims which would imply particular efficacy in arbitrarily identified patient subgroups and must be based on scientifically adequate evidence. This claim should be deleted."

The FDA required the deletion of many other misleading statements about the use of Paxil for the treatment of the elderly.

SKB left out Adverse Drug Reactions with a rate of less than 15% (p. 14), for example omitting ejaculatory disturbances which occurred at a rate of 12.9%. SKB also tried to make claims for Paxil in regard to efficacy in severe depression (p. 15). The FDA required that "All references to Paxil efficacy in severe depression should be deleted" (p. 4 of FDA letter).

(2) 8.31.94 Letter from FDA's Sherry Danese to SKB

In an 8.31.94 11-page letter another lengthy critique of SKB drafts of promotional efforts was sent from Sherry Danese, Regulatory Review Officer, Division of Drug Marketing to Michael J. Brennen, PhD of SKB (00002339). The letter lists 7 materials, such as "A Unique Profile of Benefits Brochure" (Px 1004; also Px 1014, BRS-Px:L4, Px 1634, Px 1614, Px 1554, and Px 1604). Apparently, these materials were already in use. The FDA declared, "These materials misrepresent the safety and efficacy of Paxil; contain claims and representations of superiority of Paxil over Prozac (fluoxetine); and fail to provide fair balance. Therefore, these materials are in violation of the Federal Food, Drug and Cosmetics Act. We will address each violation individually." The letter concluded, "SKB should immediately discontinue use of these and all other similar violative materials on receipt of this letter."

Some of the FDA's criticisms echoed much earlier criticisms that the drug company had seemingly failed to comply with, including the use of false claims such as Paxil is "Proven effective and safe in elderly patients."

Another outrageous claim stated “Significant improvement seen in over 86% of patients treated with Paxil” (Px 1004, p. 2; Px 1634, p. 5). The FDA pointed out that the data came from “open label” studies and was used improperly.

(3) 1.23.97 Letter from FDA’s Paul Leber to SKB

In earlier letters, SKB had been criticized by the FDA for making unfounded “pseudoscientific” claims about the safety and efficacy of Paxil in the elderly. Now the FDA criticized the company for doing the same thing in regard to children. Those SKB was unconscionably attempting to push Paxil at both ends of the spectrum of age vulnerability. Both children and the elderly are especially susceptible to adverse drug reactions. These fraudulent efforts not only illustrate a pattern of deception, they directly encourage the false notion that Paxil is especially safe for everyone, including an adult male like Mr. Lacuzong, because they are supposedly safe for children and the elderly.

Leber acknowledged a 12.17.96 letter from SKB requesting that the FDA approve “a pediatric depression indication” for the drug. Leber responded with uncharacteristic directness, “In fact, the preponderance of negative studies of antidepressants in adolescents and childhood depression raises a significant concern about such extrapolations.”

Nevertheless, more than two years later, SKB was still trying to convince the FDA to endorse the use of Paxil for children, as indicated by a 4.28.99 letter from the FDA’s Ralph Temple to Thomas Kline.

II. FDA Criticism of SKB Relevant to the Stimulating and Agitating Effects of Paxil

(1) 9.6.94 Letter from FDA’s Sherry Danese to SKB

In a 9.6.94 letter from Sherry Danese to Michael Brennen at SKB, the company's promotional materials are again heavily criticized. This letter is particularly important because it demonstrates a specific attempt on the part of SKB to mislead doctors concerning the stimulant effects of Paxil. This is directly relevant to the issue of murder and suicide, both of which can be related to the stimulating, agitating effects of antidepressants. From this material alone it can be concluded that SKB attempted to hide the dangers of Paxil in regard to stimulation and its adverse consequences of murder and suicide. In the letter, according to the FDA’s criticism, SKB made the following statement:

Effective in treating anxiety and agitation associated with depression without inducing symptoms of arousal.

The FDA observed that the above handwritten letter and a two page typed “Paxil Overview” sheet “appear to have been distributed by a SmithKline Beecham (SKB) sales representative” (p. 1). The FDA was strongly critical:

This statement suggests that Paxil is not associated with side effects that might aggravate anxiety or agitation. To the contrary, Paxil is associated with an 8.3% incidence of tremor, a 5.2% incidence of nervousness, a 13.3% incidence of insomnia, a 5.0% incidence of anxiety, and a 2.1%

incidence of agitation. Therefore this statement is false and/or misleading.
P. 3.

Importantly, the FDA analysis also establishes the rudiments of a stimulant profile for Paxil, including the following symptoms:

Tremor
Nervousness
Insomnia
Anxiety
Agitation

It also establishes that Paxil can cause or worsen “anxiety and agitation associated with depression.”

The FDA also criticizes the claim that Paxil is “less likely to cause agitation than currently available SSRIs.” The FDA states, “This claim is not supported by substantial evidence, and is false and/or misleading.”

The FDA also criticizes the unsupported claim that “Paxil costs 15% less.” According to the FDA (p. 2 of letter), “In the absence of supporting data, this claim is false and/or misleading.” Once again, these efforts to over-promote Paxil in general influenced its increasingly widespread use, leading to the increased likelihood of its prescription to Mr. Lacuzong.

(2) 9.19.94 Letter from FDA’s Paul Leber to SKB

In a letter with two dates stamped on it (9/19/94; 9/13/94), Paul Leber writes to Michael J. Brennen to suggest post-marketing changes in the label for Paxil. The “request” is unusually strong, in fact requiring that the changes be added in the “next printing (but not later than 3 months from the date of this letter.)” The changes pertain to four adverse drug events, two of which relate directly to stimulation and agitation effects. One relevant new addition is based on four reports of extrapyramidal reactions (EPS), including two for akathisia (defined below). The issue of akathisia will be addressed in more detail because akathisia is associated with violence and suicide (see below). The other relevant addition is based on two reports of serotonin syndrome, an extreme reaction involving over-stimulation of the serotonin neurotransmitter system that can include agitation and excitement.

(3) 1.11.99 Letter from FDA’s Janet Rose to SKB

Janet Rose wrote a critical letter to Donnelly concerning continued drug company efforts to sneak “depression associated with anxiety” into advertising materials as an indication for Paxil.

III. Eliminating Akathisia as Preferred Term and as an Investigator's Term

(1) Definition of Akathisia

Akathisia is a neurological disorder caused by medications. Stedman's Medical Dictionary, 27th edition (2000) defines akathisia as "A syndrome characterized by an inability to remain in a sitting posture, with motor restlessness and a feeling of muscular

quivering." The American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, IV (DSM-IV) (1994) describes akathisia in the context of neuroleptic drugs, but the clinical manifestations are the same as akathisia induced by antidepressants. The DSM-IV observes that akathisia includes the following:

.... Subjective complaints of restlessness and at least one of the following observed movements: fidgety movements or swinging of the legs while seated, rocking from foot to foot or "walking on the spot" while standing, pacing to relieve the restlessness, or an inability to stand still for at least several minutes. P. 744

In general, if the subjective experience of agitation, anxiety, irritability or similar feelings is accompanied by voluntary motor movements, such as pacing or foot swinging, the syndrome is identified as akathisia.

(2) Akathisia, Violence, and Suicide

The DSM-IV states without qualification, "Akathisia may be associated with dysphoria, irritability, aggression, or suicide attempts" (p. 745).

There is a considerable body of literature to confirm the association between akathisia and violence and suicide. I have reviewed some of the literature in Breggin and Breggin (1994) and Breggin (1997) in regard to psychiatric drugs in general and specifically the SSRIs of which Paxil is a member. Teicher, Glod, and Cole (1993) reviewed SSRI-induced violence and suicide. More recently, Glenmullen (2000) devoted a significant portion of a book to reviewing the literature and discussing SSRI-induced violence and suicide.

(3) The Expurgation of Akathisia

It is extremely important for physicians to know that a drug can cause akathisia. Akathisia, as a term, signals the dangers of emotional anguish and the potential for inducing suicide and violence. It is not only fraudulent, but hazardous to patients, to hide that a drug can cause akathisia. It is especially dangerous when the drug is being used to treat depression, because akathisia in depressed patients is especially likely to drive them to suicidal or violent acts.

Akathisia was systematically eliminated by SKB as a preferred term from the U.S. and non-U.S. studies (see ahead). This meant that symptoms typical of akathisia would not be coded as akathisia, but as something else, such as agitation or central nervous system stimulation.

Remarkably, akathisia does not even appear as an investigator's term on any U.S. reports that I located. It only appears as an investigator's term in about one dozen non-U.S. reports (see below) while symptoms attributable to akathisia abound in the summaries of adverse drug reactions. From this it must be concluded that SKB not only removed it from any lists of preferred terms, it also must have communicated to the principal investigators that the term should not be used in any of the adverse drug reports or clinical summaries.

Clearly SKB preferred not to let the FDA or the medical profession know that Paxil causes akathisia. Indeed, they left it out of the section entitled "Adverse

Experiences in Clinical Trials: Worldwide Data” (Section V—NDA. PAR Safety Summary 20-Nov-1989, pp. 83-88; also see Table V.7, p. 114).

Similarly, akathisia was left out of the section entitled “Adverse Experience which occurred during active treatment—U.S. Phase II & III Studies,” “Nervous System” (Appendix V.8, in NDA 20031-Vol 422 November 1989, pp. 189/190-275/276). There is no listing at all for akathisia but many reports of related restlessness and nervousness.

(4) Akathisia Slips Through in Non-U.S. Reports

Nonetheless, some akathisia reports slipped through in non-U.S. reports. In the section entitled “Adverse Experiences which occurred during active treatment-Non-US Phase II-III Studies,” V.1, pp. 129-199, we located 13 explicit reports of akathisia and motor akathisia (a synonym). In addition, there were many descriptions of akathisia listed under other preferred terms.

(5) The FDA Adds Akathisia to the Paxil Label

Eventually the FDA insisted that SKB add akathisia as a postmarketing finding without insisting on causation. The demand came in a letter in September 1993 from the FDA's Paul Leber to SKB (SB 0000247). Had the FDA been informed during premarketing of the large number of cases of akathisia in association with Paxil, it would have been a position to more firmly determine causation.

In response, a label version created by SKB and dated 2.05.94 does add akathisia and EPS as postmarketing findings. They should have been put in the label as a premarketing finding involving multiple cases (000022).

One of the two reports cited by the FDA was received from Ireland. However, the company already had many reports of akathisia in its possession from Europe, but must have failed to inform the FDA.

To repeat, the FDA required a mention of akathisia in the label based on merely two postmarketing reports, while SKB already had about one dozen explicitly identified akathisia reports in its possession from the non-U.S. premarketing studies and, as we shall document, dozens of other akathisia cases coded under different preferred terms, such as agitation and central nervous system stimulation, in the U.S. premarketing studies.

(6) How the FDA Codes Akathisia

The FDA has developed a coding system for adverse reaction terms. The dictionary is entitled "COSTART: Coding Symbols for Thesaurus of Adverse Reaction Terms." I have the Fifth Edition (1995) in my library, but it has not changed in regard to akathisia. Like any pharmaceutical company, SKB was supposed to base its collection and analysis of adverse reaction data on the COSTART system. This is discussed, for example, in an SKB Memorandum, "FDA Conversation Record" (9.5.91), that memorializes a conversation with the FDA's Thomas Laughren concerning, among other things, the use of COSTART terms (SB 0000158). In fact, the memo comments that Laughren (the "Division," meaning the FDA's Division of Neuropharmacological Drug Products) would make decisions about what terms to cut from the label.

From the beginning, COSTART has coded akathisia as akathisia. That is, the preferred term for akathisia is akathisia. This was true during the development of the first SSRI, Prozac.

Therefore, SKB deviated from the FDA's coding system in order to classify cases of akathisia as something else, such as agitation. In reclassifying akathisia, as well as stopping the use of the term in general, SKB made it impossible for the FDA or anyone else to accurately determine the total number of patients who suffered from akathisia as a result of taking Paxil. This was extremely fraudulent.

(7) Purposefulness of the Fraud Concerning Akathisia

The fraud had to be carried out with full knowledge, because it was well-known that the original SSRI, Prozac, caused akathisia. The original Prozac label listed akathisia but estimated its occurrence as "infrequent." However, it quickly became apparent that Prozac-induced akathisia was very common and very dangerous. In 1989 Joseph Lipinski and his colleagues from McLean Hospital and Harvard Medical School published five cases of Prozac-induced akathisia involving considerable emotional disturbance. Based on a literature review, the researchers estimated the rate of Prozac-induced akathisia at between 9.7% and 25%. In the June 1990 the Public Citizen Health Research Group (related to Ralph Nader's organization) in their Health Letter similarly estimated the rate of Prozac-induced akathisia as 15%-25%. Furthermore, as reports by Teicher et al. (1990) and Rothchild and Locke (1991) illustrate, SSRI-induced akathisia as a potential cause of suicide and violence was a subject of discussion in the literature even before the approval of Paxil.

In the next section, we shall find a direct link between suicide and stimulation, including akathisia, in SKB's own NDA files.

IV. Re-Analysis of Preferred Terms in U.S. Trials

In addition to akathisia, Paxil commonly causes a variety of related symptoms of central nervous system stimulation, including CNS stimulation itself, anxiety, agitation, nervousness, irritability, and insomnia. These symptoms of stimulation are extremely important because they, too, are associated with suicide and violence (Breggin and Breggin, 1994, Breggin 1997). It is common knowledge in the medical profession that stimulation can induce depressed patients to make acts of suicide. Therefore, it is extremely important for physicians to know that an antidepressant drug causes stimulation, and it is fraudulent and dangerous to hide that information from them.

Unfortunately, SKB not only tried to hide the facts about Paxil-induced stimulation and akathisia, the company made false claims concerning Paxil in this regard. I have already documented that the FDA protested at times against these false claims. As another example, SKB developed a lengthy document entitled "Paxil (paroxetine hydrochloride): Hospital Formulary Product Information" (SB 0000261, dated December 11, 1992). In it, SKB claimed that Paxil was effective in "depressed patients with associated symptoms of anxiety" (SB 0000271) and that the drug possessed an adverse reaction profile with "a low incidence of nervousness, agitation, and anxiety." These statements are false. In fact, as the FDA stated (above) and as we shall continue to document, Paxil causes nervousness, agitation, irritability, anxiety and related symptoms of stimulation in a large percentage of depressed patients, often in the first three days.

We shall also find that cases of akathisia were hidden in company-defined preferred terms—i.e., terms preferred by the drug company—such as agitation, anxiety, stimulation, nervousness, and tremor.

The following is a re-analysis of several categories CNS-related adverse effects that the company organized according to its selected preferred terms:

(1) Preferred Term Agitation

Agitation had 75 entries (pp. 191-193). Forty-nine of 75 agitation patients were in fact suffering from akathisia. Of these, 47 were described by the term “restless” and 10 mentioned leg or foot [one case] movement. As the definition of akathisia indicated (above), these cases are most likely akathisia. Consistent with the Lacuzong case, twenty-one occurred in the first 1-3 days. Another 11 occurred in 4-5 days. Again consistent with the Lacuzong case, seven cases developed on low doses of 10 mg.

(2) Preferred Term Anxiety

Of the 86 reports in the category for "anxiety," 24 were described as “tense” and 1 as “restlessness.” Although it is not as definitive as in the case of the preferred term "agitation," many of these cases were probably akathisia. Of great importance, 26 occurred in the first 1-3 days. Another 9 occurred in 4-5 days. Eight occurred at the 10 mg dose.

(3) Preferred Term Nervousness

Under the category "nervousness" (pp. 235-238), 44 of 91 were probably related to akathisia. They were identified by the following terms: pacing, jumpy, jittery, and fidgety. Jittery was the most common. Twenty-three of 91 reports occurred in the first 1-3 days. Another 15 occurred in 4-5 days.

(4) Preferred Term Tremor

Under the “Preferred Term Tremor,” there were a very large number of reports (pp. 268-273) that I have not fully evaluated. Many were related to akathisia.

V. Analysis of Akathisia in the Non-U.S. Phase II and III Clinical Trials

(1) Reports of Akathisia by Investigator Term

Unlike the U.S., a few cases of akathisia were reported using the investigator's term akathisia in the non-U.S. Phase II – III studies (NDA Aropax [Paroxetine], November 1989, Appendix V.1). They were coded under the preferred term CNS stimulation rather than under akathisia:

	Patient #	Onset – days
1.	2218 072 (p. 137)	NA
2.	NA (p. 138)	1
3.	664 015 (p1 138)	1
4.	NA (p. 138)	9
5.	664 012 (p. 139)	2
6.	NA (p. 139)	-6

7.	6 162 005 (p. 139)	4 Suicide attempt
8.	NA (p. 139)	5

NA indicates Not Available.

(2) Akathisia Linked to Suicide Attempt

Of the 8 patients diagnosed with akathisia, only 4 were identified by patient number. Of the 4 identified patients diagnosed with akathisia, one (25%) attempted suicide. Furthermore, the patient attempted suicide on the *same day* as the akathisia report (see NDA Suicide Report, Appendix 2, page 17).

It is very important to have the company identify the other four patients.

(3) Rapidity of Akathisia Onset

Of special importance to the Lacuzong case, akathisia often begins within the first few days of treatment. Of the 4 identified patients, one did not have onset data. Of all 7 patients with onset data, all were diagnosed in 9 or fewer days of treatment. Six were diagnosed within 1 week of treatment. Three were diagnosed within 1-2 days of treatment.

(4) Reports of “Motor Akathisia” by Investigator Term

Motor akathisia is identical to akathisia. The term simply emphasizes the external manifestation of the symptoms. There were five cases:

Patient #	date of onset
1. 7119 028 (p. 157)	16
2. 7119 058 (p. 157)	120
3. 7121 003 (p. 158)	21
4. 7124 012 (p. 158)	6 -- Suicide (completed)
5. 7126 008 (p. 158)	28

(5) Motor-Akathisia Linked to Suicide

Of the 5 patients diagnosed with “motor akathisia,” 1 (20%) committed suicide.

Thus, of the 13 identified patients diagnosed with “akathisia” or “motor akathisia,” 2 (15%) attempted or completed suicide.

(6) Completed Suicides Linked to CNS Adverse Effects, Including Akathisia

We have been able to trace five completed suicide cases to their original case summaries. Of the 5 patients who successfully committed suicide on Paxil, all were diagnosed with CNS-related AERs before suicide. Of those 5 cases, at least 2 pre-suicide diagnoses (40%), agitation and motor akathisia, were related to stimulation and/or akathisia. All of them had central nervous system adverse drug reactions.

The following are the 5 completed suicide cases followed by the investigator terms for their adverse drug reactions.

1. 1.13.126 "severe insomnia"
2. 2206.005 lightheadness, drowsiness, malaise

3. 2406.149 "restlessness (agitation)"
4. 6.47.003 vertigo
5. 7124-012 motor akathisia. "mild hyperkinesia"

VI. Rapid Onset of ADRs Documented from the Spontaneous Reporting System

Postmarketing data from the Spontaneous Reporting System dated July 1993 confirms that severe ADRs can develop in the first day or two of treatment, including reactions that adversely affect behavior (NDA20031; SB 0000912). Here is a small sample excerpted or extracted from the Adverse Experience Reports.

- Day 1: Afraid, agitated, insomnia, tension. (p 000152)
- Day 1: EPS reaction. (p 000156)
- Day 1: Tremors, restlessness, tearful. (p 000187)
- Day 1 or 2: Disorientation, insomnia. (p 000081)
- Day 1: Severe akathisia. (p 000340)
- Day 1: Extremely restless, felt like screaming, dysphoric. (p 000543)
- Day 1: Hallucinations. (page 000579)
- Day 1: Hallucinations of insects and objects moving, dizzy. (p 000507)
- Day 1: Drugged, out of body, shaky. (p 000487)
- Day 1: Amnesia. (p 000467)
- Day 1: Distressed, hot flashes, sort of breath. (p 000416)
- Day 1: Distressed, hot flashes. (p 000417)
- Day 2: Dystonia. (p 000138)
- Day 2: Hallucination. (p 000471)
- Day 2: Bugs crawling, feeling high. (p 000472)
- Day 2: Drastic blood-sugar drop. (p 000482)
- Day 2: Numbness all over. (p 000513)
- Day 3: Severe muscle spasms. (p 140)
- Day 3: Dystonia, anxiety. (p 172)
- Day 3: Suicide attempt. (p 000106)
- Day 4: Insomnia, could not walk or talk on 10 mg. (p 000372)
- Day 5: Extreme agitation, jumped out window, disappeared 2 days. (p 000554)
- Day 5: Extremely jittery, very dizzy. (p 115)

VII. The Role of "Central Nervous System Stimulation," "Irritability" and "Excitement" in Suicide and Violence

1. Stimulation and Irritability in U.S. Trials

"Irritability" is used in psychiatry to describe the emotional hyper-reactivity of individuals that can lead to inappropriate or immoderate hostility and violence. It is closely related to excitability. (See, for example, Stedman's Medical Dictionary, 2000, or the PDR Medical Dictionary, 1995).

Irritability is a much stronger term in psychiatry than in common use. In the Diagnostic and Statistical Manual of Mental Disorders, IV (1994), a diagnosis of Substance-Induced Mood Disorder can be made on the basis of any of "irritable mood" by itself (p. 374, "Diagnostic criteria for Substance-induced Mood Disorder."

Appendix V.8, "Adverse Experiences Which Occurred During Active Treatment: U.S. Phase II-III Trials" (SB 0000669, p. 198, stamped 199), lists CNS Stimulation as a preferred term. In the category of CNS Stimulation, investigator terms were usually related to abnormal behavioral reactions, such as "irritable," "irritability," and "increased irritability."

There were 19 reports relating to irritability. There were 7 reports related to "excitement" and "intense rushes of excitement." Other reports were related to feeling "wired" and "wound up."

Of these approximately 41 patients with 50 reports of Central Nervous System stimulation, many occurred early in treatment. Eight occurred within 1-2 days of the start of treatment. Five adverse events occurred at the 10 mg dose, none of which were in the 1-2 day period.

2. Anxiety and Suicide from Non-U.S. Phase II & III Studies

A hand count of "agitation" as the preferred term (NDA 420 November 1989, p. 128 ff) disclosed 43 reports, including one completed suicide (2406 149) on the 32nd day of Paxil exposure.

A hand count of "anxiety" as the preferred term disclosed 63 reports with three attempted suicides on the same day, three days after the report, and 19 days after the report.

Once again there is evidence that suicide is related to stimulation (akathisia, agitation, anxiety) from Paxil.

VIII. Placebo Comparison and Dose Dependency

A drug's capacity to cause ADRs can be studied through a comparison between ADRs reported on placebo and ADRs reported on doses of the drug. Data concerning this can be found as "Attachment to FDA Approvable Letter NDA 20-031/S-023." It is entitled "Dose Dependency of Adverse Events" (Vol. PAX-M-99 in the March section [no page number]).

The following data are taken from the section on "Nervous System:"

	placebo	10 mg Paxil	20 mg Paxil	30 mg Paxil	40 mg Paxil
		N = 102	N = 104	N = 102	N = 102
Anxiety	0 percent	2	5.8	5.9	5.9
Nervousness	0 percent	5.9	5.8	4.0	2.9
Somnolence	7.8 percent	12.7	18.23	20.8	21.6

Notice that placebo produced no increase in anxiety or nervousness, while the 10 mg Paxil showed a rate of 2% that increased to 5.8% and then 5.9% with increasing doses. In regard to the Lacuzong case, placebo produced no increased nervousness, while 10 mg Paxil produced the maximum amount.

(It is unclear why nervousness declined with the two largest doses.)

IX. The Serotonin/Anxiety Spectrum of Adverse Effects

In the extreme, SSRI-treated patients can develop a Serotonin Syndrome. The syndrome is thought to be caused by over-stimulation of the serotonin neurotransmitter system.

The drug company performed an analysis of “Serotonin Group” symptoms from the worldwide data (Appendix XI.9, Comparisons for Adverse Experiences Considered to be Related to the Serotonin group—Intent to Treat Population” (NDA 20031—V 449, October 26, 1989, pp. 223-227; SB 0000769). The serotonin group included 15 items (SB 000071): fasciculations, tremor, myoclonus, ataxia, agitation, nausea/vomiting, nausea, diarrhea, nystagmus, reflexes increased, Babinski sign positive, heel/toe gait abnormality, CNS stimulation, and sweating.

Of 2,963 patients, the found that 1343 (45%) developed these symptoms. Of 554 placebo patients, 131 (24%) developed them. The data confirms the dangerously stimulating impact of Paxil.

The company also did an analysis of “Comparisons of Adverse Experiences Considered to be Related to Anxiety Group—Intent-to-treat Population” (Appendix XI.7). Worldwide anxiety symptoms were found in 334 of 2,963 Paxil patients (11%) compared to 35 of 554 placebo patients (6%). However, the anxiety group was limited to patients with agitation, nervousness, and anxiety. When other anxiety symptoms are included, such as tremor (11%), insomnia (14%), CNS stimulation (4%) and mania (1%), the group becomes considerably larger. By contrast figures from the same source for the anxiety group were anxiety (5%), agitation (4%) and nervousness (4%) (NDA 20031 Vol, 1 November 1989, p. 153).

X. Adding Hostility to the Label

In a 4.29.96 17-page letter from FDA’s Paul David to SKB, Michael Brennen refers to “Final Labeling” based on a 4.5.96 submission. It adds “hostility” and “extrapyramidal syndrome” (EPS) to the label. The first addition of “hostility” to a draft of the label by the FDA was 3.15.96.

The FDA forces the company to add these closely related ADRs of EPS and hostility. Akathisia is an EPS.

XI. Evaluating Errors in the Compilation of Suicide Data

(1) Suicide Attempts: US Clinical Trials

A total of 14 suicide attempts were reported in the US clinical trials. None were completed suicides. An overview is presented in the following Table XI.19 (PAR Safety Summary 20-Nov-1989 p. 203, stamped p. 297).

Overview of Attempted Suicide-US Data

	Paroxetine N = 1562	Placebo N = 497	Other A.D. N = 464
Drug Overdose (imipramine)	9	0	1
Defenestration	2	0	0

Self-inflicted injury	1	0	0
Suffocation	0	1	0
Totals	12 (0.77%)	1 (0.20%)	1 (0.21%)

Note that the rate for suicide attempts on Paroxetine approaches 1% which the FDA considers "frequent."

Also note that the rate for suicide attempts on Paroxetine 3.8 times higher than for placebo and 3.6 times higher than for the comparison antidepressants (tricyclics).

Furthermore, the suicide attempt on imipramine is listed as a "possible suicide (p. 211, stamped 306).

In regard to the onset of suicide attempts, one patient (117A-004, p. 200, stamped 291) cut himself on the third day of Paxil: "One day 3 this patient attempted to slash his wrists and abdomen and was withdrawn from the study." Also note that case 647 002 (above) made attempts on days 1, 8, and 15.

This all-important United States Data is not presented in the text of SKB's April 29, 1991 report for the FDA, "Suicidal Ideation and Behavior: Analysis of the paroxetine Worldwide Clinical Database." To hide the U.S. data within worldwide data was extremely misleading.

2. Leaving Out Two Non-U.S. Suicide Attempts

There is evidence that some suicide attempts were omitted from the calculations sent to the FDA. In the report "Adverse experienced which occurred during active treatment. Non-US Phase II-III studies" (Appendix V.1), I located two patients that appear to have been left out of the summaries of non-US suicide attempts. Case 647 002 (Volume 420, p. 157) made three suicide attempts on days 1, 8, and finally on day 15 when the drug was stopped. The first two were considered "related" and the third "possibly related." Also, case 1 113 120 (Volume 420, p. 157) was considered "definitely drugged related."

These two attempted suicides do not appear in the complete list of 40 in the April 29, 1991 suicide report (pp. 17-18).

These two suicide attempts, including one patient with three attempts, are not listed in the April 19, 1991 suicide report or in any other source that we have located.

This brings the total of non-US suicide attempts to 32.

3. Leaving Out Two Non-US Completed Paxil Suicides

Two non-U.S. completed suicides appear to have been left out of all official reports, including the April 29, 1991 suicide report. The missing two are found in Appendix 5.4.2—Summary of Deaths Occurring in Paroxetine Treated-Patients (unnumbered page, SB 0000044). Here are the seven cases with their complete descriptions under the heading of "Cause of Death and Comments."

Case Number	Duration (days)	Cause of Death and Comments
DFG124/12*	?	Suicide: Method—Overdose with doxepin

HDUK13/26*	144	Suicide: Method—Hanging
29060/149*	18	Suicide: Method—Overdose ... 6 days after discontinuing paroxetine
HP-82-47/3*	47	Suicide: Method—Drowning
058/022**	?	Suicide: Method—Unknown
083.003.1090**	8	Suicide: Method—Hanging
2206.005/605*	150	Suicide: Hanging

Since only 5 non-U.S. suicides are listed in any of the tables or reports, it is apparent that there are two missing. Two more should be added to the suicide completed counts (see below).

I cross checked these numbers and have found that five are included (*see single asterisk) in the official lists of suicides.

We need to obtain the two missing cases (**see double asterisk).

Appendix 5.4.2 appears to be based on the Summary Basis of Approval data (SBA) which draws from the NDA. It was part of a list of 15 deaths described in a August 25, 1992 memo entitled "Miscellaneous Requests" from Thomas P. Laughren, M.D. of the FDA to Thomas Donnelly, Jr., Ph.D. of SKB. He notes he is adding one, 083.003.1090, from the safety update, which is also a part of the original NDA.

We need to inquire about any further correspondence or corrections concerning this list.

4. Adding Two Placebo Run-in Completed Suicides to the non-U.S. Studies

In the suicide report the following two suicide cases are listed: 7119.062 and 7119.009. However, both of these occurred during the placebo-run in (also called placebo wash out) phase. The cases can be found summarized in The PAR Safety Summary 20-Nov-1989 (7119.062 on p. 202c, stamped p. 296, SB 0000544; 7119.009 on p. 202b, stamped p. 295, SB 0000543).

There is no question that placebo run-in is a euphemism for placebo wash-out. In the April 29, 1991 suicide report a footnote states, "Suicides were committed during the placebo wash-out phase of an active control study. These two acts were committed 2 days and 7 days prior to the baseline evaluation, i.e., -2 and -7 days)."

Adverse drug effects are never reported from the placebo wash out phase. Indeed, suicide and suicide attempts are probably the only supposed adverse drug effects reported from the placebo wash-out. The placebo wash-out period is not a part of the controlled clinical trials. It occurs before the randomization. All patients are lumped into them. Furthermore, many of the patients are very likely suffering from withdrawal from other drugs they were previously taking for depression.

The inclusion of these suicides into the placebo comparison group was misleading to the extreme. They must be removed from calculations pertaining to a comparison between suicides on Paxil and on placebo.

5. Including Two Placebo Run-in Suicide Attempts in non-US Studies

The worldwide data for suicide attempts also includes placebo run-in data. This is confirmed in Table XI.21, Attempted Suicides and Overdoses—Worldwide Data (Par Safety Summary – 10-Nov-1989, p. 206, stamped page 300, SB 0000548). Exactly as in

the case of including completed suicides from the placebo wash-out phase, the inclusion of two placebo run-in patients in the non-US suicide attempt category is misleading and fraudulent. The two placebo run-in patients must be excluded from the non-US and worldwide data.

XII Re-Analysis of the Suicide Data

1. Re-Analyzing Non-U.S. Completed Suicides

Various SKB documents, including the April 29, 1991 suicide report, only list 5 completed suicides. As described above, we have found an additional 2 for a total of seven. Therefore the completed suicide rate for Paxil is seven in a population of 1401 patients for a rate of 0.499%.

As also described above, we found that two placebo wash-out completed suicides were wrongly counted in the suicide rate for placebo. The true occurrence for completed suicides in the placebo group is 1 in 544 for a rate of 0.180%. The suicide rate on Paxil is therefore 2.7 times that on placebo.

2. Creating a New Category of Suicidal Behavior or Suicides, Attempted and Completed

The five completed Paxil suicides (acknowledged by SKB) must be added together with the 42 (from table XI.21) attempted suicides to create the category of Suicidal Behavior or Suicides, Attempted and Completed. The category contains, at the least, 47 cases of suicidal behavior ($42 + 5 = 47$). SKB's analysis obscures and hides the actual rate of suicidal behavior by evaluation attempted and completed suicides as separate entities. We also need to know the overall rate of suicidal behavior.

Based on this analysis, the rate of suicidal behavior is 47 out of 2963 for a rate of 1.58%.

If we add the additional two completed suicides that seem to have been left out of the data, we now have 49 ($47 + 2 = 49$) suicidal behaviors out of 2963 for a rate of 1.65%.

Whether we use the 1.58% figure or the 1.65% figure, this combined category of suicidal behavior is far more meaningful than the split categories of suicide attempts and suicides completed. It was grossly misleading not to create a combined category.

The above calculations were based on the assumption that there were 42 suicides as indicated in the original NDA. If we added the two suicide attempts that appear to have been left out of the data, there are at least 44 total suicide attempts. The corrected total for combined suicidal behavior on Paxil then becomes 51 (44 suicide attempts $= 7$ suicides $= 51$). Fifty-one out of 2963 produces a rate of 1.72% for suicidal behavior on Paxil.

3. Re-Analysis of the Worldwide Comparisons for Suicide Attempts

We have already found that two attempted suicides on Paxil were apparently not included in the worldwide calculations. As described above, this raises the original NDA figure from 42 to 44 for attempted suicides out of 2963 cases, for a rate of 1.48%.

In addition to undercounting suicide attempts on Paxil, SKB over-counted placebo-related suicide attempts.

For placebo, 3 suicide attempts are listed. But as we have documented, the correct number for placebo suicides is only one for the worldwide group. The other two suicide attempts were placebo wash-out cases. That makes the placebo suicide attempt rate a mere 1 out of 554 for a rate of 0.18%.

Thus the corrected comparison indicates a 1.48% rate of suicide attempts on Paxil compared to a 0.18% rate of suicide attempts on placebo worldwide. Thus suicide on Paxil was 8.2 times higher than the rate of placebo.

4. Hiding the Frequency of Suicide Worldwide in the April 29, 1991 Suicide Report

In the "Discussion and Conclusions" of the April 29, 1991 report (SB 0000819, report pp. 12-13) states the following conclusion:

- 2) The incidence of attempted suicides did not differ substantively among the three treatment groups (paroxetine, placebo, active controls).

However, the report never deals with the U.S. clinical trials as a separate entity. They show a significantly higher suicide attempt rates for Paxil than for the other antidepressants or placebo.

Furthermore, there is no overall category of Suicidal Behavior or Suicides, Attempted and Completed. Therefore, when counting suicide attempts, suicides completed are excluded, badly misrepresenting the data. In addition, there appear to be two unreported suicide attempts and six unreported completed suicides worldwide.

Finally, as already noted, the worldwide figure is distorted by miscounts in both the Paxil and placebo categories. .

The April 29, 1991 suicide report also contains different numbers from the NDA. We find is that the total number of Paroxetine suicide attempts has been inexplicably reduced from 42 in the NDA to 40 two years later, while the total number of placebo suicide attempts has been inexplicably increased from three to six. These manipulations of course favor the interest of the drug company. The April 29, 1991 report in fact states that it has based itself on the original NDA data, that is, "using data which were submitted at the time of the New Drug Application for paroxetine" (p. 1, SB 0000003). But the NDA data differs to the disadvantage of SKB.

XIII. Follow Up of U.S. Suicide Attempt Cases

I was able to track many but not all of the individual case numbers listed in the compilation of suicide attempts (Table XI.19 from PAR Safety Summary 20-Nov-1989 p. 203, stamped p. 297). The cases were found separately in a book length document, "Narrative of US patients with Potentially Clinically Significant Events" (Appendix I.1 of NDA 20031, 409, November 1989). They indicate that the suicide attempts often occur in a context of various other distressing adverse drug reactions but sometimes occur without any other serious adverse effect. This contrasts with the non-U.S. data on completed suicides which indicate that the five we could track were all related to central nervous system adverse drug reactions, including akathisia and stimulation.

(1) 02-04-089 (p. 37). This patient had been taking Paxil 20 mg for 40 days. "Adverse clinical experiences ... were moderate dizziness and lack of energy (probably drug related), and moderate headaches (possibly drug related)."

(2) 04-01-009 (p. 192; SB 0000571). This patient elected to switch from a tricyclic to Paxil. After 193 days the patient was taking 50 mg and experienced the following adverse reactions:

"clenching of teeth," dry mouth, decreased libido, inability to achieve orgasm, nausea, diarrhea, urinary retention, "weakness in legs," "twitching of left cheek," lightheadness, anxiety, "speedy feeling," dizziness, "tingling," lethargy, headache and decreased concentration.

(3) 04-02-056 (Volume 409, p. 260). This patient was taking Paxil 40 mgs and at 19-20 days made self-inflicted scratches. The patient was given ECT [so probably experienced a worsening of depression]. Other than dry mouth, no other ADRs were reported.

(4) 04-06-96. This patient was on 30 mg of Paxil for 116 days. The patient could not be located in the "Narrative of US patients with Potentially Clinical Significant Events."

(5) 05-01A-030 (Volume 410, p. 65). This 23 year old patient was taking Paxil 50 mg and attempted suicide twice. The two attempts were counted only once. "The patient required hospitalization because of excessive ethanol use with violent and unpredictable behavior." She intentionally overdosed.

(6) 05-01A-075. This patient was a 37 year old female taking Paxil 40 mg for more than three years. She was not located in the "Narrative of US patients with Potentially Clinical Significant Events."

(7) 05-02B-019 (Volume 410, p. 124). This patient was taking Paxil 50 mg for 57 days when the overdose occurred. "Adverse experiences reported during the study were mild rash, diarrhea, 'shakiness' (possibly drug related), and an overdose." She took 20-50 unknown pills and was hospitalized.

(8) 05-02F-002 (Volume 410, p. 151). This patient was taking Paxil 40 mg for 38 days and attempted suicide. No other ADRs were reported.

(9) 07-01A-001. This person was taking Paxil 40 mg for 20 days. The case could not be located in the "Narrative of US patients with Potentially Clinical Significant Events."

(10) 09-01A-005 (Volume 410, p. 196). This patient was taking Paxil 40 mg and overdosed at 7 days. She was experiencing "moderate drowsiness, tremulousness, severe nausea (probably drug related), and overdose." She overdosed for a second time 7-8 days later. There were therefore two overdoses, one during drug exposure, and one apparently within a week after withdrawal.

(11) 09-01E-260. This patient was taking Paxil 10 mg for 60 days. The patient could not be located in the "Narrative of US patients with Potentially Clinical Significant Events."

(12) 09-01J-573 (Volume 410, p. 279). This patient was taking Paxil 10 mg according to the summary (p. 298) but taking 20 mg according to this case report. The

drug exposure was listed as 26 days but appears to have been 30 days. The patient “jumped from second story window” and “received multiple fractures.”

In addition to these 12 Paxil patients who attempted suicide (for a total of 14 attempts), there was one attempted suicide on imipramine and one on placebo. They follow:

(13) 04-06-088 (Volume 410, p. 50). This patient was taking imipramine 225 mg for 61 days. The patient was listed as a “possible suicide attempt.” “He reportedly had taken an unknown quantity of ‘pills’ and was intoxicated.” In fact, this is probably not a suicide attempt.

If this case is discarded, there are no other cases of suicide attempt on the comparison drug and the ratio becomes 12-14 to 0. It appears that the drug company attempted to cover up the higher rate of suicide attempts on Paxil by including this unlikely case of a suicide attempt.

(14). 02-01-009 (volume 410, p. 5). This patient was on placebo for 6 days. The case is described as “a suicide gesture by sophistication. Her husband prevented her suicide.” Notice that this case is a “gesture.” I found no “gestures” included in the Paxil group.

If this case is discarded, as well as the one imipramine case, then there were 12-14 suicide attempts among twelve patients on Paxil and none on placebo or on imipramine.

XIV. Increasing Evidence of Suicidality on Paxil

On 1.14.00 the FDA wrote a 3-page letter to Thomas Kline of SKB suggesting a label change. The FDA recommends a label change under “Overdosage/Human Experience.” Since the introduction to the U.S., 342 spontaneous cases of deliberate or accidental overdose with paroxetine have been reported worldwide (circa 1999). Seventeen involved Paxil by itself. There were 48 fatalities.

This issue is even more serious than the FDA indicates since there are obviously a large number of suicide attempts in this group.

XV. Adverse Reactions from the Original NDA Application (Volume 1, pp. 151-4).

The data in this discussion is derived from the placebo-controlled clinical trials. The table for Nervous System indicates a 1% rate for both mania and depression on Paxil, but 0% for both on placebo. Remember that 1% is considered frequent by the FDA. Yet the final label for Paxil calls manic reactions “infrequent.”

The capacity of a drug to cause manic reactions in 1% of placebo-controlled clinical trials against 0% for placebo is an extremely important piece of epidemiological scientific data.

The list of “frequent” ADRs under Nervous System (NDA 1,0 p. 157) is much more extensive than in final label, including, among other things, “depression” and “manic reaction.” This is consistent with the other data in this NDA. The following is the list of frequent CNS ADRs:

Abnormal dreams, agitation, anxiety, CNS stimulation, concentration impaired, confusion, depression, dizziness, drugged feeling, emotional lability, insomnia, libido decreased, myoclonus, nervousness, paresthesia, somnolence, tremor, vertigo, amnesia, depersonalization, lack of emotion, manic reaction.

There are only six in the final version of the label: amnesia, CNS stimulation, concentration impaired, depression, emotional lability, and vertigo.

Some appear scattered in several charts: Anxiety, tremor, insomnia, somnolence, paresthesia, drugged feeling, dizziness, confusion, concentration impaired, depersonalization, myoclonus, abnormal dreams, agitation. The scattering of these items is very misleading. The scattered ADRs cannot be comprehended as patterns, for example, of CNS dysfunction by the reader and cannot be viewed all at once for their totality. Furthermore, the relatively short list of six frequent ADRs in the more accessible paragraph is very misleading.

More misleading, for the final label some ADRs were dropped into the infrequent category: manic reaction, abnormal dreams, depersonalization, and lack of emotion.

XVI. Summaries of Worldwide Adverse Experiences: Paroxetine v. Placebo

This material is taken from Appendix V.2, Comparisons for Adverse Experiences Listed by Preferred Term within the Body System, Intent-to-treat Population (SB 0000654 and following; p. 14, stamped p. 237). US Data is in brackets and is taken from V.9. Comparisons for Adverse Experiences Listed by Preferred Term with Body Systems: Intent-to-Treat Population (SB 0000760, p. 12, stamped p. 13). US data is entered only if it differs from worldwide. For the US, Paroxetine N = 1562 and Placebo N = 497.

Selected "Nervous System" Adverse Experiences Worldwide from Appendix V.2		
Preferred Term	% Paroxetine N=2963	% Placebo N = 554
Abnormal dreams	2	1 [US 0]
Agitation*	4 [US 5]	2
Anxiety*	5 [US 6]	3 [US 2]
CNS stimulation*	4 [US 3]	3
Concentration impaired	3	0
Depersonalization	1	0
Depression	1	0
Emotional lability*	1	0
Insomnia*	14 [US 16]	7
Lack of emotion*	1 [US 0]	0
Manic Reaction*	1 [US 0]	0
Nervousness*	4 [US 6]	2
Psychosis*	3	0
Somnolence	20 [US 27]	9
Tremor*	11 [US 9]	2

Notice the overall stimulation profile that is obscured by the published label. Asterisks (*) are used to designate commonly accepted stimulant effects. However, all of the adverse effects in the chart can be caused by stimulants, including somnolence and depression. Somnolence, of course, is a less frequent and paradoxical reaction to stimulants.

In regard to mania, note that the worldwide data indicated it was frequent, while the US data did not. This may be SKB's justification for saying that mania was not frequent. When it was to their advantage in regard to suicide attempt rates, they used worldwide data. When it is to their advantage to use worldwide data, as in regard to mania statistics, they do so.

(The zero percentage for mania does not mean that there were no manic reactions about U.S. Paxil patients, but that they did not rise to a rate of 1%.)

XVII. Critique of the Rating Scales

The rating scales used by SKB, and unfortunately by many other pharmaceutical companies, are simplistic and allow for a great deal of investigator bias. Because a drug like Paxil causes very different adverse effects from the older comparison drugs, the tricyclics, and because it causes even more dramatically different adverse effects from placebo, it can be relatively easy for an investigator to determine whether or not the patient is taking Paxil.

The Clinical Global Impression Scale (GCI) of many of the efficacy conclusions (0000790 is an example). However, it is a very simplistic, subjective rating scale in which the rater is asked to rate any perceived improvement. The rater is asked, "Compared with his condition on admission to the project, how much has he changed?" The answers are then rated on a scale of 0-7 for Not assessed (0), Very much improved (1), Much improved (2), Minimally improved (3), No change (4), Minimally worse (5), Much worse (6), and Very much Worse (7).

This scale is simplistic to the point that it is worthless. Improvement is not defined. The basis for the improvement is arbitrarily left up to the "global" impression of the clinician who could make the judgment based on anything from the patient "feel good" to specific symptom improvement. In fact, depression is not a one-dimensional disorder that improves on a single linear scale. It is a complex human phenomena in which, for example, individuals often seem improved when they are actively planning suicide, and in which individuals, conversely, may look worse while they subjectively feel better. An individual may seem to have more energy when in fact the individual is becoming manic and suffering from worsened insomnia. Overall, depression involves an infinite array of feelings and symptoms that vary in every individual.

The scale also allows for the subjectivity of the investigator to run wild. Since investigators can often tell which patient is taking the SSRI rather than the placebo or the tricyclic antidepressant, it becomes relatively easy and tempting to conclude that patients on the study drug are improving.

Similar criticisms can be made of the Hamilton Depression Rating scale (SB 0000783 is an example). It plays a key role not only in rating efficacy but also in re-evaluating adverse effects, in particular suicidality. In fact, it was never intended by Hamilton to be used for quantifying depression in a scientific manner. It is relatively

useless for evaluating suicidality since it has only one relevant item out of 21 items, and the rating is subject to extreme investigator bias and variation.

Part B: Analysis of the Paxil Label

I have already described in Part A, Section XV how the data generated in the NDA was distorted when placed in the official label. There are other problems with the label as well.

Page numbers cited are taken from the 1997 Physicians' Desk Reference.

A. Problems with 1997 Label

The 1997 label for Paxil reads:

The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. P. 2683

(1) This label is misleading in that it implies that Paxil can cause a "significant remission." The term remission, according to standard medical dictionaries, indicating either a partial or complete abatement of symptoms. For example, the 1989 Psychiatric Dictionary, Sixth Edition, published by the Oxford University Press, defines remission as follows:

remission Abatement of the symptoms and signs of a disorder or disease. The abatement may be partial or complete.

Clinicians deal with this ambiguity by speaking of "partial" and "complete" remission. By using the more general term, remission, and by calling it "significant," implying it may even be complete, the label misleads physicians into believing that Paxil has been shown to cause a complete abatement or remission of symptoms. There is no evidence that Paxil brings about a significant number of complete remissions. Instead, Paxil marginally improves depression in comparison with placebo.

The label does not provide information on the number of depressed patients "Very much improved" on Paxil; but the breakdown data provided for only one OCD study (p. 2682, second column) indicates that at the 20 mg dose, placebo and Paxil both resulted in a 7% "Very Much Improved" rating on the Global Improvement Item. However, 20% achieved that rating on the 40mg and 60 mg dose. There are no data for "complete remission."

(2) The label is further misleading in that it implies there is reason to believe that the risk of suicide will be diminished after "initial drug therapy" with Paxil. There is no evidence for this. Instead, as indicated below, Paxil increases the risk of suicide.

B. Contraindications To Be Added to the Label

Note that the Contraindication category is stronger than the Warning category, as it indicates that the drug should never be used under the specified conditions. The label for Paxil should, but does not, contain information consistent with the following observations:

(1) Paxil can cause or exacerbate suicidal tendencies, and is contraindicated in patients for whom there is a risk of suicide. In U.S. clinical trials, Paxil caused suicide at a rate well-above 1% of patients and at a considerably higher rate than other antidepressants or placebo. When adjusted correctly, the worldwide rates followed the same pattern. The rate for Paxil-associated suicide attempts was many times greater than the rate for patients taking other antidepressants or placebo.

The patient and family should be warned about the danger of Paxil-induced suicidality and instructed to immediately inform the physician of any suicidal thoughts or intentions while taking Paxil.

(2) Based on data from clinical trials and clinical reports, Paxil does not reduce suicidality or the rate of suicide attempts, and therefore Paxil should not be used as a treatment for ameliorating or preventing suicidality. The patient and family should be warned that Paxil cannot be relied upon to prevent suicidal tendencies, that instead it raises the rate of suicidal behavior, and the family should be instructed to immediately inform the physician of signs of suicidal thoughts or intentions.

(3) In a substantial portion of patients Paxil causes and/or aggravates anxiety, agitation, nervousness, irritability, insomnia, tremor, and other symptoms of central nervous system (CNS) stimulation, including emotional lability and mania. CNS stimulation is known to be associated with suicide and violence. Paxil is contraindicated in patients who are experiencing or who are at risk for symptoms of stimulation. The patient and family should be warned about the danger of Paxil-induced stimulation and instructed to immediately inform the physician about any signs of stimulation.

C. Warnings To Be Added to label

(1) Paxil commonly produces severe adverse reactions during the first one to five days of exposure to the drug in the starting dose range (10-20 mg per day). As a result, the patient is at risk for a worsening of his or her condition before there is any beneficial drug effect. The patient and family should be alerted to the possibility of adverse reaction occurring soon after starting the drug, including stimulation (insomnia, anxiety, agitation), suicidality, or violence. The patient and family should be instructed to inform the physician at the earliest sign of stimulation, suicidality, or violence.

(2) Paxil commonly produces akathisia, a drug-induced central nervous system disorder characterized by feelings of irritability and anxiety in association with restlessness and the inability to sit still. Akathisia is associated with an increased rate of suicidality and violence. The patient and family should be informed about the danger of akathisia and instructed to immediately contact the physician at the first sign of akathisia.

(3) Paxil is not indicated for the treatment of suicide and is associated with an increase rate of suicidality and suicidal behavior (See other Warnings).

(4) Paxil is not indicated for the treatment of aggression or violence and can increase aggression and violence (see other Warnings).

(5) Severe adverse reactions to Paxil may develop in the first several days of treatment even a low doses, but any therapeutic effect is likely to be delayed for a longer period of time. Therefore, the first several days of exposure to Paxil are particularly hazardous (see other Warnings). The physician should take appropriate precautions to monitor the patient and to respond to any signs of a worsening condition.

(6) Paxil belongs to the pharmacological class of serotonin reuptake inhibitors and is likely to produce any adverse drug reaction associated with other medications, such as fluoxetine, sertraline, fluvoxamine, and citalopram in that class of antidepressants.

D. Other Label Issues

(1) If an adverse reaction or event is listed in tables (e.g., Tables 1, 2, & 3), it is not repeated in text under "Other Events Observed During Premarketing Evaluation" (p. 2685, first column). As a result anxiety gets left out of the systematic listing of adverse reactions under **Nervous System** in this section.

Although this method is approved by the FDA, SmithKline was obligated to make the label properly informative. It should have made a large warning that both sources need to be examined or it should have combined the adverse reactions in a summary elsewhere in the label.

(2) The table minimizes the numbers of reports relating to anxiety by providing separate data for anxiety and nervousness (Tables 1 & 2) and for anxiety, nervousness, and agitation (Table 3).

E. Burying the Stimulant Profile

SSRIs as a group have a stimulant profile. I have discussed this in regard to Prozac in some detail (Breggin, 1997; Breggin and Breggin, 1994).

The data in the label, if properly understood through careful and time-consuming scrutiny, confirms that Paxil can be stimulating. Indeed, "CNS stimulation" is mentioned as "frequent" under **Nervous System** (p. 2685, column three). However, the data on stimulation is not organized in any one place in the label, and instead is obscured by being scattered among three tables and various places in the text. Furthermore, the term "frequent" indicates "at least 1/100 patients" or 1%, and therefore does not communicate the how extremely common stimulation is.

The following two tables compile the data confirming the high risk of patients developing stimulant reactions. The label itself should have organized this data in a fashion that would have similarly warned about the dangers of the stimulant syndrome.

F. Comparison of Stimulant Adverse Effects in Depression, OCD, and Panic Disorder

Patients with an "incidence of 5% or greater and incidence for *Paxil* at least twice that of placebo" were reported separately for Depression, OCD and Panic Disorder (Table 2, summarized in text p. 2684, first column). In **Table I**, I have organized this data in parallel to more readily compare and examine the pattern.

The information in this newly created table indicates that high rates of several stimulant profile reactions were found in all three groups for sweating, tremor, and decreased appetite. In patients treated for depression, stimulation profile reactions are especially prominent and include sweating, nausea, decreased appetite, tremor, insomnia, and nervousness. Dry mouth (OCD only), nausea (depression and panic disorder) and various sexual dysfunctions (all three groups) are also consistent with stimulant effects but not as specifically characteristic.

The criteria for this particular table were unusually high. If we examine the entire range of reported adverse effects at the level of 1% or greater rather than 5% or greater (and twice placebo) we develop a more obvious stimulant profile.

Table I: Very Frequent (5%) CNS/Psychiatric Adverse Reactions from Paxil Label		
Depression	Panic Disorder	OCD
Asthenia	Asthenia	Sweating
Sweating	Sweating	Nausea
Nausea		Decreased appetite
Decreased appetite	Decreased appetite	Dizziness
Dizziness		Somnolence
Somnolence		Tremor
Tremor	Tremor	
Insomnia		
Nervousness		
Ejaculatory Disturbances	Abnormal Ejaculation	Abnormal ejaculation
Other male genital disorders		
	Impotence	Impotence
	Libido decreased	
	Female genital disorder	
		Dry mouth
		Constipation

Table II: Summary of Stimulant and Stimulated-Related ADRs from Paxil Label		
Frequent Stimulant ADRs	Stimulant-Related CNS ADRs	Stimulant-Related CNS ADRs
[at least 1%]	[at least 1%]	[less than 1%]
<u>CNS</u>		
CNS stimulation**	Depression**	Hostility**
Seizures+	Amnesia* **	Paranoid reaction**
Mania/hypomania+	Asthenia*	Antisocial reaction**
Emotional lability**	Concentration impaired* **	Manic reaction**
Anxiety*	Somnolence*	Manic depressive reaction**
Nervousness*	<u>Serotonin Syndrome</u> ++	Euphoria**
Agitation*		Psychosis**
Insomnia*	Agitation [also *]	Psychotic depression**
Tremor*	Confusion	Depersonalization* ** ++
<u>Systemic</u>	Diaphoresis [sweating*]	Hallucinations**
Sweating*	Hallucinations [also **]	Delusions**
Decreased appetite*	Hyperreflexia [reflexes increased *]	Delirium**
Weight Loss**	Myoclonus [also *]	Abnormal thinking**
Dry mouth*	Shivering [chills*]	Abnormal dreams*
Tachycardia**	Tachycardia [also **]	Lack of emotion**
Hypertension**	Tremor [also *]	Neurosis**
Palpitation*		Convulsion**
		Grand mal convulsion**

ADR=Adverse Drug Reaction. The ADRs selected for this table are among those potentially related to stimulant effects. * From the Tables; ** From "Other Events Observed..."; + From Precautions; From footnote to Table 2; ++ From Postmarketing Reports section.

In regard to the serotonin syndrome as listed in Table II, note that many of these symptoms are also reported as individual ADRs. To some extent, many of the individual ADRs may at times reflect a partial expression of a serotonin syndrome, although overstimulation other neurotransmitters may be involved. Other stimulant aspects of the serotonin system, not listed in the Paxil label, include hypertension and convulsions.

Part C: Application to the Lacuzong Case

[REDACTED]

Part D. Conclusions

The following opinions are offered to a reasonable degree of medical certainty.

A. Basic Facts of Mr. Lacuzong's Case

[REDACTED]

B. Negligence by SmithKline Beecham

The following acts of negligence and lack of due care by SKB contributed to or caused Mr. Lacuzong's suicidal and violent behavior:

(1) SKB was deceptive, fraudulent and negligent in hiding data concerning the stimulating effects of Paxil, including agitation, anxiety, nervousness, insomnia, and irritability. The label for Paxil was constructed to hide the stimulating pattern or profile of effects. Indeed, SKB attempted to promote Paxil as relatively free of these symptoms and even as an effective treatment for patients suffering from these symptoms and was criticized by the FDA for doing so.

Stimulation is an especially dangerous adverse effect in depressed patients, producing an agitated depression that can lead to suicide and violence. Physicians and patient need to know that a drug is potentially stimulating.

(2) SKB systematically eliminated the term akathisia as an investigational term and as a preferred term. In doing so, it acted in defiance of the FDA's own coding system. In this regard, SKB purposely misled the medical profession. When eventually forced by the FDA to include akathisia in the label, SKB allowed the term to be placed in the postmarketing section, lumped together with other adverse effects, rather than acknowledging to the FDA and in the label that it was detected at a high frequency in the premarketing clinical trials.

Akathisia is an extremely disturbing syndrome and is known to be associated with violence and suicide. Physicians and patients need to know the implications of akathisia and that a drug can cause akathisia.

(3) SKB hid and distorted data concerning the danger of suicide attempts and completed suicide. It manipulated the data to minimize the danger of suicidal behavior when in fact suicidal behavior was frequent on Paxil. The harm in doing this is great.

(4) SKB made no effort to develop additional controlled clinical trials to further investigate the alarming data concerning the high rate of Paxil-induced stimulation, akathisia, and especially suicidal behavior (confirmed by SKB's David Wheadon, deposition 10.18.00, p. 42 & p. 184).

(5) SKB attempted to make Paxil seem safer and more effective than other SSRIs, increasingly the likelihood that it would be prescribed to Mr. Lacuzong and that his physician and the clinic would lack sufficient concern about its dangerousness. In general SKB conducted a campaign of exaggerating the safety of Paxil, even trying to promote it for children and the elderly. Their efforts created an atmosphere in which Paxil was considered by the medical profession to be more safe than it is.

(6) SKB hid the fact that a large portion of patients develop severe adverse effects, including stimulation and akathisia, in the first one-to-three days of exposure to the drug. This data is of extreme importance, because the drug will not have its presumed beneficial effect during this time of potentially severe adverse reactions, including stimulation and akathisia. Thus the patient remains depressed while undergoing, in addition, painful stimulation and akathisia. Knowledge that adverse effects occur early in the treatment is also important because patients and many physicians falsely believe that, since it takes weeks for therapeutic effects to develop, it must take weeks for adverse effects to develop as well. In other words, physicians and patients falsely believe that the drug "doesn't take effect" for weeks when in fact it can have adverse effects with the first dose.

The development of severe stimulating adverse drug reactions in depressed patients in the absence of a corresponding beneficial effect is a prescription for disaster that the drug company has hidden from view. Physicians and patients needed this information.

(7) SKB committed various other individual acts of negligence that are noted and documented in the body of this report.

(8) Paxil's efficacy was marginal. Physicians and patients need to know both the relative lack of efficacy and the relative frequency of adverse effects in order to make an informed risk/benefit assessment. The effectiveness assessment was largely based on two very limited tests, the Hamilton Depression Scale (Ham-D) and the Clinical Global Inventory (CGI). Because of the high drop out rate due to adverse effects and lack of efficacy, patients dropped out too early to allow meaningful conclusions to be drawn.

(9) SKB failed to act on the known fact that SSRIs tend to share the same adverse reaction profile, including the production of stimulation and akathisia. Instead, it tried to cover up this similarity, falsely encouraging physicians and patients to believe that Paxil is safer than Prozac and other drugs in the same class.

(10) SKB emphasized the short-acting nature of Paxil as a pure benefit, when in fact it causes special hazards, such as the potential for interdose withdrawal.

(11) SKB representatives were discussing with at least one FDA official the possibility of future employment in the pharmaceutical industry. This could encourage leniency on the part of the FDA official. The same FDA official helped SKB manipulate their suicide data to their advantage.



E. Bibliography

Breggin, P. and Breggin, G. (1994), Talking Back to Prozac, New York: St. Martin's Press.

Breggin, P. (1997). Brain-Disabling Treatments in Psychiatry: Drugs, Electroshock and the FDA, New York: Springer Publishing Company.

Breggin. (2001). The Antidepressant Fact Book, Cambridge Massachusetts: Perseus Books.

Glenmullen, J. (2000). Prozac Backlash, New York: Simon & Schuster.

Lipinski, Jr., J., Mallaya, G., Zimmerman, P., and Pope, Jr. H. (1989, September). Fluoxetine-induced akathisia: Clinical and theoretical implications. Journal of Clinical Psychiatry, 50, 339-352.

Public Citizen (1990, May 23). Re: Citizens petition for revision of fluoxetine (Prozac) labeling. Letter to David Kessler, Commissioner, Food and Drug Administration. Washington, DC: Public Citizen Health Research Group.

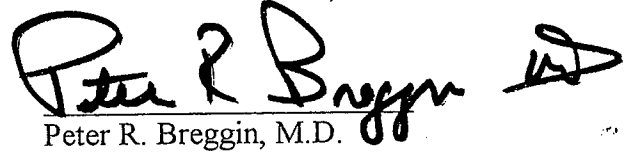
Rothschild, A. and Locke, C. (1991, December). Reexposure to fluoxetine after serious suicide attempts by three patients: The role of akathisia. Journal of Clinical Psychiatry, 52, 491-493.

Teicher, M., Glod, C., and Cole, J. (1990, February). Emergence of intense suicidal preoccupation during fluoxetine treatment. American Journal of Psychiatry, 147, 207-210.

Teicher, M., Glod, C., and Cole, J. (1993). Antidepressant drugs and the emergence of suicidal tendencies," Drug Safety 8(3):186-212.

Under penalty of perjury of the laws of the State of California, I submit this declaration to the court and arbitrator, and further believe the foregoing to be true and correct to the best of my knowledge and recollection. Executed: Bethesda, MD.

DATE: July 21, 2001

A handwritten signature in black ink that reads "Peter R. Breggin" followed by a stylized flourish.

Peter R. Breggin, M.D.

Declarant

Attached Appendices:

- (a) Summary and Annotated Resume of Peter R. Breggin, M.D.
- (b) Bibliography of Peter R. Breggin, MD.
- (c) Peter Breggin, M.D., Trial Testimony Accepted in Court.

Exhibit D

Proposed Bill – PSP Notification of Prohibition

Notification of Prohibition Bill

Amendment to 18 Pa.C.S. 6105 to the Uniform Firearms Act, 18 Pa.C.S. § 6101, *et seq.*

Section 6105:

(k) Notification of Prohibition by the State Police: The Pennsylvania State Police shall notify an individual of his firearm disability upon the individual becoming prohibited from purchasing or possessing firearms or ammunition under the Uniform Firearms Act, 18 Pa.C.S. § 6101, *et seq.*, or the Gun Control Act, 18 U.S.C. § 921, *et seq.* The notification shall be in writing and sent through verifiable means to ensure that the prohibited individual receives the notification. If, after receiving the notice, the individual disputes that he is prohibited under the Uniform Firearms Act or Gun Control Act, he may file a challenge, pursuant to 18 Pa.C.S. § 6111.1(e), where the burden of proof shall be on the Commonwealth, including in any appeal to the Attorney General. If an individual contends that he did not receiving notification of his firearms disability by the Pennsylvania State Police, unless the Commonwealth can prove, beyond a reasonable doubt, that the individual was informed of his firearm disability, the individual shall be immune from prosecution in relation to the making of false statements on any state or federal form to purchase or transfer a firearm or otherwise obtain a license to carry firearms.

Exhibit E

Proposed Bill – Relief from Disabilities

Relief from Disabilities Bill

Amendment to 18 Pa.C.S. 6105.1 to the Uniform Firearms Act, 18 Pa.C.S. § 6101, *et seq.*

Section 6105.1

(a) Restoration.--A person convicted of a disabling offense may make application to the court of common pleas in the county where the principal residence of the applicant is situated for restoration of firearms rights. The court shall grant restoration of firearms rights after a hearing in open court to determine whether the requirements of this section have been met unless:

(1) the applicant has been convicted of any other offense specified in section 6105(a) or (b) (relating to persons not to possess, use, manufacture, control, sell or transfer firearms) or the applicant's conduct meets the criteria in section 6105(c)(1), ~~(2)~~, (3), (4), (5), (6) or ~~(7)~~;

(e) Definitions.--As used in this section, the following words and phrases shall have the meanings given to them in this subsection:

“Disabling offense.” A conviction for any offense which:

(1) resulted in a Federal firearms disability and is substantially similar to either an offense currently graded as a crime punishable by a term of imprisonment for not more than ~~two~~ FIVE years or conduct which no longer constitutes a violation of law; and ~~(2)~~ was a violation of either of the following: (i) the former act of May 1, 1929 (P.L.905, No.403), known as The Vehicle Code, or the former act of April 29, 1959 (P.L. 58, No. 32), known as The Vehicle Code; or (ii) the former act of June 24, 1939 (P.L.872, No.375), known as the Penal Code;

(2) WAS A NON-VIOLENT MISDEMEANOR; OR,

(3) OCCURRED AT LEAST 15 YEARS PRIOR AND RESULTED IN A STATE OR FEDERAL FIREARMS DISABILITY.

~~The definition shall not include any offense which, if committed under contemporary standards, would constitute a misdemeanor of the second degree or greater under section 2701 (relating to simple assault) and was committed by a current or former spouse, parent or guardian of the victim, by a person with whom the victim shares a child in common, by a person who is cohabitating with or has cohabitated with the victim as a spouse, parent or guardian or by a person similarly situated to a spouse, parent or guardian of the victim.~~

Exhibit F

Proposed Bill – PSP Legal Determination

Legal Determinations Bill

Addition of 18 Pa.C.S. 6128 to the Uniform Firearms Act, 18 Pa.C.S. § 6101, *et seq.*

Definition to be added to 18 Pa.C.S. 103

“Other lawful purpose.” – shall include, but not be limited to, carrying a concealed firearm, pursuant to a validly issued license to carry firearms, as provided for in Section 6109, and the lawful open carrying of a firearm.

Definition to be added to 18 Pa.C.S. 6102:

“Person.” – shall be construed to mean and include an individual, association, company, corporation, partnership, trust, or estate.

Section 6128:

- (a) **Legal Determinations.** – Upon written request by any person, as defined in Section 6102, the Pennsylvania State Police or its counsel shall, within 30 days of receipt of the request, issue a legal determination, regarding any subject matter relating, in any manner, to this Act or any regulation promulgated thereunder, including whether any specific conduct constitutes an other lawful purpose, as defined in 18 Pa.C.S. § 103. In the event that the legal determination requests information that can only be disclosed to the requester, the Pennsylvania State Police shall ensure the identity of the requester and only disclose the response to the requester or requester’s attorney.
- (b) **Effect of Determination.** – Any legal determination issued pursuant to this Section shall be binding on the Pennsylvania State Police. Any person who relies on a legal determination issued pursuant to this Section shall be immune from prosecution, unless the Commonwealth can prove, beyond a reasonable doubt, that the person was informed, after issuance of the legal determination, that the legal determination was no longer binding.
- (c) **Aggrieved Person.** – Any person aggrieved by any legal determination issued pursuant to this Section, shall have the right, within 30 days, to *de novo* appeal in the Commonwealth Court.
- (d) **Reasonable Expenses.** – A court shall award reasonable expenses, including, but not limited to, attorney fees, expert witness fees and costs, to an aggrieved person affected in an action under subsection (c) where a final determination by the court is granted in favor of the aggrieved person.
- (e) **Database of Legal Determinations.** – The Pennsylvania State Police shall maintain, in perpetuity, all legal determinations issued pursuant to this Section. Any person may request, pursuant to the Right to Know Law, copies of any legal

determination issued, and the Pennsylvania State Police shall provide copies, provided that the legal determination does not contain confidential information that can only be disclosed to the original requester. Legal determinations containing confidential information relating to the original requester shall only be disclosed pursuant to court order, after notice to the original requester and opportunity of the original requester to be heard on any objections and/or confidentiality that may exist in relation to the legal determination.

- (f) **Reporting.** – The Pennsylvania State Police shall report to the General Assembly, on an annual basis, the number of legal determination requests received and responded to for that year.