

**EXPLORING THE RELATIONSHIP  
BETWEEN MEDICATION AND VETERAN SUICIDE**

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**HEARING**  
BEFORE THE  
**COMMITTEE ON VETERANS' AFFAIRS**  
**U.S. HOUSE OF REPRESENTATIVES**  
ONE HUNDRED ELEVENTH CONGRESS  
SECOND SESSION

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FEBRUARY 24, 2010  
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## **EXPLORING THE RELATIONSHIP BETWEEN MEDICATION AND VETERAN SUICIDE**

**WEDNESDAY, FEBRUARY 24, 2010**

U.S. HOUSE OF REPRESENTATIVES,  
COMMITTEE ON VETERANS' AFFAIRS,  
*Washington, DC.*

The Committee met, pursuant to notice, at 10:00 a.m., in Room 334, Cannon House Office Building, Hon. Bob Filner [Chairman of the Committee] presiding.

Present: Representatives Filner, Michaud, Herseth Sandlin, Mitchell, Halvorson, Perriello, Teague, Rodriguez, Donnelly, Space, Walz, Adler, Bilirakis, and Roe.

### **OPENING STATEMENT OF CHAIRMAN FILNER**

The CHAIRMAN. Good morning. The Committee on Veterans' Affairs will come to order.

I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks. Hearing no objection, so ordered.

Thank you all for attending today's hearing. I think it is an important hearing to look at the potential relationship between psychiatric medications and suicides. Not an attractive topic, but one that I think we have to address.

Certainly, we know with post traumatic stress disorder (PTSD) and traumatic brain injury (TBI) being so prevalent in the current wars in Iraq and Afghanistan, mental health issues have taken and should take center stage.

Research has shown that mental disorders and substance abuse disorders are linked to more than 90 percent of people who die by suicide. Today, as you know, suicides among servicemembers and veterans continue to increase at an alarming rate, far exceeding the comparable suicide rates among the general population, and I think higher than we had during the Vietnam War.

It is a tragedy that our servicemembers and veterans survive the battle abroad only to return home from the theater of war to fall by suicide.

We know there is a widespread availability and use of psychiatric medications to address mental health disorders, but there is apparently some dispute about whether these drugs prevent or lend a hand in suicide. Some doctors are convinced by their clinical experience that psychiatric drugs often adversely impact the individual's better judgment and lead people to lose control over their emotions and actions.

Suicides may be driven by so-called drug-induced adverse reactions and intoxications. There are, on the other hand, some studies that show suicide attempts were lower among patients who are treated with antidepressants than those who are not.

Through this hearing, we will explore the two opposing schools of thought on the relationship with psychiatric medicine and suicide. In this process, we will also seek to better understand the reasons why more and more servicemembers and veterans are taking their own lives and what the U.S. Department of Veterans Affairs (VA) and U.S. Department of Defense (DoD) are doing to prevent such deaths.

Before we hear from our first witnesses, I will recognize Dr. Roe for an opening statement.

[The prepared statement of Chairman Filner appears on p. 51.]

#### **OPENING STATEMENT OF HON. DAVID P. ROE**

Mr. ROE. Thank you, Mr. Chairman, and thank you for holding this hearing.

I think those of us who are gathered here today would be hard pressed to find a topic more heart breaking than when a servicemember makes the decision to end his or her own life. This hearing is one of the many hearings and meetings this Committee has had in an effort to combat veteran suicide and I can tell you that the stories we hear in these proceedings much like those in Dr. Breggin's book always raise difficult questions.

As painful as such anecdotal accounts are, we must take heed not to be so quick to point out to a single cause or mistaken theory for a solution. It is sound research that is critical to our efforts to put an end to these tragedies and understand the entire story.

On that front, there are many encouraging signs. In 2008, the Army and the National Institutes of Mental Health (NIMH) began a 5-year study into the factors that contribute to suicide in the Armed Forces and how to prevent them. Called the ARRM Study to Assess Risk and Resilience in Servicemembers, this is the largest study of suicide and mental health among military members ever conducted.

In addition, there is a great deal of ongoing public and private research into the causes of suicide and treatment options, including medication, to prevent it.

I am hopeful that with this research, practitioners will be able to better identify risk factors for veteran suicide and design prevention, outreach, and treatment options that are effective and practical within the VA setting.

The psychology behind why a person may see death as the only way out is more complex than any of us have the ability to fully comprehend and it is the interaction of a number of factors that may lead to this catastrophe.

In addressing these issues, one cannot simply place blame on the veteran, their military service, their illness, or their chosen treatment option. As the research goes on, we must allow our veterans and servicemembers to have the full range of approved treatment options that they decide upon with their doctors.

I want to thank our witnesses for being here this morning and I look forward to hearing and learning from each of you. It is only

by working together that we can convince every courageous yet struggling American veteran and their country that supports them that hope and help are out there.

I yield back the balance of my time.

[The prepared statement of Congressman Roe appears on p. 51.]

The CHAIRMAN. Thank you, Dr. Roe.

I want to introduce the first panel. We have Dr. Peter Breggin, Psychiatrist and Author from Ithaca, New York, and Dr. Andrew C. Leon, Professor of Biostatistics in Psychiatry and Public Health at Weill Cornell Medical College.

Thank you for being with us.

Dr. Breggin, I just have one question to start off with, to test your mental state—do you willingly live in Ithaca, New York?

Dr. BREGGIN. I lived here most of my life, DC.

The CHAIRMAN. I spent 10 years at Cornell, so I know something about the background.

Dr. BREGGIN. That is right.

The CHAIRMAN. Okay, test passed. Please enlighten us. You have the floor.

**STATEMENTS OF PETER R. BREGGIN, M.D., ITHACA, NY (PSYCHIATRIST AND AUTHOR); AND ANDREW C. LEON, PH.D., PROFESSOR OF BIOSTATISTICS IN PSYCHIATRY AND PUBLIC HEALTH, WEILL CORNELL MEDICAL COLLEGE, NEW YORK, NY**

**STATEMENT OF PETER R. BREGGIN**

Dr. BREGGIN. Well, I am Peter R. Breggin, M.D. I am a psychiatrist. And I was in this area of DC for most of my career and then we moved to Ithaca, New York, to be in the country.

In the early 1990s, I became the first psychiatrist to speak and write extensively about violence and suicide caused by the newer antidepressants beginning with Prozac, later going on to Paxil, Zoloft, Celexa, and other drugs.

I also, as a result of that early research, became a scientific expert for more than 100, I think it was like 170 product liability cases against Eli Lilly, the manufacturer of Prozac, that were combined by a court to provide the opportunity for one person to research the data and look into the company files for all of the suits. And I was chosen to be that one medical expert.

This ended up giving me experience that literally no one else in the world has had in terms of looking at the basic data from Eli Lilly concerning the development and marketing and then from some other drug companies.

I was shocked at what I found inside the company. For example, the German equivalent of our Food and Drug Administration (FDA) had become concerned that they were finding an increased suicide rate on studies of Prozac. So they asked Eli Lilly, and this is back now in the late 1980s, to go back and look at all of their clinical trials and report to them on the rate of suicide attempts in the controlled clinical trials of Prozac compared to another drug or placebo.

Lilly found, depending on how you count it, a 6 to 12 to 1 ratio of suicide attempts, not just thinking, attempts in the control or comparison group compared to placebo. Lilly never made the re-

sults public. They never gave this report that I found to the Germans. They never made it available to the FDA.

I also found memos inside Lilly explaining guilt and shame on the part of some German investigators working for Lilly that the company was classifying suicides and suicide attempts reported by doctors to them as no drug effect or other harmless kinds of entities, thereby disguising the suicide attempts and the completed suicides.

And one of these memos, the gentleman declared, how am I going to explain this to my family. He expressed a genuine feeling of shame.

At the same time, the FDA conducted a study comparing Prozac to an older antidepressant, Trazodone. After factoring in the increased number of prescriptions for Prozac and also factoring in the controversy because the controversy had not broken out yet, there were far more reports of suicidality and violence and other mental adverse effects on Prozac.

I worked on these issues for many, many years, as you know, and then testified before the FDA in 2004 on a couple of occasions and the agency distributed one of my papers written in 2003 to the panel, the FDA panel. And a lot of the language in the current label virtually reads actually very, very similar to what I had to say in my papers and books.

Now, my conclusions in this testimony are based not only on these very early studies that I discovered inside of Eli Lilly, which, by the way, you can find on my Web site, the Lilly documents I am describing, and I also described them in a couple of my books.

But my conclusions are based in part on the many citations in the paper I wrote specifically for this Committee. I actually sat down and wrote you a paper, *Antidepressant Induced Suicide and Violence: Risks for Military Personnel*, and in the hundreds of citations in my book.

My recent book, which Mr. Roe was kind to mention and which I know that you have read, Mr. Chairman, *Medication Madness*, gives an overview of my clinical experience, which now included in the book more than 50 cases of violence, suicide and crime, most of them on antidepressants.

And I actually interviewed survivors. I actually went to crime scenes, read all the medical records, police records, and clearly documented in *Medication Madness* from a clinical viewpoint that there are many, many cases like this. I actually have over 100 that are mentioned in the book and 50 documented in detail.

In 2004, after the various hearings, the FDA actually before them, required the antidepressant manufacturers to review their clinical trials. The FDA itself concluded that the newer antidepressants doubled the rate of suicidal thoughts and behaviors in children, youth, and young adults up to age 24, which, of course, is very menacing for the soldier population, the military population.

Now, you get a doubling of rates. Well, what does this mean? Well, the clinical trials are very short. Most of them average about 6 weeks. Some of the Prozac trials were 4 weeks. Suicidal patients are excluded from clinical trials.



The patient is monitored every week by experts and informed of all the dangers presumably and the patient is given huge hope. You are in this wonderful research setting where you are getting something new and wonderful. And, furthermore, there is no attempt to look for suicide attempts and to categorize them.

Now, when you get a doubling of suicide attempts and ideation under those conditions, you can assume that in the military or clinical practice it is going to be multiples, unknown multiples because there it is given for months, there it is not monitored, their psychotic patients are included, their suicidal patients are included, and all of that is excluded from the clinical trials.

Now, one of the questions that may come up today is that there were in this particular batch of trials no completed suicides. The shock is how many attempts there were because the best way to treat suicide, if there were one, would be to simply put somebody in a clinical trial and give hope because suicide is loss of hope. That is why when you get all the doctors looking at you and testing you and working with you, you almost never get suicides in any kind of clinical trial of that kind.

Now, the FDA warnings that came out of these hearings are identical for all antidepressants. The Zoloft label is the model I am going to use. And it begins with a huge black box, huge black box, very rare thing, with the title *Suicidality and Antidepressant Drugs*. And I will read you just the first line of it.

“Antidepressants increase the risk compared to placebo of suicidal thinking and behavior, parentheses, suicidality in children, adolescents, and young adults in short-term studies of major depressive disorder and other psychiatric disorders.” And later in the label, they will say that a lot of the adverse effects occur in nonpsychiatric patients.

This black box is very lengthy and many of the items are repeated over and over again in the warnings and further on. It is the only label like that that I know of. The black box is followed by a very ominous section, still in the warnings, entitled “Clinical Worsening and Suicide.” This idea of clinical worsening that is repeated in the label has not been given enough attention.

It states in this section that the following symptoms I am going to list, quote “have been reported in children and adults taking antidepressants both for psychiatric and nonpsychiatric purposes.” And the list includes “anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia,” which is psychomotor restlessness, and the DSM-IV, our major document, points out that akathisia leads to violence and suicide.

So I interrupted. “Akathisia, hypomania, and mania.” And mania is an out of control state that increases vastly the risk of violence and suicide. This is the list that is virtually taken from several of my earlier publications and note the mention of irritability, hostility, aggressiveness, and impulsivity.

Imagine causing that in young men and women who are heavily armed and under a great deal of stress. And irritability, hostility, aggressiveness, impulsivity not only lead to violence but to suicide. Many suicides are out of anger and irritability and resentments.

The CHAIRMAN. Dr. Breggin, I do not mean to interrupt. I just want to ask a specific question. If an active-duty soldier is given these medications, they may not even see that warning, right? I mean—

Dr. BREGGIN. Well, my experience, last year, I spoke at the oldest military stress conference given. Bart Billings, whom you know, retired Army officer and psychologist, runs that. And I talked to Generals and I talked to mental health professionals and they all agreed that these warnings were hardly ever presented to the soldiers and that the Army was in a sense acting as if it was unaware.

And some of these people gave me estimates not of the 15 percent of active-duty soldiers on psychiatric drugs that we often hear but up to 30 percent of soldiers in some sections. Marines in particular was one that was mentioned to me.

The CHAIRMAN. So they are not even informed of the risks?

Dr. BREGGIN. No, no. And as we go on further, we will see that the FDA tells doctors you should, and the word "should" is in the label, you should share this information with the patient and the family and make sure they understand it. It is not just you repeat it to them. You sort of, you know, "hey, I want you to understand this is what may happen to you."

That is what I do in my clinical practice. I do not say by the way, the drug may cause this or that, you know. I just make sure over a period of many sessions that the person understands the risks.

Did I answer your question, sir?

In addition to this list that is associated with the drug itself, the antidepressants, and this is mentioned in the label and mentioned in the medication guide I will tell you about, the antidepressants often cause severe withdrawal reactions in which all of those symptoms, all of those adverse reactions can develop.

In fact, I spend probably half my practice even in remote Ithaca treating people who come to me to try to get off of these drugs and are suffering violent feelings, suicidal feelings when they try to stop. And, in fact, in the last 3 weeks, I have had at least three or four patients who as we went down lower on their doses developed really, really frightening reactions and then I had to treat those, usually by raising the dose back up for a while.

Let me mention some of the science more specifically at this point. This list of mania and hypomania and agitation and aggression and so on, that list in one FDA document is stated to be a "known" effect, this whole series that I read to you, are known effects of the drugs.

And what I am going to read to you now involved mostly controlled clinical trials or epidemiological studies. No one should be able to say that causality has not been demonstrated. The gold standard for causality is the controlled clinical trial and it shows a doubling of the rate of suicidality. That is the gold standard.

And I have a discussion that is documented between the top members of the FDA agreeing at the hearings that unless somebody is cheating or there is some other malfeasance going on when you have a causal association in controlled clinical trials. I would add epidemiological studies that demonstrates causality.

In addition, Federal regulations say that the warning labels must have a reasonable degree of certainty about causality before it gets put into the label.

An overview of some of the studies that are involved, because I want you to know this is not merely my personal opinion. This is what the science has overwhelmingly taught me starting with my looking inside the drug companies.

In addition to the studies done under the auspices of FDA, we have, and this is for children and adults, we have a study by Aursnes, A-U-R-S-N-E-S, in 2005. He looked at 16 placebo controlled clinical trials in which Paxil was randomized against placebo and found increased suicidal behavior.

The references are in the article that I gave to you, attached to my testimony, as well as my books and paper.

Ferguson in 2005 searched the adult literature, found 702 randomized clinical trials of 87,000 patients and found a significant increase in suicidality on antidepressants.

Donovan in 1999, in a large British study involving 229 completed suicides, it is a big study in England, found a higher suicide rate in patients treated with the newer antidepressants.

Donovan in 2000 examined 2,776 consecutive cases of deliberate harm in individuals age 17 and older, not children, 17 and older, like soldiers, seen at the emergency department of a British infirmary. Again, the suicide rates were increased in people taking the newer antidepressants.

A fellow named Jick, J-I-C-K, in 1995 conducted an epidemiological study in the United Kingdom involving 172,000 adult patients and Prozac was associated with more suicides than the older antidepressants.

In my home State, for many years, of Maryland, Frankenfeld and some very respected researchers at the University of Maryland studied coroners' cases in Maryland and found that suicides were more violent, which is my clinical experience, in patients taking Prozac compared to older antidepressants.

Now, GlaxoSmithKline in 2006, the manufacturer of Paxil, conducted a new meta-analysis of all its adult trials, the FDA said you have to do a meta-analysis of all the adult trials, and found a statistical increase in the rate of suicidality in depressed patients of all ages, an increased rate from the clinical studies, their own, which were not oriented toward this, an increased statistically significant rate, all ages in patients with major depressive disorder. It is in a Dear Doctor letter that they sent out to all the health care, it is really now called Healthcare Letter, to all the health care professionals in the country.

A study of 1,255 suicides in 2006 in Sweden found that, which was 95 percent of all the suicides in Sweden, by Ljung, et al, L-J-U-N-G, published in 2009, found there was a greatly increased number of completed suicides exposed to the antidepressant drugs. In fact, 52 percent of the Scandinavian women who killed themselves had filled a prescription for these drugs.

Now, this is not as causal as the clinical trials. It could be other factors. But it is just part of this mountain, mountain of evidence.

A retrospective study examined the suicide rate in the VA involving a cohort, a group of people that were 887,000, that is 6 digits,

887,000 VA patients treated for depression and found, quote, “completed suicide rates were approximately twice the base rate following antidepressant starts in VA clinical settings.” That is Valenstein, et al, in 2009.

Now, again, you can look at something like this and say, well, maybe the worst patients were put on the antidepressants and that is the correlation. That is not what they concluded. And, of course, this now comes against the backdrop of the clinical trials which show causality.

Juurink, J-U-U-R-L-I-N-K, et al, in 2006 reviewed more than a thousand cases of actual suicide in the elderly and found that during the 1st month of treatment with selective serotonin reuptake inhibitors (SSRIs) there was a fivefold increase in risk in the elderly. This is no surprise because the elderly are more susceptible to adverse effects.

Fisher, et al, in a really interesting study did a phone survey of people who went to a pharmacy and got drugs, medications, and found that there was a higher rate of suicidality in people who got the SSRIs compared to other antidepressants.

I do not think there is a question about causality, although some people will raise questions of causality today, I am sure.

Finally, just to look at the literature on mania, because mania, if you read the DSM-IV, is caused by antidepressants. This is in our diagnostic manual, that all of the phenomena of mania are caused by antidepressants as well as by just simply bipolar disorder. And mania results in suicide, violence, crime. I have had a whole bunch of just dreadful cases like that.

Well, in 2001, Preda, P-R-E-D-A, found that 8.1 percent of adult psychiatric admissions could be attributed to antidepressant induced mania and psychosis, 8 percent of hospital admissions.

Another group found that 8 percent of patients treated with Paxil developed mania. In other words, they are not even looking for it. They go back and they look at records and they find that 8 percent of the patients got mania when the drug was started. Causality has been definitely established in studies like this.

Howland in 1996 again found a 6 percent rate. Look at these rates, six, eight. Very, very consistent of SSRI induced mania. To induce mania in a soldier, in an armed young man or woman is an incredibly risky affair.

Ebert, et al, in 1997 found a 17-percent rate of hypomania in patients on SSRIs. Some were suicidal or dangerous.

Martin used a national database of 7 million privately insured individuals and he found that if you look at people given antidepressants, all of a sudden, they are getting bipolar disorder diagnoses afterward, after the antidepressants.

I could go on and on, but I will not. I want to tell you one more study because this one comes out of the heart of the advocacy group for psychiatric drugs. It comes from Harvard Medical School where most of what they do is financed or much of it by the drug companies and where some of the prominent doctors were recently under investigation by Senator Grassley for taking money from the drug companies and not informing people.

Well, they did a study, this is Wilens, et al, 2003, of adverse psychiatric events on children taking these drugs, children and adoles-

cents, and they are just more susceptible than adults, but it is the same phenomena. And they found that 22 percent had adverse psychiatric events, quote, “most commonly related to disturbance of mood.”

Then they did something that is called a re-challenge. We have a few studies like this. A re-challenge is where somebody develops a symptom like suicidality. You stop the drug, the symptom goes away. You restart the drug, the suicidality comes back. You stop the drug, it goes away.

Rothschild did a study like this, not even in this paper, but you can find it my books and scientific papers. The FDA says this is a very, very good thing to do. Well, in this case, when they re-exposed the children to an SSRI, 44 percent of that group again became disturbed. And what drug-induced symptoms did they develop? The things we have been hearing about. They became irritable, anxious, manic. They developed insomnia. Four percent of the children became aggressive.

The CHAIRMAN. Dr. Breggin, I need you to—

Dr. BREGGIN. I will finish up now.

The CHAIRMAN [continuing]. Finish up right now. Okay. Thank you.

Dr. BREGGIN. I really appreciate this time to share with you my work and the literature.

Now, under FDA regulations, I want to talk about efficacy very briefly, the pharmaceutical companies can cherry pick their studies. They can do six or eight studies and just provide two that are marginally effective, statistically significant to the FDA for the purpose of pricing efficacy. It is not hard when you are purchasing the investigators and writing the protocols for them and then analyzing the data inside the drug company for the companies to develop positive studies, but it is still hard.

And when all of the antidepressant studies that are done, not just the cherry picked ones, are combined in a meta-analysis, the antidepressants are no better than placebo.

Now, as you may discover today, psychiatric associations and other groups that rely heavily on financial support are going to try to reject and deny all this.

In conclusion, there is overwhelming evidence that the newer antidepressants commonly prescribed in the military can cause or worsen suicidality, aggression, and other dangerous mental states. The documented increase of suicides in the military as well as any discovered, and I hope you will look into this, Mr. Chairman, any discovered increase in random violence among soldiers is in part caused or exacerbated by the widespread use of prescriptions for antidepressants.

Finally, little will be lost and much will be gained by curtailing the prescription of antidepressants in the military. The military instead should rely upon newly developed psychological and educational programs, many of which are being implemented and which Dr. Bart Billings, who is familiar to this Committee, has written about in his report to the Committee, including his Human Assistance Rapid Response Team (HARRT) program.

Thank you very, very much for the time.

[The prepared statement of Dr. Breggin appears on p. 52.]

The CHAIRMAN. Thank you so much for that, rather chilling testimony.

Dr. Leon, you are recognized.

**STATEMENT OF ANDREW C. LEON**

Dr. LEON. Thank you for the opportunity, Mr. Chairman and distinguished Committee Members, to discuss this topic.

My name is Dr. Andrew Leon. I know this is clearly an emotional issue. My family has been profoundly impacted by mental illness, so much so that I devoted my career to the field of psychiatry.

I am Professor of Biostatistics in Psychiatry and Public Health at Weill Cornell Medical College where I have been on the faculty for over 20 years. I have published over 200 peer-reviewed scientific manuscripts. Nearly all of my research has been funded by the National Institutes of Health (NIH).

I have served as a consultant to FDA, to the NIMH, and to industry primarily to monitor the safety of patients who are enrolled in clinical trials on data and safety monitoring boards.

All of us here in this room share a common goal and that is to do the very best for our veterans. My perspective is that doing the best requires the discipline to use empirical methods to understand optimal mental health care and suicide prevention.

I was a biostatistician on the FDA's Psychopharmacologic Drug Advisory Committee from 2003 to 2008 and participated in the FDA hearings on antidepressants and suicide, antidepressants and suicidality, I should say, not suicide deaths.

The class of medications that I will discuss is antidepressants. First, depression is a life-threatening illness. Suicidality is a symptom of depression, whether treated or untreated. My main points that I will make today are depression increases the risk of suicide. Antidepressants reduce suffering from depression that has been demonstrated in several hundred randomized controlled clinical trials where the investigators and the assessors were blinded to the treatment received by the subjects in the trial. There is not a way that it can be manipulated by a pharmaceutical company when they are blinded to the treatment received when the ratings are done.

The CHAIRMAN. I do not mean to interrupt, but I do not think the issue was whether somebody is cheating on a study. It is the selection of studies when they are finished.

Dr. LEON. Oh, no. Absolutely. That is a very important point.

The CHAIRMAN. You cannot say that cherry picking cannot result from this.

Dr. LEON. I will address that in just 1 minute.

So my three points that I want to make, then I will address, Mr. Chairman, your point, is depression increases the risk of suicide. Antidepressants, antidepressant medication can reduce the suffering from depression. And to reduce risk of suicide, clinicians must carefully monitor veterans with depression, whether treated or untreated.

Now, with regard to the clinical trials, Mr. Chairman, that you are referring to, all clinical trials conducted by a pharmaceutical company for a particular drug must be submitted to the FDA. They cannot cherry pick. They submit all. The point Dr. Breggin was

making that the FDA regulations require at least two positive trials where the medication meets another cell, typically placebo.

So the cherry picking that Dr. Breggin was referring to, whether it was submitting just part of the results or manipulating the data that come in, is simply not true. I have reviewed those data. I reviewed the data from many hearings at clinical in the FDA, not just on suicidality, but for many other indications that were being sought for other psychiatric medications.

Today I am going to discuss three different types of studies, randomized controlled clinical trials where antidepressants are typically compared to placebo, observational studies, and postmortem studies.

Three types of suicidality are reported in these studies, suicidal thinking, suicide attempts, and suicide deaths.

In 2004, the FDA reviewed 25 pediatric clinical trials for antidepressants involving over 4,400 subjects and found that patients randomized to antidepressants were about twice as likely to report suicidality. Nearly all of that was suicidal thinking. These were for pediatric clinical trials, children and adolescents under the age of 18.

There were about 3 percent of those on medication or placebo. Three percent reported feelings of suicidality. And that was mostly suicidal thinking. About 80 to 90 percent of that was suicidal thinking. There were no suicide deaths in those clinical trials, no suicide deaths.

In 2006, we reviewed 295 clinical trials of antidepressants for adults involving over 77,000 participants. Less than 1 percent of those participants reported suicidality, most suicidal thinking.

Unlike the pediatric trials, adults randomized to antidepressants were not more likely to report suicidality. In fact, antidepressants conveyed significant protection for adults over the age of 65. For the age group that was referred to earlier, ages 18 to 25, there was not a significant increase in the risk of suicidality. I mean, I reviewed the data. I wrote five papers on this topic. I have one of them here. The rate was not elevated more than we would expect by chance.

So we have clinical trials here, say maybe nearly 300 clinical trials. From those, the 11 new antidepressants, new meaning starting in 1985, a newer class, a newer generation of antidepressants, was being developed and approved. All of those antidepressants had demonstrated efficacy, that is clinical benefit for treating the symptoms of depression in more than one trial. So the efficacy, the clinical value of these was very clearly presented empirically.

Now, I am involved in the NIMH collaborative depression study, which just ended last year. It was a 31-year followup study of patients who presented with mood disorders, bipolar disorder, and depression starting in the late 1970s. And we continued to assess as many as we could follow until 2009.

One relevant paper from that is, I was able to look at those subjects during the course of the study, and, actually, this was before the 2009 data came in, so we had at the time up to 28 years of followup data, in order to examine the risk of suicidality and antidepressants.

And what is not included in the clinical trial is those who received no treatment and those subjects who were not quite severely ill enough to qualify to be enrolled in a randomized trial and those subjects who were too severely ill to be enrolled in a randomized trial. We included subjects who were suicidal. We included subjects who had co-morbidity, both psychiatric co-morbidity, substance abuse, alcohol abuse, and other medical co-morbidity. We included subjects who were taking other medications.

And during the course of this from 757 subjects, we had over 6,700 intervals during which they either received or did not receive antidepressants. We found from that that antidepressants significantly reduced the risk of suicide attempts and suicide deaths. We did not assess suicidal thinking, but there was a significant reduction in the risk of suicidal behavior, that is attempts and deaths.

The data from our observational study are much more generalizable than a randomized controlled trial because we include much more the subjects and the situations they are in more typically reflects those who are receiving antidepressants in the United States.

Our research group at Cornell has conducted several postmortem studies of suicide deaths in New York City. In fact, we examined all suicide deaths in New York City. We looked at the autopsy records over a 10-year period for youth suicides, children and adolescents under the age of 18. We looked at the toxicology to determine whether or not antidepressants were taken before their suicide death.

There were 105 adolescents and children who killed themselves in New York City over a 10-year period. Ninety-five percent of those deaths had not, of the suicides, had not taken antidepressants. Only 5 percent had been treated with antidepressants. It is a tragic story.

We repeated it again in adults. We looked at a 4-year period and there we had over 1,400 suicides. We had autopsy records of 1,400 suicides. Seventy-seven percent of those suicide deaths had not received antidepressants prior to their suicide.

This suggests that prevention of suicide requires intervention primarily among patients who are not receiving antidepressants.

A cause and effect relationship has not been established between antidepressants and suicide. This is one of the most controversial issues in the field of psychiatry. It is an issue about which many people write and speak without access to the proper data. The randomized controlled clinical trial data that the FDA reviewed is the most comprehensive database about antidepressant exposure ever assembled in the field of psychiatry.

Antidepressants have clearly been shown to reduce the suffering from depression and suffering from depression is accompanied by significant functional impairment, job loss, family disruption, and inability to get out of bed in the morning. And a great deal of that can be reduced by taking antidepressants.

However, there is a risk-benefit ratio we have to look at as with any medication. As with any medication, they are not going to be perfect. But a great deal of those patients who take the medications will get better and a very tiny percentage will have thoughts of suicidality. They may have had those thoughts before they started.



Okay. Let me wind up by saying, so the cause and effect relationship has not been established. However, antidepressants do successfully reduce symptoms of depression.

In light of the suicide risk in depression, a prudent recommendation is that veterans, whether treated or untreated, must be appropriately monitored by clinicians.

In conclusion, I would like the Committee to recognize that depression is itself a risk factor for suicide. To leave these men and women untreated is to accept suffering from the disorder itself.

I thank the Committee for the opportunity to speak here today on this critically important issue.

[The prepared statement of Mr. Leon appears on p. 66.]

The CHAIRMAN. I thank both of you for your testimony.

In your last sentence, Dr. Leon, I do not think anybody was ever suggesting not to treat people.

Dr. LEON. Good. I am glad to hear that.

The CHAIRMAN. You are setting up a false straw man there, but we will get to that.

Mr. Teague, do you have any questions?

Mr. TEAGUE. No. For the second time, I will pass for right now.

The CHAIRMAN. Mr. Rodriguez.

Mr. RODRIGUEZ. I was listening to the comments and I thought I heard that you indicated that the FDA looks at the top two studies to determine if they are positive.

Is there a review of the literature before deciding on anything or is it just the two top positive studies? I guess both of you all can comment.

Dr. LEON. Well, there will be very little literature on medication that has not been approved for sale in the United States. I mean, the literature is presented.

And just as a clarification, the FDA does not just review the top two studies. They review all of the studies. But what is required for approval, it is one of the many criteria requirement, is that they have at least two positive studies.

But when I was on the Advisory Committee, we reviewed data from all of the studies that were conducted with a particular medication.

Dr. BREGGIN. Yes. The drug company can do as many studies as it wants. And, again, they are very heavily programmed by the drug company. And then it only has to submit for efficacy to get the drug approved only two studies that are marginal.

When you put all those studies together, including the ones that were not cherry picked, say the five or six or seven others that each of the drug companies is doing, the most recent meta-analysis shows that, in fact, the drugs do not work.

It is easy to pick a study that says the drugs are efficacious. We are looking at a mountain of evidence that they cause suicidality.

I am very surprised at Dr. Leon's comments that suicidality has not been proven. He is willing to use two of the cherry picked studies to say there is efficacy and it has been approved by the FDA, but he is not willing to use the FDA's own studies, which the drug companies were forced to reevaluate, to use the FDA studies to show causality for suicidality. What is good for the goose is good for the gander. And this, I believe, is an extraordinary omission.

And also he is contradicting the FDA's basic conclusion that the risk goes to age 24. It is in the Black Box Warning. Federal regulations require that there be evidence for causality before you have a Black Box Warning.

Dr. LEON. Well, that is incorrect. Okay. The Federal regulations do not require evidence of causality. I have been involved—

Dr. BREGGIN. The warnings.

Dr. LEON. That is not correct.

Dr. BREGGIN. I can get them for you.

Dr. LEON. Dr. Breggin, you do not know what you are talking about. There are many things you have said that are incorrect and that was the most blatant error you have made today.

Dr. BREGGIN. I think—

Dr. LEON. I am speaking right now, Dr. Breggin. Thank you.

Dr. BREGGIN. Mr. Chairman, I think you actually have the regulation.

Mr. RODRIGUEZ. I think if I have time, I would like to ask another question.

Now that you are talking about suicides, one of the things you mentioned was that medication was reducing the deaths and attempts of suicides, however, that the suicidal thinking was still there.

And so, how do you determine a situation such as that? Because I know that if you are working with an individual and he is suicidal during the period of time when you are engaged with them, a lot of times if they still have the suicidal thinking, as soon as you let them go, the possibility of committing suicide or attempts will probably come back, but when you continue to be engaged with them in the studies, closer the monitoring the less they are likely to do it?

I think that is common sense. If I want to commit suicide and I am in a study, and you are watching me a lot closer, it is less likely I am going to kill myself or less likely to make an attempt; however, I still would have the suicidal thinking which you have indicated stays with them.

So what did the medication actually do?

Dr. LEON. Okay. Congressman, apparently I was not clear. I was talking about two different studies. The one study, that large observational study funded by the National Institute of Mental Health, we only evaluated, we only asked questions about—recorded information about suicide attempts and suicide deaths. We did not ask about suicidal thinking.

So in that, we did not—

Dr. BREGGIN. Why not?

Dr. LEON. Why not?

Dr. BREGGIN. Yeah. Why not?

Dr. LEON. Well, we had to—

Dr. BREGGIN. It is a very important clinical practice. It is a much more—

Dr. LEON. Thank you.

Okay. We had 28 years of followup at the time. We developed our assessment criteria back in the 1970s and the assessment criteria served as the standard for psychiatric research that is conducted today.

We actually did ask about suicidal thinking once every 5 years, but our weekly assessment records recorded suicide attempts, suicide deaths, all medications taken and—

Mr. RODRIGUEZ. But you said you only did it every 5 years?

Dr. LEON. No, no. The suicidal thinking question was once only every 5 years.

Mr. RODRIGUEZ. Because I know that as soon as a person indicates any kind of tendency for suicide, a flag goes up. And so in the studies, you would think that would be accounted for because then the family is engaged also and thus it would be less likely for the attempt to occur. If other factors are also there, then it is less likely to occur without even any medication. And that just makes sense.

But, you know, I guess we would have to see which prescription and which item because if the suicidal thinking is there, then it is still there. And as soon as you maybe take them off the support in terms of the family or anything else, whether they are taking medication or not, they might commit suicide.

Dr. LEON. It is not like a clinical trial where a comprehensive assessment battery is administered every week or 2 weeks and the medication received is controlled by the investigator. An observational study is very different.

A randomized controlled clinical trial has very strict inclusion and exclusion criteria. Typically for antidepressants, it excludes about 80 or 90 percent of the patients who want to become subjects in the trial.

An observational study on the other hand observes the treatment and the responses to treatment that subjects and the patients have and it also observes responses and the clinical course among people who are not treated. But in an observational study, the investigator does not have any control over the treatment. They receive the treatments that their clinicians choose to give them.

Mr. RODRIGUEZ. I ran out of my time. I do not know if you will allow Dr. Breggin to answer.

The CHAIRMAN. Go ahead, Doctor.

Dr. BREGGIN. Notice that Dr. Leon is using a noncontrolled study, a naturalistic study, which allows for multiple interpretations, multiple variables, all kinds of things going on in the practice, but is rejecting the gold standard that gentlemen like Dr. Leon always said was the gold standard which are the controlled clinical trials.

Every single study, save maybe two that I read to you today, the epidemiological studies and the clinical trials, were all controlled. He is basing his rebuttal or his argument on uncontrolled data. And that is notoriously not good for determining causation.

Mr. RODRIGUEZ. Now, how do you determine uncontrolled data?

Dr. BREGGIN. There is no control group to the work he is doing. He is just looking at collaborative unity.

Dr. LEON. That is incorrect, Dr. Breggin.

Dr. BREGGIN. But it is not a controlled clinical trial.

Dr. LEON. No. The difference as a researcher, as a—

Dr. BREGGIN. For causation, it is not as good, period.

The CHAIRMAN. Let Dr. Leon answer, please.

Dr. BREGGIN. Sir, you are an epidemiologist.

Dr. LEON. I am a biostatistician. I have designed dozens, hundreds of trials, Dr. Breggin. And the difference is we did have a control in our observational—

Mr. RODRIGUEZ. In layman's term, control means you have a group on one side and a group on the other? Is that correct?

Dr. BREGGIN. That are identical but receiving different treatments and you do not know which one is which.

Mr. RODRIGUEZ. Okay. I understand.

Dr. BREGGIN. You did not have that.

Dr. LEON. The investigator and the subject do not know, the patients do not know which one is which. But we did have a control in our study and that was the control that we see out in the general population, subjects either—I mean, those with depression in the general population, those veterans with depression are either treated or they are not treated. Our control in our observational study was some subjects received antidepressants, the other subjects did not receive antidepressants.

The CHAIRMAN. Is an observational study just based on data or are you looking at people in real time?

Dr. LEON. Oh, no. We are watching them over time and this was 28 years of followup. It is called observational because we observe but manipulate the treatment that is received.

The CHAIRMAN. Are you familiar with Heisenberg's Uncertainty Principle?

Dr. LEON. Well, it applies if assessing the subjects has a therapeutic benefit.

Dr. BREGGIN. The Heisenberg—

The CHAIRMAN. Right. That is the point that Mr. Rodriguez raised, who has a lot of mental health background, that is if you are studying people and showing an interest in them, that affects—

Dr. LEON. Wait, wait.

The CHAIRMAN [continuing]. In and of itself—

Dr. LEON. Absolutely, and that is—

The CHAIRMAN [continuing]. Affects the outcome. That is, as Mr. Rodriguez said, if they are being watched and followed and advised—

Dr. LEON. Yeah. That is—

The CHAIRMAN [continuing]. That may be the effect of your observation, not of whether they are receiving or not receiving treatment.

Dr. LEON. Yeah, absolutely. And that is the reason we included a control group in this, because they were also receiving those same assessments. So the change in psychopathology, the change in suicide risk that might be brought about by conducting the assessments would be held constant across the treated and the untreated groups.

The CHAIRMAN. Okay. We will get back to that. Thank you.

Mr. RODRIGUEZ. Mr. Chairman.

The CHAIRMAN. Mr. Walz.

Mr. RODRIGUEZ. I am sorry. I really need to add one additional question.

The CHAIRMAN. Sure. Go ahead.

Mr. RODRIGUEZ. I know we are talking about veterans right now, but as it deals with kids, because I am really concerned about the medication given to kids that has never been tested on kids. And now I just wanted to see if you care to comment on medication for kids.

Dr. LEON. Oh, absolutely. And I will tell you I was at several hearings on this topic at the FDA. And when we reviewed the antidepressants and suicidality in children and adolescents, those under age 18, there was a very big difference between the data that were available because with children and adolescents, we reviewed those data and there were only a few clinical trials that ever showed efficacy in children with antidepressants.

Now, the one medication that showed efficacy in children in more than one trial was fluoxetine, Prozac. That is the one. And they did get an indication or approval from the FDA. So the risk-benefit ratio when we look at most medications, in most antidepressants in children, there is not a well-established benefit.

So a very small risk really raises alarm. However, in looking at adult data, there is a great deal of data showing a benefit of antidepressants. There is several decades of data available showing us that there is a benefit.

So then when we look at a very small risk and a very large benefit, the risk-benefit ratio is much less alarming. It cannot be ignored completely. Instead what we need to do and what we insisted on when we were helping the FDA, advising the FDA in putting together the Black Box Warning, we, and I have looked at the transcripts of our meetings to confirm this, those of us who voted for a Black Box Warning, and I voted for the Black Box Warning, for antidepressants both in kids and in adults, and it is because I saw from these data, no, I cannot say there is no risk at all. I want the clinician to be aware of the risk. I want the patient to be aware of the risk and I want the family members to be aware. There is a very small risk. If we see any hint of agitation, hostility, akathisia, or suicidality, contact the physician immediately so we can deal with that problem.

The CHAIRMAN. Thank you.

Mr. Walz.

Mr. WALZ. Well, thank you, Mr. Chairman, for holding this hearing. As usual, you are a strong advocate for making sure we get things right as we care for our veterans.

And I want to thank both of you for coming.

Dr. Leon, you did mention that our ultimate goal here is to make sure we provide the ultimate care to our veterans and I am appreciative of that statement.

Just a couple things. And it might either be the schoolteacher in me or the parent of a small child, I want to bring us back to something we can agree on on this. And I appreciate listening to both sides of this. Just a couple things.

Am I right, in the Black Box Warning on this, I am trying to get this side of it, then bring it back to the veterans' care, the Black Box Warning just it may increase the risk of suicidal thinking? That is where it came from. If I am right, there was about a 4 percent rate amongst those children who were looked at?

Dr. LEON. Well, yeah. In children, I think it was at 3 percent.

Mr. WALZ. And it was amongst children is where it was put out on that. Okay.

Dr. LEON. Okay.

Mr. WALZ. And NIH does go on to say SSRIs can be beneficial and FDA says the benefits far outweigh the risk.

Now, my question to you, Dr. Breggin, and I am very appreciative of this on interactions and how things come together, do you believe there are any benefits or places where antidepressants should be prescribed?

Dr. BREGGIN. I think they do more harm than good. In this I am certainly in a position that is different than most psychiatrists who practice psychiatry and I do not want that to influence all the science I am presenting, the controlled clinical trials, on the viewpoint on the suicidality.

In my experience the way antidepressants work, if they do work, is they cause either apathy or a mild euphoria. We are now seeing patients who have been on these drugs for 5 or 10 years and they have lost their interest in life. It is an incredible tragedy. They do not love anymore. They do not care as much. They have lost their musical abilities. The drugs do not have a magic way of fixing depression, which is basically a loss of hope. Depression is where a person feels so bound down in choices, or—

Mr. WALZ. You do not think there is any physical evidence on serotonin, and—

Dr. BREGGIN. Oh no, sir. There is not. There is not. The way that—

Mr. WALZ. I say this coming from Minnesota, where the sun does not shine much.

Dr. BREGGIN. Well certainly I get a little more depressed myself in the wintertime, sir. I turn to my wife for solace rather than to an antidepressant. But no, the way that the imbalance theory came about is that even before Prozac was approved by the FDA, Eli Lilly sent doctors that they paid out to talk about serotonin imbalances. But now that the SSRIs are sort of running out the market, overwhelming the market, now they are talking about drugs like Effexor and other drugs, Cymbalta, that affect more than one neurotransmitter.

Mr. WALZ. I am going to go to two questions, then, for both of you. I was going to, and it might be for the next panel I will ask on this issue of I represent the Mayo Clinic area so some of the research I try and stay up on, and some of the drugs that are purported to stimulate neuron growth and some of those things. I would be interested at some point, maybe I will save that for the next panel but to plant this for both of you. Here is what I want to see is, if we can agree on this. And I heard Dr. Leon say it, and he ended his testimony with it. And I think this is a critical point. We must be monitoring people. And I am going to come back to people in this room who know I am a broken record on this.

The key, as we transition these soldiers who we are talking about and these veterans, is the coordination of their care from DoD to VA. And the, am I hearing from both of you, whether you believe that there is an issue for pharmaceuticals, or an issue for psychotherapy, or whichever a combination of them, or what is best, the real issue here is, and the real threat on suicides and

mental health, mood, depression, PTSD, or whatever it is, is if there is not monitoring. If there is not a clean hand off of care. If there is a veteran who is not getting a coordinated care on this, and may or may not be on antidepressants but his new physician may not know about that, or she may not be seeing someone. Is it fair for me to say that the both of you would agree that there may be the greatest risk of suicide in that lack of attention to them during this handoff period, or lack of coordination?

Dr. LEON. I would say that there, the risk of suicide would be elevated if clinical attention is not paid to the patient as they are switching from one source of mental health care to another. As a point of clarification, I do want to point out that I also support the use of psychotherapeutic interventions for many psychiatric disorders, including depression. And I have published many clinical trial results—

Mr. WALZ. It is not an either/or.

Dr. LEON. Oh, it is not an either/or. And we have published combination studies, medication and psychotherapy.

Mr. WALZ. But Dr. Breggin, you do not take that same position? Is it an either/or for you that—

Dr. BREGGIN. I think the antidepressants are ineffective, but I do not think it is the key here to the hearing. It is not what I am here to talk about.

Mr. WALZ. Is this care issue important? This handoff?

Dr. BREGGIN. Well, first about the monitoring. Remember that all of the controlled clinical trials where they got the doubling of the suicidality were heavily controlled and monitored, much more so than anything the military could ever produce in routine clinical practice. So while monitoring helps, that we agree on, in fact the best data we have on suicidality are from very heavily monitored control groups and, you know, clinical studies with placebo control groups. So I would say yes, we have to increase the monitoring if the drugs are going to be used. You always have to monitor people who are suicidal. The reason I have never had a suicide in my practice is because when somebody is suicidal I monitor them. They get my home and cell phone, they get all my phone numbers, they get whatever they need. You have to monitor in order to help people not be suicidal, not harm themselves.

Mr. WALZ. I will yield back my time, Dr. Leon, and it may come back up again. But I will let the rest of the Members ask. But I appreciate both of you coming today.

The CHAIRMAN. Thank you. Mrs. Halvorson.

Mrs. HALVORSON. Thank you, Mr. Chairman. And thank you, Dr. Leon, and thank you, Dr. Breggin. First of all, Dr. Breggin you said, and I came in late so I apologize for not hearing the entire testimony. But you said, "They don't work." Well, according to your testimony you said that they need to be curtailed. I hate to throw the baby out with the bath water but, you know, my whole remarks were going to be exactly what Congressman Walz said.

This is not about the two of you arguing over whether we need them or we do not. This is about our veterans. This is about the fact that they are not getting the care that they deserve. This is about the fact that while they are in theater, or while they are under the care of the Department of Defense and then they are

turned over to the VA, that the way that they are taken care of and the way that they are decided on how their disabilities are calculated, that they are different. And so when they go into the VA system they feel like they have been shafted somehow. And I hear it everyday. And I just think that we, I know you are here to discuss about the pharmaceuticals, and whether that, but we have lost more of our young men and women due to suicide than combat. And we need to do something about taking care of our veterans so that we are monitoring them, we are taking care of them, that they do not feel like there is a loss out there, that they do not feel good about themselves.

It is not about the fact that there are the medications that do not work, or that they are on medications versus should they or not. And it is not directed at you personally. However, I think the debate that we need to be having here, and the debate that we need to continue to be having, the bottom line being we are not taking care of our veterans the way that they deserve to be taken care of. And it is not about whether they are on medication or not. It is whether when they leave the service and go into the Department of Veterans Affairs that we need to be doing a better job of monitoring and taking care of them so that they feel a part of society again. That we give them the best hope, that we give them the health care and the best economic opportunities.

So we can argue everyday until the cows come home that we either curtail the medication, that it does work or it does not, but we cannot paint every medication with the same brush. We cannot throw them all out because you say that they do not work, because I know plenty of people that need them. So we have to monitor people. We have to do it the right way. But the bottom line here is we need to take care of our veterans the way that they deserve to be taken care of.

Dr. BREGGIN. I am in total agreement with you. One of my major concerns is that one of the major, if not the major, reason that soldiers and vets are disappointed with the treatment they get is that they get medication automatically pretty much when they go to a VA clinic or when they go and report to a corpsman or somebody else, and express that they have depression. Literally, they are staying away from treatment because they do not want the stigma of the diagnosis and they do not want to be on the meds. So I think that the government, that the military is moving in the right direction with a whole bunch of new education programs where they are encouraging the sergeants, and the corporals, to be able to talk to the enlisted men. And they are encouraging screening, and they are encouraging education on self-empowerment. You have some studies going on overcoming learned helplessness and learning to handle your emotions. I, you know, that was not my subject for today. That was going to be Bart Billings' subject—

Mrs. HALVORSON. Well so, in other words, diversity in your portfolio. You cannot throw out drugs completely but we need to add a few other things to go along with that. Dr. Leon, I do not know if you want to add anything to that?

Dr. LEON. Yes, I agree with you. What is important particularly, since we are talking about medication today I will focus on medication in responding to your question. What is most important is



those first few weeks that a patient starts on an antidepressant. Monitoring is critically important.

Mrs. HALVORSON. Right.

Dr. LEON. I mean, they have to be in touch with the, a physician has to follow up with the patient maybe more than once a week, a couple of times a week, and continue to do that perhaps for the first 4 or 5 weeks. But definitely stay in touch. It cannot be that, "Here are 90 pills. Come back in 3 months." That is thoroughly irresponsible and it is very—

Mrs. HALVORSON. Which, the people I talk to they are not even just handed medications automatically anyway. But, and I know I am running out of time. But I just want it to be known that it is not as easy as everybody thinks, that automatically they claim they have depression and they are handed a pill. From what I see, and from, what I hear from my advisory Committee, from the people who come in, because I have a full-time veterans caseworker. You know? And I have more people who come in to say that they are not getting the help that they need with regards to their depression than the people who say that they are just given a pill and told, "Take this and all your worries will go away." So I yield back. And hopefully as we move along through this I would love to continue that discussion.

The CHAIRMAN. Thank you. Mr. Donnelly. Passes. Dr. Roe.

Mr. ROE. Thank you, Mr. Chairman. And thank both of you for being here today. I was, Dr. Breggin, enthralled, but just a quick question on neurobiology. Not something I want to go back and study very much, but a very complicated subject. But you do not subscribe to any neurobiology? Any chemical changes in your brain that might have something to do with depression?

Dr. BREGGIN. Well we know—

Mr. ROE. Do I understand that right?

Dr. BREGGIN. Sorry, I interrupted you. Yes, sir?

Mr. ROE. No, go ahead.

Dr. BREGGIN. We know that some diseases and disorders, dementia, can lead to depression. We know that diabetes can lead to depression. But we do not know that any routinely treated psychiatric disorder has a specific biochemical component. Now the human brain, sir, is, literally each one of our brains is more complicated than the total physical universe. In other words, there is more going on inside our brain than a physicist is looking at when he is looking at the whole of the universe. That is how complicated neurochemistry is. To think that the five or six neurotransmitters that have been partially studied, we do not even have their subtypes—

Mr. ROE. Not to interrupt, but I agree with you that it is an extremely complicated subject. But I do believe there is some neurochemistry going on. Dr. Leon, do you have a comment?

Dr. LEON. I am not a psychiatrist. I am a biostatistician. But I do understand from my colleagues that the neurobiology of depression and the neurobiology of suicidality has been fairly well studied. And although it is, not all components of the brain that are implicated in depression might not have been identified, there is clearly some systems that have been well implicated to trigger depression.

Mr. ROE. A couple of things. I want to go back to, so you can clarify, because I have dealt with this as a practicing physician for over 30 years on the black box warning. And second, Dr. Breggin it was a little bit, your discussion about how the FDA approves a drug was a little misleading to a non-medical person, I think. Assuming that a drug company goes out and performs some studies and then they can just pick which ones they send to the FDA. And Dr. Leon you are carrying, that is the impression I got. And can you carry on with that? And then you can answer, Dr. Breggin.

Dr. LEON. Yes, certainly. Well, if we take a hypothetical situation where a pharmaceutical company has a program for a new molecular entity, that they want to see if this drug might work with this depression, they might conduct four or five clinical trials. And they will collect all of those data, submit all of the results from all of those data to the FDA. All of the data. I mean, that is required by law, to submit all of those data to the FDA. Now, the FDA does not, has standards. At least two of those trials have to be positive but also they have to show a clinical meaningful effect. So a trivial effect, or as Dr. Breggin said a marginal effect, would not be approved. The FDA, I can only speak for psychopharmacologic agents but I have seen it many times. They want to see that the magnitude of the effect is clinically meaningful.

Mr. ROE. Dr. Breggin.

Dr. BREGGIN. I certainly did not mean to give a misimpression. My point was very simple, that the drug companies can conduct as many studies as they want. They do get submitted to the FDA, of course. But they only need to cherry pick two that show efficacy. Now, it is not quite, I believe, the way Dr. Leon says. I have cited in my book a discussion within the FDA between Paul Lieber, who was the head of the psychiatry section at the time, and his boss Rob Temple about how the approval of Zoloft was so marginal they were embarrassed to do it, and how it had not been approved in Europe.

And secondly, Dr. Leon is incorrect, giving an incorrect impression when he says they send all the data to the FDA. The data if it were, let us say, in boxes would fill this room. Now, I have gone through that kind of data. And I have said to the FDA, "Hey, I have gone through the Prozac data. I can show you the suicidality." All of that data is not looked at by the FDA. The FDA looks at generally the summaries and the reviews sent into them. They do not have the manpower or the interest to look at all of the data or to go back and find it.

Mr. ROE. I want to go ahead with my question because my time is short. We are here to talk about veterans and treatment of veterans. And we had 400 and something veterans last year in America commit suicide. And I think what we need to do, as an observational study, is to see the ages of those veterans. Whether they had or had not been in the VA, whether they had or had not had treatment. To me that is pertinent information. Were they older veterans? I am a Vietnam Era veteran. Is it Vietnam Era? Are they new veterans? Where are these suicides occurring?

And I also, and I will leave it at that because my time is expired. But I had two cases of, in my 31 years of suicide, in patients of mine. One I did not see coming from anywhere. It was absolutely

none whatsoever. The other patient, after 20 years of treating with you it was not a surprise to me. I am astonished that in all of your years of practice that not even a single patient ever committed suicide. And of course, some may have been lost to follow up. I understand how that goes.

Dr. BREGGIN. Oh, of course. Well sir, I think I am lucky. I think I am blessed. And I really, really care about my patients. And I really, really work hard. And I did not even have a serious suicide attempt from 1968 to the present until this year in a young man who was new to my practice and who was having serious difficulties.

I believe that as a professional if you really get involved with your patients, if you really care about them, they can call you any time of the day or night, you are willing to even see them for free for an extra time if they do not have the money. You want to see their moms, their dads, their kids, and bring the family together to help them care about each other. And you have blessings, that suicide becomes extraordinarily rare in my experience.

Mr. ROE. I had even read studies, Dr. Breggin, though, that when psychiatrists interfered with a patient, the suicide rate went up. So you can read anything in a study. I yield back my time.

Dr. BREGGIN. Well, I believe that, sir. That is maybe the drug effect, sir. And the demeaning experience of getting a label rather than being told there is hope, that you can master the issues that are overwhelming you, that the doctor can work with your wife and you, or your husband and you, over the issues that are demoralizing you. That the, what has happened to you in the service can really be dealt with, you can get that support and hope. And that is what really matters. It is the hope and guidance you get toward a better life when you are depressed, how to find your way out of it.

And by the way, I could not make, I am a public figure. If I made these claims falsely about no suicides, people would line up.

Dr. LEON. Not the suicide deaths.

Dr. BREGGIN. No, their families would. They would be suing me. A public figure like me? It would be on the front pages of the *American Psychiatrist Association* newspaper, Doctor sued for suicide in his practice.

The CHAIRMAN. Okay. Thank you both. Dr. Leon, you mentioned in your opening statement that you had mostly been funded by NIH, and served as a consultant to FDA, NIMH, and to industry. I am just wondering which industries you were consulting to?

Dr. LEON. I have worked with, which company?

The CHAIRMAN. Yes.

Dr. LEON. Pharmaceutical company? I have worked with quite a few of them. Right now, as a matter of fact, I monitor the safety of subjects who are enrolled in trials by, conducted by Pfizer and by Astra Zeneca.

The CHAIRMAN. I mean, how about some of the common antidepressants. Have you been consultants on those?

Dr. LEON. Most of the common antidepressants were approved in the late, well Prozac was the late 1980s. No I did not work on any of the Prozac. And most of the SSRIs were approved in the early

to mid-1990s. I did not work on any of those. The safety and monitoring work I have done maybe the last 4 or 5 years.

The CHAIRMAN. A couple of things—yes, please, Dr. Breggin.

Dr. BREGGIN. I am concerned that Dr. Leon implied that I am not always telling the exact facts. The Federal regulations are cited per page in the report I gave you that say you have to have reasonable evidence of causation. And I believe that you can find them there. And I think that Don Farber, the attorney, will draw your attention as well to those Federal regulations.

The CHAIRMAN. Okay, thank you. The thing that struck me getting into this subject was that there was a lot of media hype, there was a cover story on *Newsweek*, for example, that said the way we were treating these issues in active duty was basically to just throw pills at them, getting them back onto the front lines, or getting them back into battle. We did not want to lose them from the battlefield, basically. From reading your books, and seeing and hearing what you said, even hearing what Dr. Leon said, that is very, very dangerous in that they are not being monitored. They are being thrown some pills, at least this is my sense, and I do not know how true it is. If we had commanders here testifying I do not know what they would say.

It appears from testimony we get from our own constituents, that when given pills, you are not going to read the black box and you are not being monitored. And guess what? We have incredible numbers of suicides. I think it was Dr. Breggin who stressed that there is other violence besides suicide. You cannot just study suicide. The last time I saw this, and it has probably been updated, the *New York Times* reported that a third of our young men and women who have been diagnosed with PTSD had already committed felonies of which several hundred were homicides. That is often their own spouse or their kids. These kids did not come home to kill their spouse or their children, but something happened, whether it is the PTSD, or the treatment. It seems to me that these servicemembers may not show up at the VA anyway and may not get any treatment whatsoever. They may be taking these pills without being monitored. It looks to me that that is what is happening. We are throwing pills at them, they commit suicide, and they commit homicide. It is not everyone but there is so much of it that as a policymaker I have to be concerned. Dr. Leon, although you guys had differences in some fundamental things you would not advocate that active-duty servicemembers are given these pills without further monitoring. I think that is what is happening. I am sure you would not be in favor of that?

Dr. LEON. Oh, absolutely.

The CHAIRMAN. But I do not think it can happen. In the nature of what war is, it is hard to monitor. If the psychiatrists or the commanding officers who are with these troops think that you can just throw the pills at them, that is a pretty dangerous solution. That is what I am trying to get at. When they become veterans we may not even see them until it is too late and we do not even know about all of their records, as Mr. Walz pointed out.

Dr. LEON. Well as the black box warning says, there are two or three main points—

The CHAIRMAN. I know, but they do not see the black box.

Dr. LEON. No, no, no. But I just want to paraphrase from the black box to respond to you. The concern is, one is the depression itself is life threatening. So some kind of treatment, some type of intervention is needed.

The CHAIRMAN. You said, here you wrote, "Depression increases risk of suicide and antidepressants decrease suffering from depression." It seems you have not included the problems, and the probability of the problems. That is, I read all the baldness side effects because, and it says, "We will treat the baldness but you are going to be sexually impotent."

I do not see where the following of depression reduces the risk of suicide, and drugs decrease suffering, therefore, you argue, you have to take the drugs. I would argue, therefore, you have to explain the risks. You have not judged those risks, so I will have less depression but I will go out and commit suicide. It sounds to me like that is what you are saying.

Dr. LEON. All right, no. I agree with the first two points you made, but I did not say, therefore, drugs have to be used. I said, my third point was to reduce the risk of suicide clinicians must carefully monitor our veterans whether they are treated or untreated. And the ones who are treated, I mean, some might have mild enough depression they just need a watchful eye. Some of them might need psychotherapy. Others, a short-term psychotherapy, I am not talking about 10 years on the couch, but a short-term psychotherapy like cognitive behavioral therapy which has been shown to work for depression. But others with more severe depression will probably do better by taking antidepressants. And that is—

The CHAIRMAN. Well I would be afraid to go to you if I was depressed. Because you are telling me that it is most important to get rid of the symptoms of depression. You will tell me that maybe suicidality will occur. What Dr. Breggin is saying is this is the fundamental distinction. You say in your testimony the cause and effect relationship has not been established. Dr. Breggin says it has been established. Why the difference? Obviously that affects the therefores, right? It seems to me he established it. Why do you not think he has?

Dr. LEON. Well, Dr. Breggin is not a scientist and he does not primarily rely on—

Dr. BREGGIN. Wait, wait, wait, wait, wait. I have written dozens of articles—

The CHAIRMAN. He is a psychiatrist.

Dr. BREGGIN. I am the editor of—

Dr. LEON. Dr. Breggin is not an empirical scientist. I want to make a couple of points.

The CHAIRMAN. Well that may be a compliment, by the way. Empiricism in and of itself is not science either, frankly.

Dr. LEON. Okay. A couple of points—

The CHAIRMAN. Because of the uncertainty principle and other things.

Dr. LEON. A couple of, a couple of—

Dr. BREGGIN. See the desperation—

The CHAIRMAN. Let him talk.

Dr. LEON. A couple of points of clarification. Please do not come to me for treatment of depression. I am a Ph.D., I am not an M.D. I am a biostatistician, I am not a psychologist. I do not have a clinical practice, I do not have a license.

The CHAIRMAN. You are saying he is not a scientist and you are not a doctor. Why should I listen to you?

Dr. LEON. I am not a physician, that is correct, but I am a biostatistician with over 20—

The CHAIRMAN. I would say you lie with statistics. You seem to be saying empiricism, he is not an empirical guy. I would say empiricism is a lie. So how do you respond to that?

Dr. LEON. Well respectfully, Congressman, I disagree with you. Statistics used appropriately with methods that are defined before seeing results are, can be used to help guide us to help treat veterans in the most important—

The CHAIRMAN. Only if you have some judgment there with it.

Dr. LEON. Right. I do want to make another point of clarification. We do hear about these tragic deaths. And each one of them is a terrible tragedy, and a great deal of suffering for any family. But I do want to make a point that the number I have in front of me is from 2005, but there were 180 million antidepressant prescriptions filled in the United States. One hundred eighty million, that might translate to, what, 20 million, 25 million took antidepressants in 2005. And we hear about, so that is the group at risk of, those exposed to antidepressants are the group at risk of treatment induced suicidality. We do not hear about those 180 million, or 20 million patients. We hear about the handful of tragic cases that destroyed families. And those, that is why—

The CHAIRMAN. When you say a handful, it is out of a controlled study. We have not done a controlled study of those 25 million, right?

Dr. LEON. The 25 million? No, no. No, that is the data from antidepressant prescriptions—

The CHAIRMAN. Right. That is how many people are taking it. But you have said, we cannot study 25 million people. So we do a controlled study of several thousand.

Dr. LEON. Oh yeah, absolutely.

The CHAIRMAN. His conclusions come from that, those controlled studies. Why do you dispute that it is not a causality?

Dr. LEON. Oh, because the controlled studies do not provide definitive evidence of a causal link, particularly in adults. There is no association of an, there is no evidence of an increase in risk of suicidality when an adult takes an antidepressant. The data are very clear. For the older patients, it actually protects them. I imagine quite a few veterans in the United States are 65 years of age and older. The data are very clear, the risk of suicidality is absolutely reduced. For those between 18 and 65, we do not see an elevation in the risk of suicidality. For those under 18, the evidence is very different, and I am not advocating the use of antidepressants for those patients.

The CHAIRMAN. Okay. Just to conclude the panel, do you want to respond to that?

Dr. BREGGIN. Yes, just briefly. First, let me indulge myself and describe my scientific credentials briefly since he has literally said

I am not a scientist. For example, I was the scientific presenter at the Federal NIMH Consensus Conference on ADHD and Its Treatment on the subject of adverse effects of psychiatric drugs. I was the only scientist on that issue. I was the scientist at the Consensus Conference by NIMH on Electric Shock on the specifics of the biochemical and biological injuries from electric shock. I have been a consultant to the Federal Aviation Administration on whether fliers should be allowed to use drugs like Zoloft. I am an editor on the *International Journal on Risk and Safety in Medicine*, which is the scientific journal that does risk and safety. And I founded a journal called *Ethical Human*, well now called *Ethical Human Psychology and Psychiatry*, with 50 board members, many of them renowned scientists. And I have published dozens of scientific peer-reviewed articles. And finally, I have written a very scientific tome called *Brain Disabling Treatments in Psychiatry*, which is in its second edition, but really its third or fourth, by Springer Publishing Company, a premier scientific publisher.

I would like to point your attention to one last thing. Which is the Veterans Administration has done one study, and I think that it provides you an opening for looking more deeply into this issue. And it is the study by Valenstein in 2009, which involved a group of 887,000 vets and found this increased rate of suicides and suicide attempts in vets soon after they were started on the newer antidepressants. That gives you a beginning of how you might sponsor or encourage research in this area and I would be happy to contribute to any thinking that you do in that area.

The CHAIRMAN. Thank you. Dr. Roe.

Mr. ROE. Just one brief comment. I do want to stand in defense of the Department of Defense. I have been a battalion surgeon in an infantry battalion, in an infantry division overseas. And we do not just write prescriptions and throw them at patients and let them walk out the door, I can tell you that.

The CHAIRMAN. Where were you?

Mr. ROE. In Korea. And at the demilitarized zone in Korea, Second Medical Battalion, Second Infantry Division.

The CHAIRMAN. What year was this?

Mr. ROE. 1973 and 1974.

The CHAIRMAN. So you were not there during the Korean War.

Mr. ROE. It was not during the Korean War, no. It was a little after that. But the point is, is that I think we have some very fine physicians and medical people in the Department of Defense. And I do not know whether they are going to, if that is part of the next panel, and it probably is. But anyway, I just want to make that clarification, that that is not the way I saw patients treated.

The CHAIRMAN. I would not argue with you based on your experience. During combat situations when you are suffering because of the volunteer Army and there is a shortage of people, you are not doing anything to get people off of active duty, you want to keep them there. All of the testimony that I have read, and all of the talking to soldiers, and young veterans, is that clearly there are some ethical things that any doctor should address. Basically, they want to get them back onto the front lines as soon as possible and psychiatry or counseling is not the quickest way. We give them a

pill, they will feel better, and go back. The problem is when they get finished with battle or go home, they do not feel good.

We thank both of you for your testimony. You have obviously started an important discussion, and we will continue it with Panel Two. Thank you again, you will be excused.

Dr. David Rudd is Dean of the College of Social and Behavioral Science at the University of Utah, who is here on behalf of the American Psychological Association; Annelle Primm is the Deputy Medical Director for Minority Affairs at the American Psychiatric Association (APA); and Commander Donald Farber, Retired, comes to us from the U.S. Navy in San Rafael, California. Thank you all for being here. Dr. Rudd, if you will begin and because we have votes coming up we want to limit your oral testimony to 5 minutes. We have your written testimony for the record.

**STATEMENTS OF M. DAVID RUDD, PH.D., ABPP, DEAN, COLLEGE OF SOCIAL AND BEHAVIORAL SCIENCE, THE UNIVERSITY OF UTAH, SALT LAKE CITY, UT, ON BEHALF OF AMERICAN PSYCHOLOGICAL ASSOCIATION; ANNELLE PRIMM, M.D., MPH, DEPUTY MEDICAL DIRECTOR FOR MINORITY AFFAIRS, AMERICAN PSYCHIATRIC ASSOCIATION, AND ASSOCIATE PROFESSOR OF PSYCHIATRY, JOHNS HOPKINS SCHOOL OF MEDICINE, BALTIMORE, MD; AND COMMANDER DONALD J. FARBER, ESQ., USN (RET.), SAN RAFAEL, CA**

**STATEMENT OF M. DAVID RUDD, PH.D., ABPP**

Mr. RUDD. Yes, thank you, Chairman Filner and Members of the Committee. I want to express my appreciation for the opportunity to testify here on behalf of the 152,000 members and affiliates of the American Psychological Association regarding the relationship between veterans suicide and medication.

I do not want to repeat some of the previous testimony, and so I am going to summarize a number of points and emphasize a few additional points regarding this issue. Confusion following the warning label has been shared among both practitioners and the general public, and I think that is a critical issue, is that the warning label has created considerable confusion. I think it is confusion that was evidence when you looked at some of the previous testimony. There are a number of facts as a part of this that are often-times overlooked.

First, that there were no suicides in the original pediatric and adolescent clinical trials, and that is a total of 4,400 patients. There simply were no suicides in those original trials that drove the warning label. Although there were suicides in the adult trials, as was stated previously, the number was not sufficient to reach any conclusion about drug effect on suicide. They were comparable across both the clinical arm of the trial as well as the placebo arm of the trial.

Given the failure to demonstrate any clear relationship between medications and death by suicide the warning label focuses broadly on the issue of suicidality and that includes suicidal thinking as well as suicidal behaviors. And I think it is important to recognize that when we talk about suicidality in terms of these findings it is defined as present or absent. So we do not know the severity of



the suicidal thinking. There is something very different between having suicidal thoughts and having suicidal thoughts with definitive plans and intent to act on those thoughts. That is something that gets lost in this discussion and I think it is a critical part of that discussion. It is one thing for an adolescent to have a thought about suicide. It is another to have a definitive plan, motivation, and intent to act on that thought. And you can say the same thing about suicidal behaviors. When we look at the frequency and occurrence of suicidal behaviors in this literature there is not a distinction between lethality of behavior. So we are simply talking about the presence of a suicide attempt, what is defined as a suicide attempt, what is defined as a suicide attempt in the absence of that. So we do not have any understanding of those suicide attempts, the lethality, the potential lethality of those attempts. And those are a couple of critical variables that would really help us understand the nature of this risk much more clearly.

There are a couple of other points to make about the confusion that has been created among both practitioners and the general public, including the follow up periods for these various drugs are very short. We are talking about a period of a few weeks to several months. So we simply do not know the duration of the effect. We do not know if in fact the increase, the increase in suicidality, does it endure for more than a few weeks? What are the recovery curves? Do people experience this only in the initial phase? How long does it endure over the long haul? And ultimately, how does that impact treatment and eventual recovery, which is very much a critical variable.

Another point, neither the warning label nor the medication guide provides any specific information about age-related data. A point that was made earlier is that there is no risk for adults, that that evidence is fairly clear in terms of an escalation of risk for adults. And in fact in the elderly, there is good evidence, and I would tell you very compelling evidence, that antidepressants actually reduce risk for the elderly population and that is the group in which suicide risk is the greatest. And that is by a fairly significant margin.

And then a final point to make is that as evidence of the confusion that has been created by the warning label in some of this literature, we did a small study that looked at general practitioners, and looked at the issue of whether or not general practitioners, who prescribe the overwhelming majority of antidepressants in this country, understand the warning label. Ninety-one percent of the general practitioners made errors in their understanding of the warning label, believing that the risk was actually for death. The worry is that they communicate that to patients and that we are not accurately communicating to patients the nature of risk, and as a result can reduce the likelihood that people will actually pursue care and be willing to receive care during these periods of high risk.

Given that as high as 75 percent of depressed adults looking for treatment receive medication and an estimated 50 percent of adults receive both psychotherapy and medication, it is a critical issue for veterans. I would tell you that it is more likely than not that the majority of depressed, anxious individuals, those suffering PTSD,

that receive care are likely to look at medications as well as psychotherapy as an alternative. Unintended consequences of the warning label are something that we really need to guard against.

A few points that I would like to make about the effectiveness of behavioral treatments. I think it is important to recognize, and I understand my time is passing fairly fast here. But I wanted to make a few points about the efficacy of psychotherapy. We now have a number of studies, as has been mentioned previously, in terms of cognitive behavioral therapy, cognitive processing therapy, prolonged exposure, that are very effective for depression, that are very effective for post traumatic stress disorder, as well as a range of anxiety disorders that emerge following combat experience and they are relatively simple to do. The behavioral treatments that are available today are manualized treatments. We know how to do them well. We can train individuals to provide that care and do it with very high fidelity. And we now know that they are very effective in reducing the rates of suicide attempts following treatment. And I would tell you currently the data I think is fairly overwhelming, fairly compelling, that the best approach is the combination of medicine as well as behavior therapies for these kinds of problems. There are periods of acute risk in which medications are essential. And I think that is another issue that gets lost in this conversation. When a soldier comes in, when a veteran comes in and is acutely distressed and acutely disturbed, and having significant sleep disturbance, significant anxiety symptoms, during those periods we need to do something quickly in order to resolve those symptoms and to help them adjust during these periods of acute and imminent risk. Medicines do that. They do that far more effectively in terms of short term gain than psychotherapies. One of the problems with psychotherapies is that they are essentially skill based treatments. You can see that in my testimony. And as a result, we are targeting the developing of skills, the development of abilities, that have essentially been deficient in those individuals for any number of reasons. But over time, we have demonstrated the ability to help them develop those skills. And I think as Dr. Briggen so nicely put it, to develop hope. That is essentially what provides suicide, is the establishment and the maintenance of hope over time.

Medicines in the early phase of that process I have found essential. I do a fair amount of treatment in this area. I am going to tell you about 60 percent of the people that I treat are on medications. A high number of those individuals have simply had their lives saved because they have had symptom reduction during these early phases of psychotherapy. Thank you very much.

[The prepared statement of Dr. Rudd appears on p. 67.]

The CHAIRMAN. Thank you. Dr. Primm.

#### **STATEMENT OF ANELLE PRIMM, M.D., MPH**

Dr. PRIMM. Thank you for the opportunity to speak before the Committee today on behalf of the American Psychiatric Association, APA, the medical specialty organization representing 37,000 psychiatric physicians nationwide. APA's critical goals and activities include advocating for patients and the profession; ending discrimination against Americans who need treatment for mental ill-

ness, including substance disorders; supporting education, training, and career development of psychiatrists; enhancing the scientific basis of psychiatric care; and defining and supporting professional values and ethics.

The APA vigorously advocates for immediate and seamless access to care for psychiatric and substance disorders for America's military personnel and their families. We continue to staunchly support increased Federal funding of psychiatric and brain injury research. We remain concerned that despite concerted efforts of the VA and the DoD, stigma still discourages from seeking care those who need help for PTSD and other disorders. We also note with increasing concern the reported increase in suicide attempts and completed suicides by veterans and those currently serving, and strongly urge direct and effective action to address this serious problem.

Today's invitation by the Committee requested that the APA provide its position on the effectiveness and safety of psychiatric medication. I know that many of the most dramatic improvements in the effective treatment of mental illness have come as a result of newer and better medications, especially a class of antidepressants called SSRIs which can be utilized to help manage PTSD symptoms. These medications have meant remarkably positive changes in the lives of tens of millions of Americans. Simply put, it is the position of the APA that a patient's decision to take a psychiatric medication should be based on the best medical advice and scientific evidence available. Medications, when utilized, should be used in conjunction with supportive therapies, such as cognitive behavioral therapy. The prescribing and monitoring of brain medications should, however, be overseen by those with medical education, training, and clinical experience.

First, I want to emphasize the importance of access to data from clinical trials, including data from negative trials, unpublished research, and post-market studies for physicians, other health personnel, and researchers. Patients need to be sure that their treatment is based on the best information in order to make fully informed decisions about treatment options.

Next, let me address medication in general, and the SSRI antidepressants in particular, which are a class of medications often used to help treat PTSD symptoms. Research has clearly demonstrated that medication can be helpful, and even lifesaving, for many people with psychiatric disorders. Contrary to frequent reports in the popular media, there is little or no evidence that confirms that SSRIs increase the risk of actual suicide. It does appear that these medications may increase the likelihood that some patients will actually tell someone about their suicidal thoughts or even about a suicide attempt. From my perspective as a psychiatrist, this is actually a good thing because it means you have the opportunity to intervene and keep the person safe.

Since the early 1990s the teenage suicide rate in the country had actually declined by over 25 percent, consistent with the increased use of SSRI antidepressants. That trend continued until 2004, when the FDA issued a black box warning about an increased risk of suicidal thoughts or behavior in children and adolescents treated with SSRIs. This was based on a data review in which no com-

pleted suicides occurred. In 2006, the black box warning was extended to include young adults up to age 25. The APA was concerned then, and remains so now, that the warning has in fact had a chilling effect on the use of SSRI medication in this population. Unfortunately, in the years since the FDA black box warning was issued, the rate of completed suicides for young people has increased dramatically according to the Centers for Disease Control and Prevention. This data is detailed in my written statement.

As noted, we believe it is crucial for patients and family members to have access to current information on all issues related to recognized treatment options. To this end, the APA and other physicians and patient groups have jointly developed [www.healthyminds.org](http://www.healthyminds.org) to provide patients, families, and physicians with as much information as possible about the evaluation and treatment of depression, PTSD, and substance use disorders. APA is also a proud partner of Give An Hour, a volunteer program that provides mental health and substance use disorder treatment services through a network of mental health professionals who volunteer their services for an hour a week to active and returning military, National Guard, veterans and their families.

We hope today's hearing will promote better information, encourage expanded support for research, and enhance the ability of returning military personnel and their families to advocate effectively for the treatment they deserve. Thank you for the opportunity to testify, and I would be pleased to answer your questions.

[The prepared statement of Dr. Primm appears on p. 69.]

The CHAIRMAN. Thank you so much. Commander Farber.

**STATEMENT OF COMMANDER DONALD J. FARBER, ESQ, USN  
(RET.)**

Commander FARBER. Thank you, Mr. Chairman. I am Don Farber. I practice law in San Rafael, California. And since 1999, a majority of my cases have been antidepressant suicide, either representing the heirs or the family themselves. I am also a 25-year Navy veteran, half that time at sea. I was not a lawyer in the Navy.

In 2010, the Committee asks a compelling question. Do antidepressants cause suicide or don't they? This 20-year question has to be asked because those expected to know have not sought an answer. Who is most credible in this debate? If the year were 1530 and the Committee asked whether the Earth was flat or round, one would ask Magellan's map makers rather than the flat Earth advocates. Similarly, in 1940, one asking how to deal with Hitler would ask Churchill, not Neville Chamberlain.

Individual psychiatrists like Peter Breggin, David Healy, and Joseph Glenmullen were citing the antidepressant risk in the 1990s, as Dr. Breggin has testified. In contrast, antidepressant enthusiasts assured us antidepressants were safe with no evidence linking to suicide. They did not say, "Well, antidepressants are safe in adults but not in kids." They did not say, "Antidepressants are safe after the 7th day but not in the first few days." Antidepressant manufacturers and organized psychiatry staked out their absolute positions in 1990 and have not wavered since.

The shock came in 2004, when the FDA issued the anti-depressant suicide warnings that many witnesses have discussed. Most of organized psychiatry has been on the wrong side of anti-depressant history as it has unfolded. The American Psychiatric Association would not only have denied patients of the public awareness of the suicide risk on the labels, but to primary care physicians as well who prescribe a majority of the antidepressants. In 1991 at the original Prozac hearing, when there were 350 completed Prozac suicides reported, APA persuaded the FDA to forego the warning, stating at that time, "We feel that labeling must be based on sound science and not sensationalism."

In 2004, pediatric suicide events from antidepressants were excessive and the FDA scheduled another hearing. Rather than support the FDA's inquiry, the APA, declining to make a labeling recommendation, admonished the FDA for the fuss, stating, "We are concerned that the publicity surrounding this issue may frighten some parents and discourage them from seeking help for their children." The FDA did issue the generalized suicide warnings and ordered additional evaluations of the pediatric data. After reevaluation confirmed suicidality causation in children, another hearing was held to vote on the black box, the highest form of warning.

APA suddenly found religion with the old warning, stating at the hearing, "We support the continuation of the current FDA warnings with respect to SSRI antidepressants. We believe the language is appropriate and consistent with our current knowledge and understanding of scientific data."

In 2006, APA repeated the cycle with young adults. The data did show a beneficial effect of antidepressants in the elderly, as Dr. Rudd has pointed out. But again opposing the black box and a lost cause, APA could not bring itself to acknowledge the FDA's young adult data, claiming instead, "data showed that adults collectively show no increased suicide risk although there was some variation by age, including a protective effect for people 65 and above." This heralding the positive and suppressing the negative on antidepressants has been organized psychiatry's 20-year pattern.

Most telling in this debate, antidepressant enthusiasts have sat silent for 20 years as the antidepressant manufacturers have refused to test for suicidality. There has never been a prospective trial designed to test the link between antidepressants and suicide. This should be a big deal. I leave with the Committee 27 sources confirming this fact from all varieties, mostly pro-antidepressant enthusiasts I might add. And Chief Executive Officers I left, it is not in my prepared statement, but I left with the staff a 10-page, 27 sources of quotes, and there is no dispute about this fact.

FDA officials conducting their suicide reviews reported last year in the *British Medical Journal*, "Antidepressant drugs can have two separate effects. An undesirable effect in some patients to promote suicidal ideation or suicidal behavior, and a therapeutic effect in others."

So, do antidepressants cause suicide? Of course they do. Antidepressant manufacturers would not secretly settle the suicide lawsuits for the large sums they do if these were merely nuisance lawsuits. Going forward it would be responsible for VA, or DoD, to

investigate rising suicides by dismissing FDA's antidepressant suicide warnings. Thank you, sir.

[The prepared statement of Commander Farber appears on p. 72.]

The CHAIRMAN. Thank you, sir. We thank you all. We have a series of three votes going on right now. We must recess for about 15 to 20 minutes, and when we return we will have questions from the panel. I need a certification that nobody is on these drugs so there will be no violence until we return.

[Recess.]

The CHAIRMAN. I apologize for the forced recess. The only thing that trumps a Committee hearing is votes on the floor, so we have to get there.

Again, I thank the panelists for being here. Thank you for waiting. Let me just ask before my colleagues get here. Commander Farber, on the issue of causality it seems to me that you are saying it is basically defacto settled by the settlements that the drug companies have made. Would that be fair?

Commander FARBER. That is a fair statement. The causality—I heard the exchange between Dr. Breggin and Dr. Leon. And Dr. Breggin is mostly correct. But Dr. Leon is not totally incorrect.

The law says there shall be reasonable evidence of a causal association before you can put out the warning label. And that is up to the sponsors that these labels are voluntarily submitted. Yes, the FDA has a heavy hand. But it is a voluntary thing. So all the manufacturers agree by definition that these drugs have a causal association between the two.

The CHAIRMAN. What would you say to your co-panelists who said it can't be either or? There are situations, especially with acute circumstances and short term treatment. You have to be closely monitored and there is room for these antidepressants.

Commander FARBER. Well, I'm not for banning them. In my testimony, and I think maybe Dr. Breggin probably disagrees with me, but antidepressants both cause and prevent suicides. The data I have seen on the statistical both are possible. And that is what the FDA, in fact, said.

And the problem is when you do a 30-year medical analysis and you look at everything, if it is true that they both cause and prevent suicide, you are going to get for a long period of time a statistical dead heat that is insignificant therefore.

But that doesn't change the fact that there are a lot of caused suicides, and you have to deal with it.

The CHAIRMAN. In the legal arena, you said there have been lots of settlements that the drug companies have made.

Commander FARBER. I have made many settlements, large settlements. I can't talk about them. I am sworn to secrecy.

The CHAIRMAN. Oh, tell me one. Come on.

Commander FARBER. I have lost a few, too. But lawyers on both sides see this similarly. When I go in with a pharmaceutical lawyer and we talk about settlement, we all talk the same language. We are not at each other's throats, because we see what all the damages are and the facts.

There are bad cases. And when I get referred to a case, I take only a select, probably less than 20 percent of them. But there is

definite causation. And if you don't believe that, you can go back to the early 1980s when you see all these clinical trials that are not submitted to the FDA. And I won't say most, but five, 10 percent of the cases on suicidality the provider, the investigator, will say in his opinion that this suicidal act was caused by the antidepressant. They know all this thing about statistical, there is no proof, and all that. But if you go into the inside papers, they will say that.

One other thing. Back in 2004, when big Pharmaceutical Research and Manufacturers of America (PhRMA) was getting all this static about openness and published studies and whatnot, they came out and said, oh, we are going to publish everything on the Internet, whether it is successful, or positive, or negative. They did. GlaxoSmithKline was very good at publishing all their studies on the Internet.

The problem is, they based it on efficacy. If it is a failed study, they published it on their Internet on efficacy. But they screened out all the suicidal events. They screened out all the causation assessments by the principal investigators. I don't want to call it hiding. I think the pharmaceutical industry does what Toyota does. They all do it. They are not going to put forward unfavorable data. But suicidal causation is definitely in there.

The CHAIRMAN. Dr. Leon mentioned that there are 180 million prescriptions to 25 million families who have taken these drugs. Nobody has ever studied it, but those are the positive. Those who think that there is a relationship are focusing on just a few dramatic cases. What would you say to that?

Commander FARBER. Well, if you turn it over to a statistician, and I have no doubt the statisticians do a proper job, and I have no doubt that statisticians do a proper job. They are honest people. They are technicians and they look.

The CHAIRMAN. But they are not scientists.

Commander FARBER. And if you don't focus on the suicidal cause, you are going to miss it. The statistics for suicide are buried in the haystack.

In 1990, a Harvard psychiatrist did this explosive article. He came out with this. He said 3.5 percent were suicidal. Nobody knows. Nobody knows whether it is 1 percent, 10 percent, 3 percent, or whatever.

So you have to do the study. And no studies have been done simply because the Food, Drug, and Cosmetic Act really doesn't require it per se. All, as Dr. Breggin pointed out, it requires to get the drug on the market is two successful, well-controlled studies on efficacy.

So if nobody is pushing the drug companies, and I have it in my paper why the FDA has backed off of that, they are not going to do the studies. So we are going to continue this 20-year debate another 20 years until somebody in Congress or somebody—a university says we are going to do the studies with a focus of trying to link antidepressants and suicide.

But all these studies, these 4,000 studies, they have never looked at it. And as I said, look at my work product. And I cite those 27 sources.

The CHAIRMAN. Thank you. Do either of the representatives—they are both APA. You both are APA, right?

Mr. RUDD. That is correct.

The CHAIRMAN. Do you want to respond to anything that you have heard today before we adjourn the panel?

Oh, I'm sorry, Mr. Roe will have the last question.

Mr. ROE. Well I think two points need to be made. I think, one, the issue about causation. It is important I think about relative risk that is embedded in the use of a medicine.

That if you look at relative risk, you think—you can take the child and adolescent trials as an example of that. Four thousand four hundred patients in the combined aggregated trials. Out of those, the difference in terms of people that experience suicidality in the clinical arm versus the placebo arm was 176 to 88. We are talking about a difference of 88 patients out of 4,400. The relative risk is marginal at best.

And now for those 88 patients, that is a significant risk. And there are certainly lives that can be disrupted because of the suicidality and the potential for loss of life. But 88 patients out of 4,400 is a very marginal risk. And I would tell you that the efficacy of the medicines far outweigh the risk. And this is something critical for us to always consider and think about.

And when you talk about active-duty personnel and you talk about veterans, that the relative risk is far greater to limit their access to medicine than to somehow have a message that is unclear and confusing as to what the nature of that risk is. I think that is a critical variable that oftentimes gets lost in this discussion.

The CHAIRMAN. Dr. Primm.

Dr. PRIMM. I wanted to say two things. One is that suicidality is associated with depression in the first place. And really the watchword is monitoring.

The second point I wanted to make is about some of the comments that Mr. Farber made before, namely that he was quoting selectively from our 2004 and 2006 testimony. And if you are interested, we would be happy to provide you with the full documents.

The CHAIRMAN. Thank you. I appreciate that.

Dr. Roe.

Mr. ROE. Thank you, Mr. Chairman.

Mr. Farber, you made the comment. I just heard the tail end of your testimony. But you made the comment that antidepressants cause suicide.

Commander FARBER. Yes.

Mr. ROE. Did you say that?

Commander FARBER. Yes.

Mr. ROE. How can you say that?

Commander FARBER. Well, when you see the evidence. I am not a scientist. But we are all asked to look at evidence. As jury members—

Mr. ROE. I think we have been—excuse me a minute. We have been doing that all morning. To make a statement that antidepressants cause suicide is ridiculous.

Commander FARBER. Why?

Mr. ROE. With all due respect.

Commander FARBER. Why is it ridiculous?



Mr. ROE. There is no evidence to prove that whatsoever.

Commander FARBER. I have been hearing that for 20 years. Let us find out the evidence.

Mr. ROE. That I don't—

Commander FARBER. But my answer—

Mr. ROE [continuing]. That I don't disagree with.

Commander FARBER. My answer is if the drug companies think there is evidence, if we see in the pediatric population and the young adult population, that FDA notice of October 15, 2004, stated we have established evidence of causation. I am paraphrasing.

At that time, the FDA did not have authority to order label changes, so they didn't like that. They protested at the FDA and said we don't like the causal association, because these are all short-term trials that we didn't focus on it, and so on and so forth. So the FDA changed the wording to make it acceptable.

Mr. ROE. One of the things—excuse me. I don't have a lot of time. But one of the things that we do in medicine and it was born out by Dr. Rudd is that there is a risk-benefit ratio for everything we do.

If you take an antibiotic, if you take penicillin, a certain percentage of those people are going to have anaphylaxis and a very rare patient will die. But there is a benefit to that also.

And that is what we as physicians try to do is to balance the risk and the benefit to any particular treatment. And this one is very difficult to treat, depression. Obviously, I mean, you are not a clinician, and nor do I expect you to be able to answer this, but in the clinical setting with patients, it is very, very hard to know what is in between somebody's ears.

And you are correct in saying we need to study these things and use best practices. And we don't—I have never relied on, in my 30-plus years of practice, I have never relied on the drug companies to continue the studies that we do afterward.

What happens when there is a particular medication that comes out, it is studied by many others by what we do, by other studies that come out funded by NIH, or whomever. So it is not just drug studies that look at drugs and the effect of those, because I agree with you.

Look, good people can make—can draw the wrong conclusion. We have had two people here today who are both educated, both with the same information drew different opinions. That happens. Good people do that. It doesn't mean one is dishonest or the other.

Commander FARBER. But, Mr. Roe, I never said antidepressants had no value. I never said there was—in fact, I said they prevent suicide. You can have both.

Mr. ROE. Well you just said they cause suicides.

Commander FARBER. They do.

The CHAIRMAN. If you will yield? Before you came in we were discussing something similar. Would you explain what leads to that warning on a black box?

Commander FARBER. Well, first of all, causation. All right. If you go the FDA hearings, they talk about statistical significance on suicidal safety information. The 4 percent to 2 percent in the pediatric community was causation. It was determined by the Board on September 14th, 2004, to be causation.

Mr. ROE. Not suicide. No one in that study committed suicide.

Commander FARBER. I said suicidality.

Mr. ROE. I thought you—well, maybe I misunderstood.

Commander FARBER. I make another point about completed suicides. I think that is a bogus argument. If Toyota came in here or Goodyear and said, you know, we have 20,000 accidents on the freeway due to bad tires, and we make bad tires. But you know they are really safe, because not very many people are killed in those accidents, that witness would be laughed off the stand on the *Washington Post* and so forth. Because if you commit suicide, okay, it is not a completed suicide. But it is a very dangerous situation. And these are short-term trials. But that is true. There were 4,400 patients and there were no completed suicides.

But when you get out into the general population where there is very little monitoring and so forth, I am not disagreeing that they have benefit, Mr. Roe.

Mr. ROE. Thank you.

Mr. RUDD. But equally—I need to respond to that. The other thing you are assuming though is that all of the suicidality in those trials was severe. You have absolutely no evidence to suggest that all of the suicidality, either the ideation or the attempts, was of significant lethality, duration, or frequency. You have no data to make that argument. I have looked at that data.

And so the assumption that is embedded in this is that any emergence of suicidality is very severe. Now I would take a serious clinical issue that you can't make an assumption that it is severe and significant without data.

Mr. ROE. I am running short of time. But, Dr. Primm, you made a statement. And this was—I hadn't connected this and didn't know the data until I listened to your testimony and read some of it about teenage suicide rates going down. And I don't know that you can make a cause and effect as you may have tried to do, or maybe I misunderstood you about when the black box labeling and doctors then became reluctant to prescribe SSRIs to the teenage group. But the suicide rate then went up after that. Are you saying that there was a cause and effect because less young folks were treated?

Dr. PRIMM. Yes. There appears to be a chilling effect that occurred after that 2004 FDA black box warning. And I believe 1994 to 2003 we saw a steady decline in teenage suicides. So the chilling effect of the black box warning has led to an increase in suicides because of people being fearful of prescribing these medications.

Mr. ROE. So what you are saying is that maybe—not that there could be a cause and effect, because again that is observational what we are doing after this occurred. But other things may have occurred too. But you are saying that maybe it cost—do you have any number of lives or young people?

Dr. PRIMM. You know, I would refer—we would be happy to provide more detailed information after the hearing to give you more specifics on those statistics.

Mr. RUDD. It is around 1,700, whether it was the number of deaths that actually were increased during that interim after the warning label.

And there is clear data to indicate several things. One, a lack of willingness for general practitioners, non-psychiatric physicians, general practitioners to prescribe medications and a decrease in the willingness of families to even pursue care for treatment as well as take medications. Those are all consequences of the warning label.

Commander FARBER. I agree with the statement that after the initial warnings that there was a decrease in prescriptions. I mean that was one of the reasons for opposing the warning is because these are so casually prescribed. So I would agree. It is the logical product of that.

But I would go beyond that. What if it is true? What if it is true that these warnings have cost lives? That does not at all affect informed consent. When I go to the doctor I am entitled to his best estimate on the warning and so forth. And even if it causes a societal increase, that doesn't affect individual consent. And we are entitled to that as Americans.

Mr. ROE. I agree with that. I yield back.

The CHAIRMAN. I thank you all. Although I would interpret the decrease over—what did you say 1994 to 2003? I mean, there was a Democratic President. Then you had a Republican President. Obviously more suicides. It is scientific. You are looking at me as if you don't agree with me.

All right. We thank you for helping us out here in this very complex situation.

Our Panel Three is Dr. Ira Katz, the Deputy Chief Officer of Mental Health Services in the Department of Veterans Affairs, accompanied by Dr. Janet Kemp, who is the National Suicide Prevention Coordinator for the VA, and Brigadier General Loree Sutton, Director of Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury.

We also have accompanying Dr. Katz, Michael Valentino, Chief Consultant for Pharmacy Benefits Management Services.

Dr. Katz, you have the floor.

**STATEMENT OF IRA KATZ, M.D., PH.D., DEPUTY CHIEF OFFICER, MENTAL HEALTH SERVICES, OFFICE OF PATIENT CARE SERVICES, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY JANET E. KEMP, RN, PH.D., ASSOCIATE DIRECTOR, EDUCATION AND TRAINING, VETERANS AFFAIRS NATIONAL SUICIDE PREVENTION COORDINATOR, U.S. DEPARTMENT OF VETERANS AFFAIRS; MICHAEL A. VALENTINO, R.PH., MHSA, CHIEF CONSULTANT, PHARMACY BENEFITS MANAGEMENT SERVICES, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; AND BRIGADIER GENERAL LOREE K. SUTTON, M.D., DIRECTOR, DEFENSE CENTERS OF EXCELLENCE FOR PSYCHOLOGICAL HEALTH AND TRAUMATIC BRAIN INJURY, SPECIAL ASSISTANT TO THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, U.S. DEPARTMENT OF DEFENSE**

**STATEMENT OF IRA KATZ, M.D., PH.D.**

Dr. KATZ. Thank you. Chairman Filner, Ranking Member Roe, and Members of the Committee, thank you for the opportunity to

appear here today to discuss VA's response to the mental health needs of America's veterans.

I would like to request that my written testimony be included in the record.

The CHAIRMAN. Yes. It will be done for everybody. Thank you.

Dr. KATZ. Thank you. My testimony makes four points. First, the appropriate use of psychotherapeutic medications is a key component of overall mental health care. But medications, like all treatments, can be associated with risks as well as benefits.

Second, VA has systems in place to monitor for adverse effects associated with medication use and programs to enhance the safety of pharmacological treatments.

Third, VA's mental health programs have been designed to optimize the safety of psychopharmacological treatment and to provide effective alternatives.

And fourth, young adult veterans, those who may be most vulnerable to suicidality as an adverse effect of antidepressant medications, have lower suicide rates when they come to VA for health care.

It has been more than 50 years since clinical research began to establish the benefits of psychopharmacological treatments for serious mental illness. Over the last half century, there has been a steady accumulation of scientific evidence further supporting their effectiveness.

In fact, substantial components of the evidence has come from VA research. Today, the effectiveness of the medications as key components of mental health care is as well established as the use of antibiotics for infectious disease or chemotherapy for cancer. However, all of these treatments can be associated with risks as well as benefits. As we have been discussing, the Food and Drug Administration has required a black box warning for all antidepressant medications, noting increases in suicidality in children, adolescents, and young adults.

The warning emphasizes the use of antidepressants can be associated with both benefits and risks. And the patients receiving antidepressants should be monitored for adverse effects. VA has programs in place to ensure that this occurs.

VA recognizes that the use of any medication can be associated with adverse effects. Accordingly, VA has developed comprehensive systems to identify potential adverse drug effects and to provide information about them to providers as quickly as possible.

VA's electronic medical record has allowed it to develop the only national system for electronic reporting of adverse drug effects. By analyzing computerized databases, VA is able to identify drug safety signals, assess the significance of external drug safety issues in its patient population, and rapidly track trends of known safety issues.

Using these programs, the VA has provided guidance to its facilities and FDA, addressing suicidality and other potential mental health side effects for a number of medications, and these have been listed in my written testimony.

VA has enhanced access to mental health care by requiring that mental health services are integrated with primary care. To ensure that veterans are monitored appropriately while they are receiving

mental health services, VA requires that these programs include evidence-based care management, providing repeated contacts with patients to educate them about their conditions, about medications, and about other treatments, as well as ongoing evaluations of both therapeutic outcomes and adverse effects.

Research has demonstrated that these care management interventions can decrease depression and other conditions and that they can reduce suicidal ideation.

VA offers veterans a number of alternatives for mental health care. For over a generation, VA has offered problem focused read-justment counseling for combat vets in its Vet Centers, as well as evidence-based mental health services in its medical centers and clinics.

For several years, VA has provided training to clinical mental health staff to ensure that therapists in each facility are able to provide evidence-based psychotherapies for the treatment of PTSD, depression, and other conditions as alternatives or adjuncts to pharmacologic treatment.

VA implemented the broad use of specific psychotherapies in response to evidence that, for many patients, they are the most effective of all treatments. Our goal is to make meaningful choices between effective treatments available to those who come to us for care.

Working with the National Violent Death Reporting System, VA recently calculated rates of suicide for all veterans from 16 States, including those who use VA health care services and those who don't.

Among the youngest veterans, those aged 18–24, those who came to VA were 56 percent less likely to die from suicide in 2005, 73 percent less likely in 2006, and 67 percent less likely in 2007.

VA recognizes concerns about the use of antidepressant medications among young adults as a potentially vulnerable population. But it has found that the risk of suicide is lower among the young adults who come to VA for care and that the rates appear to be dropping. In sum, VA's care works.

Thank you again for the opportunity to appear. My colleagues and I are available to address any questions.

[The prepared statement of Dr. Katz appears on p. 79.]

The CHAIRMAN. Thank you so much.

Doctor/General, which one do you prefer by the way, General or Doctor in this setting?

Dr. SUTTON. Thank you. Dr. Sutton is fine.

The CHAIRMAN. Thank you. Dr. Sutton.

I must say that wherever I go to discuss this subject Loree Sutton always comes up, so you must be doing very good work and you have a visible job. So thank you for what you are doing.

**STATEMENT OF BRIGADIER GENERAL LOREE K. SUTTON, M.D.**

Dr. SUTTON. Well, thank you, Mr. Chairman. It is a great team effort. And I am privileged to sit at the table here with our colleagues from the VA.

In my over 20 years in uniform, there has never been such a collaborative, close partnership. And I echo what Dr. Katz has said

in terms of laying out the essential role of medication, antidepressants as one tool in our tool kit.

I would like to thank you first of all for certainly inviting me. My formal remarks lay out the many actions that are going on across the Department of Defense within each of the services and in collaboration with our Federal partners as well as with organizations, institutions, and communities across the country and around the world.

Perhaps I could then use my allotted time to provide a perspective that has not yet been represented this morning. And that is of those whom I represent, the soldiers, sailors, airmen, Marines, Coast Guardsmen in uniform; yes, and the veterans; yes, the retirees; the mothers, the fathers, the sisters, the brothers, the widows, the widowers. We are all in this together.

And there could not be a more important topic, Mr. Chairman. Thank you so much for calling this session together, because when it comes to suicide, this is not an academic or a scientific discussion.

These are our brothers. These are our sisters. We are a family. And it takes the efforts of all of us in the cross generations, individuals like Sergeant Andy Brandi, a Marine Corps Sergeant who is writing extensively, working with individuals and families across the country to bring hope, to keep it alive.

So where is the hope? Let me just highlight three brief areas, one of which Dr. Roe you mentioned at the beginning, the STARRS Study. This pioneering study, landmark study, the study to assess risk and resilience in servicemembers.

The Army has reached out to the National Institute of Mental Health. This 5-year study promises to revolutionize the way that we benchmark our practices, the way that we bring applications to the field, gain the evidence, bring them back to apply and improve as we go.

This study will certainly benefit all of our servicemembers and their families. The data collection starts in March and April of this year. And so we are very heartened and very hopeful about what this will find.

There will be quarterly reports going back to the services, particularly the Army who sponsored this study, so more to follow.

But second, what has not been mentioned today, I think really bears mentioning, is that we are on the frontlines of a revolution. And that is a revolution in pharmacogenomics. I would refer you to Dr. Francis Collins' recent book, *The Language of Life*, where he talks about all that we are learning now about what our personal human genetic code means in terms of how we respond to medications.

We know that depression, for example, carries a strong genetic component. When you look at the twin studies, the concordance rates are approximately 40 percent in identical twins. And so I think that this is certainly going to revolutionize the way in coming years that we talk about medication, that we personalize our medical care. And I look forward to developing that concept with our partners at the NIH and within the VA.

Third, the revolution in neuroscience. It has been said today that the brain is the most complex organ. Indeed it is. We all thought

the human genome project was complex in itself, which it was. Three billion DNA-based pairs, part of the double helix ladder, yielding 20,000 genes that code proteins. That make us the human beings that we are.

But think of the brain. Fifty to 100 million neurons with over 100 trillion connections all here within the confines of our brain. So is it any surprise that this is such a complex challenge that the human being mind, body and spirit? It is not subject to command and control. And there is much that we are learning.

And there is much reason for hope, whether it be the neuroplasticity, the stories of neurogenesis and leading research that, for example, Dr. Norman Doidge in his book, *The Brain That Changed Itself*, tells that story like a gripping novel. And it is one that I would commend to each of us as citizens of this great country.

Let me just conclude my remarks with what is fundamentally underlying everything that we do. That is to say, that we are in the middle of a cultural transformation. One that takes us in which DoD and the services, I would say in combination with our VA partners, is leading the country from what has been a very narrow medically focused culture in the military, suck it up and drive on, which has served us well in some ways for years. It is no longer at year 9 in this conflict sufficient.

We are moving to a public health model, one that emphasizes resilience and strength. This cultural revolution is being led at leadership by leaders at all levels. From the Secretary of Defense who has said repeatedly how other than the war itself, there is no higher priority. To the Chairman of the Joint Chiefs of Staff, Admiral Mullen, who has repeatedly said that these wounds that are unseen, the spiritual, the psychological wounds of war, which we have come to understand, can be the most deadly of all. They are just as important as the psychological wounds.

I would say to you, to anyone who wonders if those of us in uniform care about this issue. One only has to sit at the Army's monthly suicide review meeting led by the Vice Chief of Staff of the Army, General Corelli, while commands around the entire Army, the entire world, every command who has had a suicide event during that last month, reports on that event. Every command in the Army listens, and learns, and takes action so that we can make a difference and stem this tide.

And so the message at all levels of leadership, which of course it is not enough to have it at the top levels, now our challenge is to drive these messages, this hope to the deck plate, to the foxhole, to the flight line, and to the kitchen table. These messages are simple but powerful.

One, you are not alone. Second, the unseen wounds of war are real. Third, treatment works, and the sooner we can intervene, the better. And finally, reaching out is an act of courage and strength.

I look forward to your questions, Mr. Chairman.

[The prepared statement of General Sutton appears on p. 86.]

The CHAIRMAN. Thank you, thank you all. I don't think anyone doubts, Dr. Sutton, the concern of the people up the line.

But there is a fact that suicides have increased and I guess I was going along with some of the statistical data that I heard that

when the black box appeared, we had more suicides. As the concern went up, you had more suicides. Well, I wouldn't make that association, but that is what some people were doing earlier.

That is, the suicides have increased. They are at a higher rate than they were during Vietnam. So something is going on that your concern is not meeting.

I would just like you respond specifically about the fact that a lot of pills are given out under battlefield conditions. There have been a lot of popular articles, testimony from individual soldiers, et cetera, that there is still the pressure to get back into the—pull yourself together, kid. Get back up. Here are a couple of pills to do it.

Also what has concerned me most about the increase of PTSD, the increase of suicide, and other manifestations is that tens of thousands of our young people leave Iraq or Afghanistan without having a competent medical professional address PTSD and/or brain injury. There are self-administered questionnaires. There are only a few questions, and if people want to get home, they know how to check them off. There is not sufficient personnel to handle it.

Yet it seems that would be the first step. With all this concern, with all this strength and courage, let everybody be forced to have an hour with a competent medical professional before they leave. That is not happening as far as I have understood.

So we still have lots of these pills being given out. We have lots of suicides. We have lots of PTSD, lots of brain injury, and we are not really dealing with it either in DoD or the VA.

Dr. Katz gave some statistics about how they come to the VA and they reduce those odds. Well, we wait for them to come. If that is the case and you so are passionate about it, what about the outreach to get them first? Everybody has to come to the VA after they leave. You are the Army, and the Marines, and the Navy—get everybody.

If we have all this evidence that it cuts down on suicides, have everybody come in. I think we have tens of thousands of young people out there, whether they are on the medication or not, capable of suicide, homicide, and other violent behaviors. We simply have not come to grips with the intensity of this issue.

Dr. SUTTON. Mr. Chairman, I share your concern. Certainly on this journey—

The CHAIRMAN. I always say that to constituents.

Dr. SUTTON [continuing]. I share your concern, Mr. Chairman. We are all on this journey together. And we recognize that for as many improvements as we have made, certainly screening it is important. But it is not enough, which is why you may be interested to know of some of the current initiatives which I believe get to the heart of your concern. Certainly it is a concern that we share.

First of all, under development right now is a Virtual Lifetime Electronic Record (VLER), which will allow individuals from the date of a session at the MEP Station to have a lifetime electronic health record that will then travel with them to the VA at whatever point they leave the service.

We agree. Sharing medical information is critical. And so that is going to—



The CHAIRMAN. I don't mean to be cynical, and I hope what you are saying is right, but we have been saying this for 30 years. You have two different electronic records.

We have the Secretaries of DoD and VA talking every week supposedly about how to integrate them but they have not been done. To say that we can do that is just not the fact.

Dr. SUTTON. Well actually, Mr. Chairman, you might be interested in knowing that, in fact, increasingly there is the ability to interoperate between the two systems of Armed Forces Health Longitudinal Technology Application (AHLTA) and VistA. For example—

The CHAIRMAN. I understand that. But when—

Dr. SUTTON. What we are able to share—

The CHAIRMAN. But we are still not sharing all the data.

Dr. SUTTON. Not all of the data yet. No, that is correct, sir. But we are sharing the screening data. We are sharing the periodic health assessment data, which contains a wealth of information. And it is given to every troop every year regardless of their deployment status.

We are also sharing the personal and social data that includes risk factors, family history. And as I mentioned, we are moving toward a Virtual Lifetime Electronic Record.

The CHAIRMAN. Maybe we could talk about it further because the people out in the field that I talk to don't have that same sense of comprehensiveness or optimism.

Dr. SUTTON. Well, we are not there yet, Mr. Chairman. I will give you that.

The CHAIRMAN. Thank you.

Dr. SUTTON. But this is where we are going. Let me give you—

The CHAIRMAN. Oh, it sounded like we were there.

Dr. SUTTON. Let me give you a couple of other examples. First of all, we are, as we speak, piloting a mandatory event driven protocol for the management of concussions in theater. There is a brigade from Fort Campbell, which is currently on its way to Afghanistan. This is a protocol that has been pulled together with the best expertise across the Federal Government and around the country.

Mr. Chairman, what this will do is in the event of an improvised explosive device explosion, whether it be in a vehicle, whether it be a dismounted troop, whether it be in a building, or if a leader sees something is not quite right with the troop, there is a mandated protocol now that doesn't depend upon the knowledge of the medic on the ground or the leader who is closest by.

The CHAIRMAN. That is great. People have been calling on this for a decade and you are just doing it with one—what did you call it, brigade, or I didn't hear what the—

Dr. SUTTON. This is the pilot study.

The CHAIRMAN. So you got to a pilot study 10 years after everybody said why aren't we doing this. I am glad you are doing it and you are very impressive as a witness, but I would say you are at least a decade behind and the kids are suffering.

Dr. SUTTON. Mr. Chairman—

The CHAIRMAN. You are just piloting it—why don't you do it for everybody? I mean, we know we have to do this.

Dr. SUTTON. Mr. Chairman, we are moving this out rapidly. We are following with a post traumatic stress and psychological health protocol, which will absolutely—

The CHAIRMAN. And what about the tens of thousands who have already been discharged? What are we doing about them?

Dr. SUTTON. Oh, sir, first of all, the VA has contacted several hundred thousand individuals, everyone that they could possibly contact. And I really would ask Dr. Katz to perhaps—

The CHAIRMAN. I would be a little bit—

Dr. SUTTON [continuing]. Provide detail.

The CHAIRMAN. I would be a little bit more skeptical about those claims, but go ahead.

Dr. SUTTON. Okay.

The CHAIRMAN. Look, they say they have these outreach programs, but they don't outreach. They simply do not get the people in. So I don't know what they are doing or if they are doing it completely but I will tell you, it is not working.

Dr. SUTTON. Well, and Mr.—

The CHAIRMAN. As the Army or the Navy you can order these folks in if you want to. The fact is, I don't care what they are doing, they have not come in.

Dr. SUTTON. Well, and here is what we have—

The CHAIRMAN. The folks who need it most come least, right, or at least—

Dr. SUTTON. That is one of the challenges, sir. You are right. Within the services, Special Operations Command, the Marine Corps, the Army, Navy, and Air Force have reached out to all of those individuals, those servicemembers who were not part of the screening process, not part of the improvements that are currently with us at this time.

But we know that that is not sufficient. So we have partnered with the USO, and the Red Cross, and the Vet Centers. And we have just completed a pilot of training the USO staff members in over 140 airport facilities around the world. We are working to develop a kiosk and a far forward USO site that will bring together green bean coffee, Vet Center peer-to-peer counselors, Bonnie Carroll and her Transition Assistance Program for Survivors personnel, the Red Cross. And be able to reach out to individuals who are at risk in our airports, in our hospitals.

The CHAIRMAN. I am glad you are doing all that and I don't want to argue that it is not effective because it is.

On the one hand you are doing this outreach and you have this small pilot study but you are still putting tens of thousands of kids in jeopardy without being adequately evaluated for mental illness or brain injury.

You want to catch up here, but you are pouring more into the ocean so you will always be behind.

Dr. SUTTON. Mr. Chairman, we are working this at all levels. We understand that we are in uncharted territory. Never in the history of our republic have we ever placed so much trauma on the shoulders of so few, on behalf of so many, for so long. So this is—

The CHAIRMAN. Vietnam was a good case study by the way.

Dr. SUTTON. And hope, I guess as I sat here this morning, Mr. Chairman, it has concerned me. We can talk about this issue of

medication, and safety, and efficacy as well as suicide prevention in the safety and the confines of this great Capitol building.

But what if I am a young troop or a family member and I am watching this Web streamed around the country and around the world? And I am wondering, I am on antidepressants right now. Does that mean that I am going to die, that I am going to go crazy, that I am going to kill my spouse? If I am feeling depressed, feeling despair, maybe my buddy died in my arms last week, and I am thinking I need help. I am not sure that I would have the courage or the hope to get help after what I have heard here today.

The CHAIRMAN. Well, you should have more confidence, because they haven't heard it yet. They don't get those warnings.

I would rather that if my kid was in that situation to be fully informed than to say—

Dr. SUTTON. I would—

The CHAIRMAN [continuing]. Oh, I guess I am going to be crazy, and I won't take that. That is not what information does.

Dr. SUTTON. No, that is correct, sir. The black box warnings that the FDA put out were never designed to decrease the number of antidepressant prescriptions. What they were meant to do was to inform providers and consumers of the known—

The CHAIRMAN. Right.

Dr. SUTTON [continuing]. Association with increased suicidality so that providers, family members, patients alike could monitor themselves, monitor—

The CHAIRMAN. But you didn't answer my question about the— all the literature about kids just getting lots of pills. Obviously, they are not going to read the warning because they are not going to get the black box. Is that just media hype, or is that going on?

Dr. SUTTON. Sir, this is one of our challenges. We know that medication in and of itself is not enough. It is one of the tools. And it is not always the primary tool by any means. There are other evidence-based therapies, whether it be cognitive behavioral therapy, cognitive processing therapy, whether it be prolonged exposure therapy that are very effective and in combination.

There are also complimentary therapies, which we—

The CHAIRMAN. I agree with you, but why is it that we hear that they are just doing one in the battlefield conditions?

Dr. SUTTON. Sir—

The CHAIRMAN. People don't have time to really think about that.

Dr. SUTTON [continuing]. We are on a journey. We are not where we want to be yet. But we are putting the investment into learning about the—

The CHAIRMAN. Okay.

Dr. SUTTON [continuing]. Effects of acupuncture, tai chi, chi-gong, other mindfulness—

The CHAIRMAN. Okay.

Dr. SUTTON [continuing]. Mediation techniques.

The CHAIRMAN. No, I appreciate that, and we want to help you in that process, certainly.

Dr. SUTTON. Thank you so much, Mr. Chairman.

The CHAIRMAN. We will be partners with you on that journey.

Dr. SUTTON. That is great.

The CHAIRMAN. Thank you. One question before I get to Mr. Roe.

Dr. Katz, you heard Dr. Breggin's testimony. And he mentioned several times this Valenstein study, which he quotes, "Completed suicide rates were approximately twice the base rate following antidepressant starts in VA clinical settings."

Is that what was done in 2009? You never mentioned it in your study. Is it relevant? Why didn't you talk about it?

Dr. KATZ. The issue is the need for monitoring when antidepressants are started, when doses are changed, or when medications are stopped. The balance between the benefits and the risks are enhanced with appropriate monitoring. That is why VA has implemented requirements for care management, for—

The CHAIRMAN. I didn't understand a word you said.

Dr. KATZ. You can make the increase—

The CHAIRMAN. There was a study that says of 887,000 plus VA patients treated for depression, it found that, and I am quoting Dr. Breggin's testimony. "Completed suicide rates were approximately twice the base rate following antidepressant starts in VA clinical setting." Is that true or not?

I don't know what you are talking about when you talk about monitoring stuff. This is a conclusion looking at almost a million people. Doesn't that tell you something?

Dr. KATZ. Yes, sir.

The CHAIRMAN. What does it tell you?

Dr. KATZ. This is what it tells me. Let me draw an analogy. Dr. Roe talked about the risk of anaphylaxis when penicillin is given. You don't not give penicillin. But you watch people like a hawk when you do give it to catch early signs of side effects and then do what you can to reduce them.

The CHAIRMAN. Does that mean we weren't doing that from the VA for these million patients?

Dr. KATZ. The time covered in Dr. Valenstein's study was a number of years, sometime ago. I will get back to you.

[The VA subsequently provided the following information:]

**Statement of Marcia Valenstein, MD, MS**

Respectfully, I would like to clarify the message of my paper, "Higher Risk Periods for Suicide Among VA Patients Receiving Depression Treatment: Prioritizing Suicide Prevention Efforts," which was cited during testimony before the House Committee on Veterans' Affairs on February 24, 2010, on "Exploring the Relationship Between Medication and Veteran Suicide."

The purpose of this research was to identify the periods during treatment for depression that are high risk for suicide to help physicians prioritize suicide prevention efforts. In this observational study, we did not attempt to causally link antidepressant use to suicide death. The purpose of our paper was to alert clinicians and policy makers about high risk periods in regular, ongoing clinical care—and to note that all age groups (not just younger patients) were at higher risk during these treatment periods. Randomized, clinical trials would be necessary to appropriately address causality regarding antidepressants and suicide, and any inference of such an association is unsupported by this research.

This study calculated suicide rates for five sequential 12-week periods following different treatment events: psychiatric hospitalizations, new antidepressant starts (more than 6 months without fills), "other" antidepressant starts, and dose changes. We found that suicide rates were highest for patients immediately following psychiatric hospitalizations at 568 per 100,000 person-years, compared to a base rate of 114 per 100,000 person-years in the overall population of Department of Veterans Affairs (VA) patients in depression treatment. Suicide rates were also higher than the base rate at

210 per 100,000 person-years following new antidepressant starts. Adults aged 61–80 years were at highest risk for suicide in the first 12-week periods following these treatment events. Although suicide rates were higher following antidepressant starts, we did not indicate that antidepressants were the cause of suicide deaths—just as we did not indicate that the hospitalizations were the cause of suicide deaths following hospital discharge. Instead, patients who are hospitalized or who start a new antidepressant are likely more symptomatic, and the increased risk of suicide death likely ensues from the issues and symptoms that prompted the treatment intervention.

The research recommended that health systems should prioritize prevention efforts following psychiatric hospitalizations to have the greatest impact on suicide. VA has done just this, instituting mandatory weekly followups for all veterans leaving an inpatient mental health program. The study further noted that close monitoring was also warranted in the first 12 weeks following antidepressant starts, across all age-groups. As VA's testimony indicated, physicians and patients alike are advised about the potential for adverse effects and are closely monitored during the period immediately following any new prescription for antidepressant medications.

The CHAIRMAN. I hope so. Dr. Roe.

Mr. ROE. Thank you, Mr. Chairman.

Not to understate the obvious, but the least way to get your anxiety raised is not get shot at. That helps a lot when you are not being fired at and what Dr. Sutton said.

We can't forget why we are here. When I leave—what the military does—when I leave here today I am going to Arlington to bury one of our soldiers who was killed in Afghanistan recently. So I will leave this hearing and go to Arlington to do just that.

And you are right. And we can't thank our young men and women enough for what they do every single day so we can sit here. As you just pointed out, General, in this nice, warm, safe building, so thank you. We thank them. And we will be going to Afghanistan in a few weeks to visit the troops again.

A couple of points. Unseen wounds are real. And to dovetail to what the Chairman was saying, when I ETS'd from the military, it was basically a—you can be out in 48 or 72 hours. You go this, this, and this. And I hit the door. And then that was the last anybody ever heard of me, saw me.

That really wasn't the way to do it. And what he is saying I think he is right is you don't—you can't command an ex-veteran to do anything. They will point that out right quickly. They are not going to follow any orders after that that they don't want to. They have been doing that for however long they have been doing that.

So if you are going to do it, it has to be done while they are still in the military. And I think certainly having a very good evaluation, seeing this uptick in suicide, is a very, very good idea. And then be able to hand that off, because Dr. Katz makes some good points.

Whether you use antidepressants, or don't, or whether you use just therapy, whatever, in the 18–24 year olds that was from 2005 through 2007. That was some pretty significant reductions in suicides when you get to treatment. I think what the Chairman is saying is what about those that never get to treatment. We don't identify those.

I think that is what he is—if we can identify those or have markers on the way out, hand them off to the VA. I think that is what

this Committee wants to do. In a nutshell I think in how do we treat them. Best practices will determine that.

Certainly there is a difference of opinion about that. And we are not here to decide that today. But, Dr. Katz, I think your data that you gave, the 18–20 year olds, is impressive that therapy works. Whether it is just a psychotherapy, or medication, or whatever the therapy you use, it is working. So I think we have determined that.

And the question, Dr. Sutton, you may not have an answer for this, but what percent of the troops that we have now are on SSRIs?

Dr. SUTTON. Yes, sir. The utilization data we have, and by the way let me just say that this is one of the questions that we know that the STARRS Study will help us answer with more precision.

But here is what we know now. We know that across the force our utilization rates for SSRIs, for example, is approximately 17 percent, which as you heard earlier, closely approximates what you see in the general population. I think the number was closer to 20 percent before. But that is what we know in terms of our utilization data across the force.

Now what we also know we have had electronic health records in theater for the last 2, now going on 3 years. We know that the prescription rate in theater varies from 3 to 6 percent.

So in other words, you have individuals who deployed at theater with perhaps a 6-month supply, which is routine. And then we have 3 to 6 percent who then get resupplied in theater. It is an imprecise estimate. But I would say that our—given the 17 percent that we know from utilization data across the force, 3 to 6 percent in theater or roughly at about 20 percent of the force are using antidepressants. The majority of those, as you mentioned, the SSRIs.

Mr. ROE. Well there is no question that the force, as you pointed out, I mean I have known people now that have been deployed four and five times, is under tremendous stress. No doubt about that.

So I agree with the Chairman completely. We need to make this work. Also we have been to great lengths. Chairman Mitchell in our Oversight and Investigations Subcommittee, I guess a month or so, 6 weeks ago, and I don't think that seamless transition is going to work by the October date. It didn't look like that is. So there is a great hurdle yet to where the DoD and VA can speak to each other in an intelligible language.

So that has got to happen, or either we got to scrap it and start over after a 20-year start. And I don't want to be sitting here 10 years from now and then have the same answers, well, we are still working on it. We think we are going to get it to work. And I know that is not your bailiwick. That is an IT problem. But it is a practical problem for the medical personnel.

I want to thank the Chairman for having this meeting. And I want to thank all of the witnesses today. I didn't get a chance to thank the first panel and the second panel for being here.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Dr. Roe.

We thank you all for being here. We appreciate your passion and your commitment to our Nation's active duty and our veterans. I think we all want to do a better job, because they are our children.

Thank you so much.

[Whereupon, at 1:24 p.m. the hearing was adjourned.]

## A P P E N D I X

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### **Prepared Statement of Hon. Bob Filner, Chairman, Full Committee on Veterans' Affairs**

I would like to thank everyone for attending today's hearing. The purpose of today's hearing is to explore the potential relationship, if any, between psychiatric medications and suicides.

With PTSD and TBI being the signature wounds of the current war in Iraq and Afghanistan, mental health issues have naturally taken center stage.

Research has shown that mental disorders and substance abuse disorders are linked to more than 90 percent of people who die by suicide. Today, suicides among servicemembers and veterans continue to increase at an alarming rate, far exceeding the comparable suicide rates among the general population. It is a tragedy that our servicemembers and veterans survived the battle abroad only to return home and fall to suicide.

With the widespread availability and use of psychiatric medications to address mental health disorders, it begs the question of whether these drugs prevent or lend a hand in suicides.

There are some doctors who are convinced by their clinical experience that psychiatric drugs often adversely impact the individuals' better judgment and lead people to lose control over their emotions and actions. Suicides may be driven by so-called drug-induced adverse reactions and intoxications.

On the other hand, there are research studies that show suicide attempts were lower among patients who were treated with antidepressants than those who were not. In other words, antidepressants had a protective effect and did not support the hypothesis that antidepressants place patients at greater risk of suicide.

Through this hearing, we will explore the two opposing schools of thought on the relationship with psychiatric medication and suicides. In this process, we will also seek to better understand the reasons why more and more servicemembers and veterans are taking their own lives and what the Department of Veterans Affairs and the Department of Defense are implementing in this struggle to prevent more suicides.

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### **Prepared Statement of Hon. David P. Roe, a Representative in Congress from the State of Tennessee**

Thank you, Mr. Chairman.

I think those of us gathered here today would be hard pressed to find a topic more heartbreaking than when a servicemember makes the decision to end his or her own life. This hearing is one of many hearings and meetings this Committee has had in an effort to combat veteran suicide and I can tell you that the stories we hear in these proceedings—much like those in Mr. Breggin's book—always raise difficult questions.

As painful as such anecdotal accounts are, we must take heed not to be so quick to point to a single cause or mistake theory for solution. It is sound research that is critical to our efforts to put an end to these tragedies and understand the whole story.

On that front, there are many encouraging signs. In 2008 the Army and the National Institute of Mental Health began a 5-year study into the factors that contribute to suicide in the armed forces and how to prevent them. Called the Army Study to Assess Risk and Resilience in Servicemembers (or, Army STARRS), this is the largest study of suicide and mental health among military members ever conducted.

In addition, there is a great deal of ongoing public and private research into the causes of suicide and treatment options, including medication, to prevent it.

I am hopeful that with this research, practitioners will be able to better identify risk factors for veteran suicide and design prevention, outreach, and treatment options that are effective and practical within the VA setting.

The psychology behind why a person may see death as the only way out is more complex than any of us have the ability to fully comprehend and it is the interaction of a number of factors that may lead to this catastrophe. In addressing these issues, one cannot simply place blame on the veteran, their military service, their illness, or their chosen treatment option.

As the research goes on, we must allow our veterans and servicemembers to have the full range of approved treatment options that they decide upon with their doctors.

I want to thank our witnesses for being here this morning. I look forward to hearing and learning from each of you. It is only by working together that we can convince every courageous yet struggling American veteran that their country supports them and that hope—and help—are out there.

I yield back the balance of my time.

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**Prepared Statement of Hon. Harry E. Mitchell,  
a Representative in Congress from the State of Arizona**

Thank you, Mr. Chairman, for calling this hearing today. I commend your leadership for addressing suicide prevention and treatment for returning soldiers and our veterans.

Among the many important issues that this Congress and Administration must address in the 111th Congress, I firmly believe we need to do more to prevent veteran suicide.

As we all know, many of our newest generation of veterans, as well as those who served previously, bear wounds that cannot be seen and are hard to diagnose.

There are over 20 million veterans in our country, and only a fraction of them are directly connected to the VA. We must continue to be proactive and innovative to reach those who may need help but may not know where to turn.

Proactively bringing the VA to our veterans, as opposed to waiting for veterans to find the VA, is a critical part of delivering the care they have earned in exchange for their brave service.

We persuaded the VA to overturn its self-imposed ban on television advertising as a method of outreach. The VA then produced a public service announcement and began an outreach campaign to inform veterans and their families about the suicide prevention hotline.

What began as a limited DC area pilot program has been expanded nationally, and it has been effective. Since its inception in July of 2007, nearly 225,000 calls were received from veterans. And the hotline has been credited with saving 7,000 lives.

Through measures like the hotline, the VA is able to reach out to many more veterans that it might otherwise be unable to help.

While I applaud the VA and Secretary Shinseki for expanding and extending outreach, I believe we need to do more. We need to expand and extend outreach efforts, including the use of e-mail, Twitter, Facebook and new media, to let veterans know where they can get help.

As I told a group of Iraq and Afghanistan veterans who visited with me recently, we need to “have the back” of every veteran.

Thank you again to all of our witnesses. I look forward to hearing your perspectives.

I yield back.

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**Prepared Statement of Peter R. Breggin, M.D., Ithaca, NY  
(Psychiatrist and Author)**

I am Peter R. Breggin, M.D., a psychiatrist in private practice in Washington, DC, for several decades and now in Ithaca, New York. In the early 1990s I became the first physician to speak and write extensively about the new antidepressants causing violence, suicide and other abnormal behavioral reactions. I became the scientific expert for more than 100 combined cases against Eli Lilly concerning Prozac-induced violence and suicide, and wrote many related books and scientific articles. In 2004 the FDA finally upgraded the warnings for all antidepressant drugs. The FDA's language was virtually borrowed from one of my scientific publications (Breggin, 2003), which the agency had provided to each member of its review committee.



My conclusions in this testimony are based on dozens of citations listed in the scientific paper I have written specifically for this hearing, “Antidepressant-Induced Suicide and Violence: Risks for Military Personnel.” My conclusions are further based on hundreds of scientific citations in my published papers and in chapters 6 and 7 of my 2008 medical book, *Brain-Disabling Treatments in Psychiatry, Second Edition* (New York: Springer Publishing Company).

My other recent book, *Medication Madness* (2008, New York: St. Martin’s Press) presents more than 50 cases in which I have personally evaluated the medical and police records, and interviewed perpetrators and survivors. Based on voluminous scientific data and clinical experience, individuals with no prior tendencies toward suicide, violence or mania can be driven into these states by antidepressants.

In 2004 the FDA required the antidepressant manufacturers to review their previous clinical trials in regard to suicidality. The FDA concluded that the newer antidepressants **double** the rate of suicidal thoughts and behaviors in children, youth, and **young adults up to age 24**. The actual rates will be much more than doubled in routine clinical practice in the military and elsewhere. In routine practice the medications are administered for longer periods of time than a mere few weeks, monitoring is much more casual, drug cocktails are common, and suicidal and more disturbed patients are not excluded as they were in the clinical trials.

The FDA’s new warnings provide a consensus of FDA-appointed experts. For convenience, I will cite the October 2008 FDA-approved label for Zoloft. The warnings are similar or identical to the other antidepressants. The Zoloft label begins at the top with the following Black Box bold warning:

**Suicidality and Antidepressant Drugs**

**Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. . . .**

The black box is followed by a lengthy warning section ominously entitled **Clinical Worsening and Suicide Risk**. It states:

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric.

For emphasis, the FDA repeats this array of dangerous symptoms throughout the label. Note the specific mention of irritability, hostility, aggressiveness, and impulsivity—a prescription for violence as well as suicide, especially in already stressed and heavily armed soldiers.

Federal regulations require that these warnings must be based on “reasonable evidence of a causal association with a drug.”

The FDA-approved label concludes with a Medication Guide that prescribers are advised to give and discuss with patients and their families. The guide lists the following risks associated with the drugs.

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

Meanwhile, the efficacy of these drugs is in doubt for both children and adults. Under FDA regulations, pharmaceutical companies can cherry pick their studies to find only *two* that show minimal effectiveness. However, antidepressants do not

prove effective compared to placebo when **all** controlled clinical trials conducted for the FDA are included in a meta-analysis.

As you may discover today, medical and psychiatric organizations that rely very heavily on financial support from the pharmaceutical industry have unconscionably resisted and even dismissed the FDA's warnings, and all the science behind them.

In conclusion, there is overwhelming evidence that the newer antidepressants commonly prescribed in the military can cause or worsen suicidality, aggression, and other dangerous mental states. There is a strong probability that the documented increase in suicides in the military, as well as any increase in random violence among soldiers, is caused or exacerbated by the widespread prescription of antidepressant medication.

Little will be lost and much will be gained by curtailing the prescription of antidepressants in the military. The military instead should rely upon the newly developed psychological and educational programs described by Dr. Bart Billings at today's hearing.

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## **Antidepressant-Induced Suicide and Violence: Risks for Military Personnel**

**By Peter R. Breggin, M.D.\***  
Ithaca, New York

### **I. Introduction**

Evidence pertaining to violence and suicide induced by the newer antidepressants has been growing for years (Breggin and Breggin, 1994; Teicher et al., 2003). Recently public concern has been expressed about the increased prescription of psychiatric medications, especially antidepressants, to military personnel (Thompson, 2008). At the same time, the military has voiced concern about escalating rates of suicide among active duty soldiers (Lorge, 2008). At a military conference on combat stress, this author pointed to an association between increasing rates of antidepressant prescription and increasing rates of suicide in the military (Breggin, 2009).

This paper focuses on evidence that antidepressants frequently cause suicide, violence and manic-like symptoms of over-stimulation—and therefore present a serious hazard when given to military personnel. Studies with children will be included, because they commonly involve youth up to age 17 or 18 and because medication risks for all age groups often show up first or most obviously among children.

### **II. Research Leads to FDA Label Changes for the Newer Antidepressants**

#### **A. FDA Label Changes**

Because of concerns about reported cases of suicide in association with the newer antidepressants, the FDA required a re-evaluation of all controlled clinical trials conducted on children and youth during the FDA approval process. The selective serotonin reuptake inhibitor (SSRI) antidepressants were re-evaluated including fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft), citalopram (Celexa) and escitalopram (Lexapro). In reports issued by the FDA (e.g., Food and Drug Administration, March 22, 2004d) four other potentially stimulating antidepressants were found to produce similar adverse behavioral and mental effects and were included in the group: venlafaxine (Effexor), mirtazapine (Remeron), bupropion (Wellbutrin or Zyban) and nefazodone (Serzone). The study included 4,582 patients in 24 trials (Hammad et al., 2006). The meta-analysis found that the risk of suicidal ideation and behaviors was doubled for children and youth taking the antidepressants compared to placebo (4 percent versus 2 percent) (Food and Drug Administration, October 15, 2004a). The eventual label changes, however, were applied to all antidepressants, including older ones where no new evidence was available.

To illustrate the FDA-mandated label changes, the following excerpts are taken from the Zoloft (sertraline) label as of October 2008 (see attachments for complete label). Identical or nearly identical warnings and information can be found in all antidepressants labels, most of which appear in the *Physicians' Desk Reference*. A Black Box at the top of the label warns about the increased risk of suicidal behavior in children and youth, and also young adults ages 18–24, which includes many young soldiers.

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\*Peter R. Breggin, M.D., 101 East State Street, Ithaca, New York, 14850. Phone 607-272-5328. www.breggin.com. This paper was written as background for Dr. Breggin's testimony before the U.S. House of Representatives, Veterans' Affairs Committee, Hearings on "Exploring the Relationship Between Medication and Veteran Suicide," February 24, 2010.

The Zoloft label begins with the following Black Box Warning:<sup>†</sup>

**Suicidality and Antidepressant Drugs**

**Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. . . .**

The Black Box Warning provides additional information. Then the label continues with an elaborate **WARNINGS** section subtitled, **Clinical Worsening and Suicide Risk**, which contains the following statement:

**There has been a longstanding concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18–24) with major depressive disorder (MDD) and other psychiatric disorders.**

This section continues with a specific warning about the increased risk of medication-induced suicidality during “the initial few months of a course of drug therapy, or at times of doses changes, either increases or decreases.” It then describes an activation or stimulant-like array of adverse effects:

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric.

Note the specific mention of “irritability, hostility, aggressiveness, impulsivity”—a virtual prescription for causing suicide and violence, especially in already stressed individuals, including soldiers.

Further in the section on **Clinical Worsening and Suicide Risk**, this FDA-approved label recommends information that the prescriber should share with patients and caregivers. It repeats the array of dangerous stimulant or activation symptoms described above.

A section titled **Discontinuation of Treatment with Zoloft** describes similar dangers associated with stopping or withdrawing from Zoloft and the other newer antidepressants, including “dysphoric mood, irritability, agitation . . . anxiety, confusion . . . lethargy, emotional lability, insomnia, and hypomania.”

Under the heading **Information for Patients** the label addresses the importance of informing patients about all of these risks. In this section, the FDA-approved label once again warns about **Clinical Worsening and Suicide Risk** and again describes the activation syndrome, including “the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down.” It warns “families and caregivers of patients should be advised to look for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient’s prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient’s presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication.”

The probability that these warnings will be given to military personnel is not high, and of course their families will often be unavailable to monitor them.

A Medication Guide appears at the end of the label. The label states, “The prescriber or health professional should instruct patients, their families, and their care-

<sup>†</sup> Bold emphases also appear in the label.

givers to read the Medication Guide and should assist them in understanding its contents.” The Medication Guide is not restricted to any age group. Its application to all ages was confirmed in a communication from the FDA’s Senior Regulatory Project Manager, Division of Psychiatric Products to attorney Don Farber in 2008, which stated, “In 2007, FDA revised the MG [Medication Guide] to expand the age range to all patients. . . . The revised MG was approved for all antidepressants in July and August 2007” (Grewal, 2008).

The Medication Guide gives specific guidance about identifying danger signs associated with the use of antidepressants:

**Call a health care provider right away if you or your family member has any of the following symptoms especially if they are new, worse, or worry you:**

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

**To add to the risks, all of the above symptoms can occur when the dose is reduced or stopped. Withdrawal from antidepressants is very dangerous and must be done carefully and with supervision (Zoloft label; Breggin, 2008a&b).**

Once again note the array of dangerous adverse reactions, including not only suicide but many emotional and behavior reactions that would be especially hazardous in a soldier, including, “feeling very agitated or restless,” “new or worse irritability,” “acting aggressive, being angry, or violent,” and “acting on dangerous impulses.”

### **B. Canadian Drug Regulatory Changes**

On June 3, 2004, before the FDA issued its formal label changes, Health Canada (the Canadian drug regulatory agency) issued an Advisory for all of the newer antidepressants, including Zoloft, emphasizing the risk of both “harm to self” and “harm to others” in children and adults taking these drugs.

### **After consultations with Health Canada, Pfizer also upgraded its warnings for Antidepressant-Induced Suicide and Violence: Risks for Military Personnel**

Zoloft on May 26, 2004. In a black boxed warning under the rubric “Adult and Pediatrics: Additional data,” the company warns about the risk of “self-harm or harm to others.” It too describes an activation or stimulant like array of drug-induced symptoms: “The agitation-type events include: akathisia, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment.”

### **III. Confirmation from the *Diagnostic and Statistical Manual of Mental Disorders***

The official American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders* (2000) is considered a consensus document drawing on current expertise in psychiatry. It is the most commonly used authority in the field and provides the official diagnostic system. In the section on mania and elsewhere, it makes clear that antidepressants can cause all the symptoms and behaviors associated with mania: “Symptoms like those seen in a Manic Episode may also be precipitated by antidepressant treatment such as medication . . .” (p. 361). Symptoms and behaviors associated with mania, including the medication-induced disorder, emphasize high-risk behaviors: “criminal” behavior, “antisocial” behavior, “irritability, particularly when the person’s wishes are thwarted,” “assaultive behavior,” “physically assaultive” behavior, “physically threatening” behavior, “suicidal” behavior, and shifts from anger to depression (pp. 359–261). By causing mild to severe degrees of manic behavior, antidepressants can cause suicide, violence and a wide variety of antisocial behaviors.

The official diagnostic manual also makes clear that SSRI antidepressants can cause akathisia, including suicide, aggression, and worsening of psychosis or behavioral dyscontrol (American Psychiatric Association, 2000, p. 801).

#### IV. Overview of Scientific Studies

##### A. Antidepressant-Induced Suicidality in Children and Adults

In addition to the studies done under the auspices of the FDA (above), a large body of research confirms an increased risk of suicidality in children and adults (of all ages) when taking antidepressants. Aursnes et al. (2005) located unpublished data on adult controlled clinical trials not previously available for a total of 16 studies in which Paxil had been randomized against placebo. They found a statistically significant 7 suicide attempts among patients taking Paxil and 1 among patients receiving placebo. They concluded, "Our findings support the results of recent meta-analyses. Patients and doctors should be warned that the increased suicidal activities observed in children and adolescents taking certain antidepressant drugs may also be present in adults."

Fergusson et al. (2005) searched the adult literature and found 702 randomized clinical trials (87,650 patients) comparing an SSRI to placebo or an active non-SSRI control medication. They found a statistically significant increased risk of suicide attempts on SSRIs compared to placebo.

Donovan, Kelleher, Lambourn, and Foster (1999) found a significantly increased rate of suicide among adult patients treated with SSRIs compared to those treated with tricyclic and other antidepressants. The large British study involved 222 suicides.

Donovan, Clayton, Beeharry, Jones, Kirk, Waters, et al. (2000) conducted a prospective study of 2,776 consecutive cases of deliberate self-harm in individuals age 17 and older who were seen at the emergency department of a British infirmary. The relative incidence of deliberate self-harm was significantly higher ( $P < 0.001$ ) in patients who were prescribed the SSRIs fluoxetine, paroxetine, and sertraline compared to patients who were prescribed older more sedating antidepressants.

Jick, Dean and Jick (1995) conducted an epidemiological study of reports from general practices (primary care) in the United Kingdom involving 172,598 adult patients who had been given at least one prescription for antidepressants. Even after taking into account a past history of suicidal behavior and other variables, fluoxetine remained twice as likely to be associated with suicide as older more sedating antidepressants.

Frankenfield, Baker, Lange, Caplan and Smialek (1994) conducted a retrospective case review of all deaths in Maryland where either fluoxetine or tricyclic antidepressants were forensically detected. The study covered a 3½ year period of time and found a statistically significant increase in *violent* suicides in association with fluoxetine (65 percent versus 23 percent).

Under guidance from the FDA, GlaxoSmithKline conducted "a new meta-analysis . . . of suicidal behavior and ideation in placebo-controlled clinical trials of paroxetine in adult patients with psychiatric disorders . . ." (GlaxoSmithKline, 2006, p. 1). The company found a statistically significant increase in suicidal behavior in adults of *all ages* treated with Paxil for Major Depressive Disorder.

In a non-controlled study of suicide attempt cases admitted to a psychiatric unit in a general hospital, suicide attempt cases were more likely to have received antidepressants and benzodiazepines than non-suicide cases. The study noted the possibility that antidepressants and benzodiazepines "can induce, worsen or precipitate suicidal behavior in some patients . . ." (Raja et al., 2009, p. 37). It advised warning patients of the risk.

A study of 1,255 suicides in 2006 in Sweden (95 percent of all suicides in the country) examined the frequency of psychiatric medication usage up to 180 days before death (Ljung et al., 2009). The study reported that 32 percent of Scandinavian men and 52 percent of Scandinavian women filled a prescription for antidepressants in the 180 days prior to death by suicide.

A retrospective study examined the suicide rates among 887,859 VA patients treated for depression between April 1, 1999, and September 30, 2004. It focused on 12-week periods after various events including hospitalization and antidepressant starts or dose changes. The authors found that "completed suicide rates were approximately twice the base rate following antidepressant starts in VA clinical settings" (Valenstein et al., 2009).

Juurlink et al. (2006) reviewed more than 1,000 cases of actual suicides in the *elderly* and found that during the first month of treatment the SSRI antidepressants were associated with nearly a five-fold higher risk compared to other antidepressants.

Fisher, Kent and Bryant (1995) conducted a phone survey of pharmacy patients taking various antidepressants and found a higher rate of suicidality on SSRIs.

The studies in this section confirm that the risk of antidepressant suicidality is not limited to children, youth, and young adults, but encompasses all ages.

### **B. Antidepressant-Induced Mania in Adults**

A considerable body of research demonstrates that the newer antidepressants frequently cause mania. Preda, MacLean, Mazure, and Bowers (2001) carried out a retrospective study of 533 adult psychiatric hospital admissions over a 14-month period and found that 43 (8.1 percent) could be attributed to antidepressant-induced mania and/or psychosis. Morishita and Arita (2003) carried out a retrospective review of 79 patients treated for depression with paroxetine and found that 7 (8.6 percent) developed hypomania or mania.

Howland (1996) examined approximately 184 adult patients treated at a university clinic and hospital with SSRIs, including fluoxetine, paroxetine, and sertraline. He identified 11 cases (6 percent) of SSRI-induced mania, mostly severe.

Ebert et al. (1997) carried out a prospective study of 200 adult inpatients over a total of 8,200 treatment days with the SSRI Luvox. Fourteen patients (17 percent) developed hypomania and some became potentially suicidal or dangerous.

Levy et al. (1998) carried out a blind retrospective chart assessment of 167 adult patients with anxiety disorders. They reported, "Five patients (2.99 percent) were identified as having an episode of antidepressant-associated mania within 3 months of initiation of treatment."

Martin et al. (2004) used a national database of more than 7 million privately insured individuals, aged 5–29 years, to find new diagnoses of bipolar illness made in association of antidepressant treatment. They found a statistically significant correlation between exposure to antidepressants and a subsequent diagnosis of bipolar disorder.

Individuals who already have a tendency to become manic have vastly increased risk of mania when exposed to SSRI antidepressants (Henry et al., 2001; Ghaemi et al., 2000) with rates that exceed 20 percent.

The SSRI antidepressants pose a very serious, indeed an extreme, risk of causing mania in patients with and without a prior history of manic-like symptoms. This alone should contraindicate their use among active duty soldiers.

### **C. Antidepressant-Induced Aggression in Adults**

Studies of antidepressant-induced mania often cite cases of violence. In addition, Healy et al. (2006) evaluated controlled clinical trial data produced by GlaxoSmith-Kline (2006a) concerning Paxil and found an increased rate of hostility for children and adults taking the medication. Healy (2000) conducted a randomized double-blind crossover study comparing the effects of sertraline (Zoloft) to a non-SSRI antidepressant (reboxetine) in a group of healthy volunteers. Many of the 20 individuals developed adverse mental and neurological effects while taking the sertraline and two became severely disturbed with tendencies toward suicidal and violent behavior.

The FDA conducted an unpublished epidemiological study comparing fluoxetine to trazodone in regard to spontaneous reports concerning hostility and intentional injury (Food and Drug Administration, 1991; available on [www.breggin.com](http://www.breggin.com)). Ever after the greater number of prescriptions for fluoxetine were factored in, fluoxetine had a higher frequency of reports for aggressive and violent behavior.

In a phone survey of pharmacy patients taking antidepressants, Fisher, Bryant and Kent (1993) compared fluoxetine with a more sedating antidepressant, trazodone. They concluded that fluoxetine caused "a higher incidence of psychological/psychiatric adverse clinical events, including delusions and hallucinations, aggression, and suicidal ideation" (p. 235).

### **D. SSRI-Induced Apathy Syndrome in Adults**

The mixture of apathy and disinhibited aggressiveness reported by Healy and others is found in a portion of patients who act uncharacteristically violent as a result of taking SSRIs (Breggin, 2008a&b). Hoehn-Saric, Lipsey and McLeod (1990) describe "Apathy and Indifference in Patients on Fluvoxamine and Fluoxetine," including apathy, indifference, loss of initiative and disinhibition with and without hypomania in five patients.

Antidepressant-induced apathy has become sufficiently common to be described in the American Psychiatric Press *Textbook of Psychiatry* (Marangell et al., 2003; also see Marangell et al., 1999). Patients who become apathetic lose their ability to care about others and may have an increased tendency toward both suicide and violent (Breggin, 2008b).

### E. A Broad Range of Adverse Behavioral Effects in Children and Youth

Studies of children often include youth as old as age 17 or 18. There are many studies confirming suicidality and aggression in children and youth (see earlier in this report and Breggin, 2008b). Also, children are often more sensitive to drugs and are more likely to display adverse effects that will also appear with less frequency in adults.

Researchers at Clinical and Research Program in Pediatric Psychopharmacology at the Massachusetts General Hospital and Harvard Medical School systematically evaluated 82 charts of children and adolescents treated with SSRIs for depressive or OCD symptoms over a mean period of 26.9 months (Wilens et al., 2003). Psychiatric Adverse Events (PAEs) were found in 22 percent, “most commonly related to disturbances in mood.” Remarkably, “Re-exposure to an SSRI resulted in another PAE in 44 percent (n=13) of the group.” Of the 82 children, 21 percent developed mood disorders, including 15 percent who became *irritable*, 10 percent who became *anxious*, 9 percent who became *depressed*, and 6 percent who became *manic*. In addition, 4 percent of the children became *aggressive*. Sleep disorders afflicted 35 percent of the children, including 23 percent *drowsy* and 17 percent *insomnia*. Finally, 10 percent became *psychotic*!

Go et al. (1998) reviewed the cases of 40 youths, ages 12–18, treated with antidepressants for OCD. Thirty percent (6 of 20) developed hypomanic or manic symptoms. Jain, Birmaher, Garcia, Al-Shabbout and Ryan (1992) made a retrospective examination of the medical charts of children and young men age 9–18, who had taken fluoxetine at university clinic. The researchers found that 23 percent of fluoxetine-treated young people developed mania or manic-like symptoms. Another 19 percent developed drug-induced hostility and aggression, including a grinding anger with short temper and increasing oppositional behavior.

Constantino, Liberman and Kincaid (1997) prospectively studied the course of aggressive behavior in 19 SSRI-treated psychiatrically hospitalized adolescents, age 13–17. The group was not pre-selected for potential aggressiveness. They found symptoms of physical aggression toward self or others in 12 of 19 patients on SSRIs.

Another study of children and youth age 8–16 in a university setting found that 50 percent developed two or more abnormal behavioral reactions to fluoxetine, including aggression, loss of impulse control, agitation, and manic-like symptoms (Riddle, King, Hardin, et al, 1990/1991). The effects lasted until the fluoxetine was stopped.

A second research study from the same university setting described a number of youngsters (6 of 42 or 14 percent in their cohort) age 10–17 who became aggressive and even violent while taking fluoxetine (King, Riddle, Chappell, et al., 1991).

A controlled clinical trial found that fluoxetine caused a 6-percent rate of mania in depressed children and youngsters age 7–17 (Emslie et al. 1997), causing the youngsters to be removed from the study.

As already mentioned, Martin et al. (2004) studied a national database for more than 7 million privately insured individuals, aged 5–29 years, and found that exposure to antidepressants increases the probability of a subsequent diagnosis of bipolar disorder.

In combination with the FDA’s suicide warnings in regard to children, youth, and young adults, the studies in this section should lead to the discontinuation of antidepressants in the treatment of children and youth.

## V. Determining Causation for Drug Research

### A. Bradford Hill Criteria for Causation

The nine Bradford Hill criteria for causation (Reekum, et al., 2001; Bailey et al., 1994) were easily met by the FDA studies on antidepressant-induced pediatric suicidality as well by the great majority of studies reviewed in this report concerning antidepressant-induced suicidality, mania, aggression, and other behavioral disturbances both in children and in adults. The one exception was the Bradford Hill criterion called “Specificity,” which is described by the authors as outmoded. Although not all of the criteria must be met to confirm causality, each of the studies do fulfill all or most of criteria, including Strength of the Association, Consistency of Evidence, Temporal Sequence, Biological Gradient, Biologic Rationale, Coherence, Experimental Evidence, and Analogous Evidence.

Although it is a rare occurrence in psychiatry, the research on antidepressant-induced suicidality and mania in children and adults even meet the most stringent and convincing Bradford Hill criterion—Experimental Evidence (Reekum, et al., 2001):

Experimental evidence is the most compelling evidence of causation. If it can be shown that experimentally (ideally randomly) inducing the causative agent consistently produces the outcome, at greater rates than in a non-

exposed control sample, this is clear and compelling evidence of causation. However, it is obvious that such evidence will be rare in neuropsychiatry. . . . P. 8.

The capacity of controlled clinical trials to establish causality was confirmed in a discussion between FDA officials Russell Katz, MD, Director of Neurological Products, and Ralph Temple, MD, Director of Medical Policy, the Center for Drug Evaluation and Research. The verbal exchange took place during an FDA Advisory Committee Meeting (Joint Meeting of the Peripheral Nervous and Central Nervous System Drugs Advisory Committee . . . 2006, pp. 274 and 275). Katz and Temple agreed that when “controlled clinical trials” demonstrate a statistically significant difference from placebo, then “that is operationally defined as causality.”

### **B. Causation in Regard to the FDA Suicide Studies of Children and Youth**

The FDA-mandated review of all placebo-controlled antidepressant clinical trials for children, youth and young adults strongly established the causal relationship between the newer antidepressants and suicidality. Thomas Laughren, at the time the Director, Division of Psychiatric Products of the FDA, wrote, “The pediatric data presented at the September 2004 PDAC meeting represented the first systematic demonstration of a *causal link*” (Laughren, 2006, emphasis added). Cynthia Pfeffer (2007), a physician and consultant at the FDA meetings, stated in regard to the pediatric trials, “The Committee concluded that a causal link exists between antidepressant treatment and pediatric suicidality . . .” (p. 844). Thomas Newman (2004), a physician and epidemiology on the FDA Advisory Committee further observed, “The fact that an association emerged from the meta-analysis with a P value of 0.00005, for an outcome that the sponsors of the trials [pharmaceutical companies] were not looking for, and presumably did not wish to find, was quite convincing” (p. 1598).

The FDA Advisory Committee voted 25–1 with 1 abstention for “Yes” in response to the question, “Do the suicidality data from these trials support the conclusion that any or all of these drugs increase the risk of suicidality in pediatric patients?” It then voted 27–0 that “we are unable to conclude that any single antidepressant agent is free of risk at this time” (Food and Drug Administration, 2004c, “Questions to the Committee,” unnumbered).

Five members of the Advisory Committee wrote a review of the FDA’s deliberations concerning antidepressant-induced suicidality in children and youth (0 up to age 18), and made clear that causation had been established (Leslie et al., 2005). They stated, “the causal link demonstrated in the FDA analyses therefore focused entirely on suicidal ideation and behavior” (p. 200) and that “there was an increased risk for suicidality causally related to the use of the SSRIs and related antidepressants” (p. 200).

The FDA originally required the pharmaceutical companies to state in their antidepressant labels that “A causal role for antidepressants in inducing suicidality has been established in pediatric patients” (Food and Drug Administration, October 15, 2004b). Later this wording was modified to an “increased the risk,” which is substantially the same. The FDA’s definitive publication on its findings speaks directly of “the absolute increase in the risk of the event of interest due to treatment” (Hammad et al., 2006). The FDA report concluded, “when considering 100 treated patients, we might expect 1 to 3 patients to have an increase in suicidality beyond the risk that occurs with depression itself owing to short-term treatment with an antidepressant” (p. 336).

Under clinical conditions in the real world rather than in controlled clinical trials, the rates of suicidality would be much higher than those in the clinical trials. Controlled clinical trials educate and inform the patients in detail, involve weekly monitoring, last no more than several weeks, avoid drug combinations, and exclude suicidal patients. In addition, they provide great hope and inspiration to the subjects and their families who seek to find a “new cure” for their emotional problems by participating in the experimental clinical trials (Breggin, 2008b). Because of these factors it is very rare for a patient to actually commit suicide during a trial, and none occurred in FDA’s pediatric trials.

### **C. FDA Warnings for Children, Youth and All Adults**

We have seen that the FDA-approved labels for Zoloft and all other antidepressants contain elaborate warnings about medication-induced suicidality in children, youth and young adults, as well as warnings for a wide array of other symptoms including impulsivity, hostility, aggressiveness, and mania. The Federal regulations that govern the warnings sections in drug labels dictate that the inclusion of these adverse reactions must be based on “reasonable evidence of a causal association with a drug.” According to the Code of Federal Regulations (2008):



In accordance with Sec. 314.70 and 601.12 of this chapter, the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established. P. 29.

In a Talk Paper, the FDA confirmed that the array of stimulant-like or activation symptoms associated with the antidepressants was in fact caused by the drugs when it referred to “certain behaviors known to be associated with these drugs, such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania, and mania . . .” (FDA, 2004d, p. 1, emphasis added).

This array of activation or stimulant-like symptoms is described in the antidepressant labels as occurring in children and adults. Consistent with this, the Talk Paper stated, “The agency is advising clinicians, patients, families and caregivers of *adults* and children that they should closely monitor all patients being placed on therapy with these drugs for worsening depression and suicidal thinking, which can occur during the early period of treatment” (FDA, 2004d, p. 1, emphasis added).

## VI. Case Examples

### A. Causation Established by Clinical Case Reports

The pharmaceutical industry has attempted to discredit case reports as evidence for causation. However, case reports have led to most FDA changes in labels and to most withdrawals of psychiatric drugs from the market, and are a mainstay in the FDA for evaluating adverse drug reactions (Food and Drug Administration, 1993 & 1996; Government Accounting Office, 1990; Breggin, 2008b, pp. 263–269). The FDA itself described principles for determining causation from clinical reports (now called adverse event reports) in a table titled “Useful Factors for Assessing Causal Relationship Between Drug and Reported Adverse Event” (Food and Drug Administration, 1996, p. 6, emphasis added). Drawing on an international consensus meeting on the subject (Standardization of Definitions and Criteria of Causality Assessment of Adverse Drug Reactions, 1990), the FDA listed six potential criteria: chronology or temporal relationship, course of event when agent stopped (dechallenge), known etiological roles of agents in regard to the event, response to readministration of the agent (rechallenge), laboratory test results, and “previously known toxicity of agent.”

Because clinical trial, epidemiological and other research evidence is so strong in regard to the antidepressant-induced mental and behavioral abnormalities, the following clinical cases are included mainly for illustrative purposes.

### B. Clinical Cases

In my clinical and forensic practice I have evaluated more than 50 cases of violence, suicide, mania and crime induced by psychiatric medications, especially the newer antidepressants (Breggin, 2008a). In the cases that I reviewed, the suicidal, violent or criminal behaviors were unprecedented and seemed in retrospect to be very alien and inexplicable to the individuals. Recidivism was zero when the medications were stopped. In evaluating the cases, I interviewed surviving victims and their families and acquaintances. In all but one of the cases I had complete access to medical, educational, occupational and police records. In all cases I interviewed the individuals if they survived, as well as witnesses and family members. In many cases my expert reports lead to acquittal on the basis of involuntary intoxication, reduced charges, shortened sentences, or release from incarceration. Most of the cases were evaluated for legal purposes and some were clinical consultations or treatment cases.

As the patterns emerged from re-examining these cases, I was struck by the fact that victims of drug-induced abnormal mental states and behavior almost never had an inkling that they were acting irrationally or that they were under the influence of their psychiatric drugs. This led me to formulate the concept of medication spell-binding (intoxication anosognosia)—the concept that psychoactive substances reduce the individual’s capacity to appreciate mental and behavioral adverse reactions (Breggin, 2006, 2008a&b).

Case A: A gentle 37-year-old man with previously mild depressive symptoms and no history of violence became psychotic shortly after starting the SSRI antidepressant sertraline (Zoloft) and believed that his wife had been taken over by a dangerous alien from another world. In order to destroy the alien inside her, he undid her safety belt and drove their car into a barrier, nearly killing her. In a legal case in which I played no role, he was found Not Guilty by Reason of Insanity. Only after he began to recover over the subsequent weeks of psychiatric incarceration did he begin to suspect that medications might have caused his psychosis. He was re-

leased after several months of commitment to a mental hospital whereupon he was referred to me to gradually remove him from a cocktail of medications. He has done very well after more than a decade of drug-free followup.

Case B: Without using a disguise, a 20-year-old college man with no history of crime committed a series of eight knife-point robberies of his local gas stations, including those he and his family frequented, and was easily identified and caught. He had been recently started on the SSRI antidepressant paroxetine (Paxil) which was continued during his trial and sentencing. He was allowed to return home briefly before serving a lengthy incarceration and immediately robbed another local gas station using an identical knife and the same automobile, and was easily apprehended. My report on the effects of Paxil on his behavior convinced the court to give him a considerably reduced sentence.

The above cases had manic features. In other cases, compulsive suicidal or violent behaviors developed without associated manic-like features.

Case C: A 16-year-old girl was begun on fluoxetine (Prozac) to relieve the stress associated with an undiagnosed gastrointestinal disorder. Although there were no serious conflicts in the family, shortly after starting on the fluoxetine, she began to feel intensely compelled to stab her mother in the back. As the urge peaked, she confessed her intentions to her mother, and completely recovered when removed from the antidepressant.

Case D: A 38-year-old highly responsible man with minimal symptoms of depression and no history of crime or violence was prescribed sertraline (Paxil). Within weeks the medication caused him to suffer from akathisia (extreme restlessness and agitation) and obsessive suicidality. He drove his car into a policeman in order to knock him down to obtain his gun to shoot himself. The officer was seriously injured but with the help of a bystander he managed to subdue his assailant. After my expert report in the case, the police officer agreed that drugs must have caused the assault, and a plea agreement was reached that led to only a brief incarceration. On followup he has done well for several years.

Familiarity with medication effects does not necessarily protect the individual from abnormal emotional and behavior reactions. In several of my cases (Breggin, 2008a), the victims of drug-induced abnormal behaviors were physicians.

Case E: A sophisticated psychiatrist with no history of violence gradually became manic while taking the SSRI antidepressant fluvoxamine (Luvox). He violently assaulted a female colleague with a tack hammer and then made a bizarre suicide attempt. He was convicted of assault and continued on the antidepressant in prison. He remained in a medication-induced mildly manic-like condition in prison and did not realize that the drug had caused his violent behavior until he was removed from it several months later. While still incarcerated, he asked me for a consultation to clarify what had occurred.

### **VII. Antidepressant-Induced Reactions that Result in Suicide and Violence**

The various antidepressant-induced clinical syndromes and reactions associated with suicide and violence have been reviewed elsewhere (e.g., Teicher et al., 1990, 1993; Breggin, 1993 and 2008a&b). Almost all are now described in the FDA-mandated label changes under **Clinical Worsening and Suicide Risk**, including the activation or stimulation spectrum of adverse drug effects: "the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down."

All of the above adverse reactions are associated with suicide and violence. The antidepressant labels confirm that these can occur when the drug is given for "both psychiatric and nonpsychiatric" purposes. In a study of patients treated with fluoxetine and paroxetine, and suffering from nothing more than learning disabilities, 31 percent suffered from stimulant symptoms including elevated mood, hyperactivity, overtalkativeness, agitation, and aggression (Biswas et al., 2001).

Individually, some of the causal syndromes or adverse reactions include: (1) anxiety and agitation with or without hyperactivity (akathisia); (2) worsening depression; (3) compulsive suicidality; (4) irritability, hostility, and aggressiveness; (5) apathy and indifference; (6) behavioral dyscontrol or impulsivity; and (7) mania and psychosis.

### **VIII. Lack of Efficacy**

It is relatively easy to prove that antidepressants frequently cause serious and even life-threatening harm, while it remains difficult to prove that they are helpful. In order to obtain FDA-approval, pharmaceutical companies cherry pick their studies in order to find two that show some effectiveness. However, when all adult con-

trolled clinical trials, including the unsuccessful ones, are pooled in a meta-analysis, antidepressants do not prove effective (Kirsch et al., 2008; Moncrief and Kirsch, 2005). Meanwhile, studies of children and youth almost uniformly fail to show effectiveness (Whittington et al., 2004, ages 5–18; Jureidini et al., 2004, Tonkin and Jureidini, 2005; studies reviewed in Breggin, 2008b).

### IX. Conclusion

There is overwhelming evidence that the SSRIs and other stimulating antidepressants cause suicidality and aggression in children and adults of all ages. The evidence suggests that young adults aged 18–24 (the age of many soldiers) are especially at risk for antidepressant-induced suicidality. There is a strong probability that the increasing suicide rates among active duty soldiers are in part caused or exacerbated by the widespread prescription of antidepressant medication. In addition, antidepressants frequently cause manic-like reactions, including loss of impulse control and violence, posing potentially grave risks among military personnel. Little will be lost and much will be gained by stopping the prescription of antidepressants to military personnel. The military should rely upon the psychological and educational programs that are currently under development for preventing suicide and ameliorating other psychiatric disorders among servicemembers. Antidepressants should be avoided in the treatment of military personnel.

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**Prepared Statement of Andrew C. Leon, Ph.D.,  
Professor of Biostatistics in Psychiatry and Public Health,  
Weill Cornell Medical College, New York, NY**

My name is Dr. Andrew C. Leon. I know that this is clearly an emotional issue. My family has been profoundly impacted by mental illness—so much so, that I have devoted my career to the field of psychiatry. I am Professor of Biostatistics in Psychiatry and Public Health at Weill Cornell Medical College, where I have been on the faculty for over 20 years. I have published over 200 peer-reviewed scientific manuscripts. Nearly all of my research has been funded by NIH. I have served as a consultant to FDA, NIMH and to industry, primarily to monitor the safety of participants in clinical trials.

All of us here today share a common goal: to do the very best for our veterans. My perspective is that doing the best requires the discipline to use empirical methods to understand optimal mental health care and prevention of suicide.

I was the biostatistician on the FDA's Psychopharmacologic Drug Advisory Committee from 2003–2008 and participated in FDA hearings on the topic of antidepressants and suicidality. The class of medications that I will discuss is antidepressants. Depression is a life threatening illness. Suicidality is a symptom of depression, whether treated or untreated.

My main points today are paraphrased from the FDA Black Box Warning on all antidepressants: (1) Depression increases risk of suicide (2) To reduce suicide risk, clinicians must carefully monitor veterans with depression, whether treated or untreated.

I will discuss three types of scientific studies: randomized controlled clinical trials (comparing antidepressants and placebo), observational studies, and post-mortem studies. Three types of suicidality are reported in these studies: suicidal thinking, suicide attempts and suicide deaths.

In 2004, the FDA reviewed 25 pediatric clinical trials for antidepressants involving over 4,400 subjects and found that patients randomized to antidepressants were

about twice as likely to report suicidality. However only 3 percent reported suicidality—mostly suicidal thinking. There were *no suicide deaths*.

In 2006 the FDA reviewed 295 clinical trials of *antidepressants for adults* involving over 75,000 participants. Less than 1 percent reported suicidality, mostly suicidal thinking. Unlike pediatric trials, adults randomized to antidepressants were NOT more likely to report suicidality. In fact, antidepressants conveyed significant protection from suicidality for ages 65 and higher.

At least one, large longitudinal observational study of mood disorders, funded by the NIMH, extended the clinical trial conclusions, finding that antidepressants significantly reduced risk of suicide *attempts* and suicide *deaths in adults*.

Our research group at Cornell conducted post-mortem studies of suicide deaths in New York City. Ninety-five percent of the youth suicides and 77 percent of adult suicides had NOT taken antidepressants immediately before their deaths. This suggests that prevention of suicide requires intervention primarily among patients who are not receiving antidepressants.

A cause and effect relationship has not been established between antidepressants and suicide. In light of the suicide risk in depression, a prudent recommendation is that veterans, whether treated or untreated, must be appropriately monitored by clinicians. In conclusion, I would like the Committee to recognize that depression is itself a risk factor for suicide. To leave these men and women untreated is to accept suffering from the disorder itself.

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**Prepared Statement of M. David Rudd, Ph.D., ABPP, Dean,  
College of Social and Behavioral Science, The University of Utah,  
Salt Lake City, UT, on behalf of American Psychological Association**

Chairman Filner, Ranking Member Buyer, and Members of the Committee, I want to express my appreciation for the opportunity to testify on behalf of the 152,000 members and affiliates of the American Psychological Association (APA) regarding the relationship between medication and veteran suicide. Attention to this issue is particularly timely given the considerable confusion about medications and suicide risk since the 2004 Food and Drug Administration (FDA) black box warning label was placed on certain antidepressants being prescribed for children and adolescents. As you know, the label was subsequently updated in 2007 and expanded to include young adults up to 24 years of age. Since then, there has been a “spillover effect” for adults beyond this age. In 2008, the FDA also issued an alert that antiepileptic drugs include a warning in their labeling to inform patients about the possible risk for suicidality.

Given the confusion that has followed the warning label and more recent FDA alert, along with its potential impact on direct clinical care, the field of psychology can make a significant difference in helping to inform the discussion regarding the actual nature of risk, the role of medications in the treatment of suicidality, and the utility of psychotherapeutic treatment approaches as a primary treatment option or in combination with medications. While the vast majority of the data are not specific to the veteran population there is no reason to believe the observable trends for adults in the general population would be different.

Confusion following the warning label has been shared among both practitioners and the general public. Among the facts frequently overlooked are the following: (1) there were no suicides in the original pediatric and adolescent trials (a total of 4,400 patients), (2) although there were suicides in the adult trials, the “number was not sufficient to reach any conclusion about drug effect on suicide” with comparable numbers across the placebo and clinical components of the studies, (3) given the failure to demonstrate any clear relationship between medications and death by suicide, the warning label focuses on “suicidality” defined as “suicidal thoughts” of unknown frequency, severity and duration and “suicidal behaviors” of unknown lethality, (4) the rates of suicidality in the clinical trials were low and in terms of actual numbers, very small differences were significant and resulted in a warning label, (5) the followup periods for the various drug trials were quite short (i.e., several months), and we do not have much needed data to understand potential recovery curves and treatment effectiveness after the initial 4–8 week window of the trials, (6) neither the warning label nor the medication guide provides any age-related data regarding suicide risk, with little context to understand the implications of the findings (particularly since suicide risk increases with age), and (7) practicing general and family physicians have demonstrated error rates as high as 91 percent in terms of an accurate understanding of the nature of the risk for suicidality com-

municated in the FDA warning label, with most believing the warning label communicates a risk for death by suicide.

Given that as high as 75 percent of depressed adult patients looking for treatment receive medications and that an estimated 50 percent receive both psychotherapy and medications, this is a very critical issue for our veterans. Not only have there been unintended consequences of the warning label and widespread media coverage of the link between medications and suicidality, but also the effectiveness of behavioral treatments has often not been considered.

Acute and chronic suicidality is a particularly difficult clinical problem. It is one that requires an accurate understanding of the role and effectiveness of medications, along with behavioral treatments. There is evidence available to suggest that not only have practitioners been hesitant to diagnose and treat problems like depression since the FDA warning label, but also that patients have been less willing to pursue treatment, with both groups inappropriately believing medications raise the risk for death by suicide. It is not surprising that our efforts to reach veterans in serious need of care are hampered when death by suicide is inappropriately considered a significant risk of treatment. This concern extends to the family members of veterans as well.

The reality is that the efficacy of treatment (both psychotherapy and medications) far outweighs the observed risk for suicidal thoughts and behaviors. There have been a number of well designed, rigorous studies demonstrating a marked reduction in suicide risk associated with selective serotonin reuptake inhibitor (SSRI) use, cutting across the full spectrum from early to late adulthood. For high-risk suicidal individuals, medications can be very effective in managing symptom severity (e.g., sleep disturbance, agitation, anxiety) during periods of imminent risk and prove an important complement to behavioral treatments. During periods of acute risk, patients often experience difficulty fully participating in psychotherapy because symptoms limit their ability to concentrate, engage, and most importantly, learn.

Since many, arguably all, suicidal patients consider suicide as an option in an effort to reduce or eliminate their emotional suffering, medications can play an important and strategic role. They provide a treatment option that can more quickly target symptoms facilitating a patient's feeling of hopelessness. Behavioral treatments take time, with patients gradually building critical skills and resolving traumas. Until adequate skills are established and refined, medications can help fill the gap, buying what is oftentimes lifesaving time.

Despite the concerns about medications and suicide, we now know scientifically that a number of behavioral treatments help reduce the risk of death by suicide. There are a number of reviews of psychotherapies that have proven effective in the treatment of suicidal behavior. I completed a recent review driven by a simple question, what are the common elements of treatments that work? There are a handful of treatments proven to be effective at reducing suicide attempts after treatment, with considerable overlap in the nature and type of treatment. In the case of behavioral treatment, simple interventions can help save lives.

First, all of the effective treatments have simple and understandable models that are shared with patients. Patients need to understand why they have become suicidal and the benefits of the treatment in order to fully invest in care. When a patient understands why they have been suicidal and how treatment will help, the net result is hope, improved motivation, less shame, better compliance and more effective care. This is a simple step and can be carried out in any setting and by a range of health professionals. Second, effective treatments target identified skill deficits. Patients that consider suicide evidence skill deficits that can be identified, targeted and improved. Third, effective treatments emphasize self-reliance, self-awareness and personal responsibility in a number of concrete ways. Patients are encouraged to assume a considerable degree of personal responsibility for their own care by use of commitment to treatment agreements and safety plans. As might be apparent, the ability to take personal responsibility for one's care is very much an identified skill. Fourth, effective treatments emphasize the importance of crisis management, removal of available lethal methods, and access to care during and after treatment, with written and accessible treatment plans. This includes the involvement of family and friends. Finally, effective treatments incorporate compliance protocols. When a patient drops out of treatment, specific steps are taken to try to engage the patient in care, with a concerted effort to identify and target the reasons the patient withdrew. It is critical to keep at-risk patients engaged in treatment.

These are very simple actions that can save the lives of our veterans who are experiencing thoughts of suicide. They can be accomplished across the full range of settings and by a variety of providers. Especially for those hesitant to consider medications as an alternative, behavioral treatments have much to offer, either as an independent treatment or in combination with medications. We owe it to our vet-



erans to ensure that they have the mental and behavioral health care that they need and deserve and the psychology community remains committed to assisting in this effort.

Thank you. I appreciate the opportunity to speak with you today and welcome the chance to respond to questions.

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**Prepared Statement of Annelle Primm, M.D., MPH, Deputy Medical Director for Minority Affairs, American Psychiatric Association, and Associate Professor of Psychiatry, Johns Hopkins School of Medicine, Baltimore, MD**

My name is Annelle Primm. I am the Deputy Medical Director for Minority Affairs of the American Psychiatric Association and an Associate Professor of Psychiatry at the Johns Hopkins School of Medicine. Thank you for the opportunity to speak before the Committee today on behalf of the American Psychiatric Association (APA), a medical specialty organization which represents 37,000 psychiatric physicians nationwide.

APA also promotes the highest standards of care for our patients and their families, and to that end we strive for standards of excellence in psychiatric research and in the education and training of our psychiatrist workforce. Critical goals and activities of the American Psychiatric Association include:

- Advocating for patients and for the profession, and fighting discrimination against people suffering from mental illnesses, including substance use disorders.
- Supporting education, training and career development of psychiatrists and other physicians.
- Enhancing the scientific basis of psychiatric care.
- Defining and supporting professional values and ethics.

The APA vigorously advocates for immediate and seamless access to care for psychiatric and substance use disorders for America's military and their families. We continue to staunchly support increased Federal funding of psychiatric and brain injury research. We remain concerned that despite concerted efforts of the VA and DoD, stigma still shadows those who seek psychiatric care and discourages those who need care from seeking it. The unprecedented length and number of deployments of U.S. military personnel, as well as the nature of our current military engagements, have placed an enormous strain on those serving in all facets of the military as well as their families. As physicians, researchers and family members, the APA has noted with increasing concern the increase in suicide attempts and completed suicides by veterans and those currently serving, and has advocated for direct action to address this major problem.

Beginning in 2002, the suicide rate among soldiers rose significantly, reaching record levels in 2007 and again in 2008 despite the Army's major prevention and intervention efforts. In response, the Army and NIMH partnered to develop and implement "STARSS" (Study To Assess Risk and Resilience in Servicemembers) the largest study of suicide and mental health among military personnel ever undertaken. Many APA members are involved in the NIMH-Army study which will identify—as rapidly as possible—modifiable risk and protective factors related to mental health and suicide. It also will support the Army's ongoing efforts to prevent suicide and improve soldiers' overall wellbeing. The length and scope of the study will provide vast amounts of data and allow investigators to focus on periods in a military career that are known to be high-risk for psychological problems. The information gathered throughout the study will help researchers identify not only potentially relevant risk factors but potential protective factors as well. Study investigators will move quickly to provide information that the Army can use immediately in its suicide prevention efforts and use to address psychological health issues.

***Medication Safety***

Today's invitation from the Committee requested that the APA provide its position on the effectiveness and safety of psychiatric medications. I note that many of the most dramatic improvements in the effective treatment of mental illness have come as a result of newer and better medications, especially a class of antidepressants called SSRIs which can be utilized to help manage PTSD symptoms. These medications have meant remarkably positive changes in the lives of tens of millions of Americans and would not have been possible without the resources of the pharmaceutical industry to research and development.

Simply put, it is the position of the American Psychiatric Association that a patient's decision to take a psychiatric medication should be based on the best medical advice and scientific evidence available. Medications, when utilized, should be in conjunction with supportive therapies such as cognitive behavioral therapy. The prescribing and monitoring of brain medication should, however, be overseen by those with medical education, training and clinical experience.

First, the APA would like to emphasize the importance of open access to non-individually identifiable data from clinical trials, including data from negative trials, unpublished research and post-market studies. Physicians and patients clearly need access to this kind of information in order to make fully informed decisions about treatment options. For this reason, the APA has been in the forefront of the call for the development of a national registry of clinical trials. Such a registry should be comprised of non-individually identifiable data for those with an approved need, such as physicians, researchers and clinicians. This registry needs to be carefully designed in order to avoid a huge 'data dump' which can lead well-intentioned reviewers to erroneous conclusions. The data in such a registry needs to be meticulously coded in the same manner across many domains in order to be truly useful.

Next, let me address medication, in general, and the SSRI antidepressants, in particular, which are a class of medications often used to help manage PTSD symptoms. Research has clearly demonstrated that medication can be helpful and even lifesaving, for many people with psychiatric disorders, but medication is most effective when used as a key component of a comprehensive treatment plan, individualized to the needs of the patient.

Let me take a minute to address the complex issue of whether or not the SSRIs increase the risk of suicidal thinking or behavior. At this point, here's what we actually know, from a scientific perspective: Contrary to frequent reports in the popular media, there is no evidence to suggest that these medications increase the risk of actual suicide. It *does* appear that these medications may increase the likelihood that some patients will actually *tell someone* about their suicidal thoughts or even about a suicide attempt. From my perspective, as a psychiatrist, this is actually a *good* thing, because it means you have the opportunity to intervene and to keep the person safe. The teenage suicide rate in the country had actually declined by over 25 percent since the early 1990s, in a manner consistent with the increased use of SSRI antidepressants.

In October of 2004, following a review of clinical trial data, the U.S. Food and Drug Administration (FDA) issued a public warning about an increased risk of suicidal thoughts or behavior in children and adolescents treated with SSRI antidepressant medications. In 2006, an advisory committee to the FDA recommended that the agency extend the warning to include young adults up to age 25, given that brain development continues well into a person's 20s.

In the 2004 FDA review, the data showed that no completed suicides occurred among nearly 2,200 children treated with SSRI medications. However, about 4 percent of those taking SSRI medications experienced suicidal thinking or behavior, including actual suicide attempts—twice the rate of those taking placebo, or sugar pills. In response, the FDA adopted a "black box" label warning indicating that antidepressants may increase the risk of suicidal thinking and behavior in some children and adolescents with major depression. A black box warning is the most serious type of warning in prescription drug labeling.

The warning notes that children and adolescents taking SSRI medications should be closely monitored for any worsening in depression, emergence of suicidal thinking or behavior, or unusual changes in behavior, such as sleeplessness, agitation, or withdrawal from normal social situations. Close monitoring is especially important during the first 4 weeks of treatment. SSRI medications usually have few side effects in children and adolescents, but for unknown reasons, they may trigger agitation and abnormal behavior in certain individuals.

Following the notable 2004 black box warning there was a decrease in initial prescribing of antidepressants. The APA was concerned then and remains so that the warning has the unintended consequence of a 'chilling effect' on people and their families considering treatment for depression.

According to data from the Center for Disease Control and Prevention, the suicide rate for 25–34-year-olds declined an average of 0.9 percent annually, or about 17 percent when comparing 1985 with 2004. The suicide rate for teens began declining sharply in the mid-90s. During the 10 years 1994–2003, suicides dropped an average of 3.8 percent annually, or 33 percent when comparing 1994 with 2003. Rates rose in 2004: the rate of suicide in young people under 20 increased 18 percent over 2003—the first increase in 12 years. The rate decreased somewhat from 2004 levels over the past 3 years but has remained above the 2003 level.

Recently, results of a comprehensive review of pediatric trials conducted between 1988 and 2006 suggested that the benefits of antidepressant medications outweigh their risks to children and adolescents with major depression and anxiety disorders. The study, partially funded by the National Institute on Mental Health, was published in the April 18, 2007, issue of the *Journal of the American Medical Association*. In the meantime, the increase in suicides following the FDA action should serve as a very strong caution against reaching conclusion and taking action too quickly.

APA welcomes more information about how to best use these medications in the treatment of our patients. In particular, we support long-term followup studies on both safety and efficacy. Fortunately, several such studies are currently underway, with funding from the National Institutes of Mental Health.

Finally, let me emphasize the importance of advocacy for returning military with psychiatric and substance use disorders. Families, in particular, need to be advocates for their loved ones. They need to make sure their family members has a comprehensive evaluation by a trained and qualified mental health professional and that they have access to necessary and appropriate ongoing treatment services. They should also ask lots of questions about any proposed diagnosis or treatment plan. To this end, the APA has jointly developed a Web site, [www.Healthyminds.org](http://www.Healthyminds.org) to provide patients, families and physicians with as much information as possible about the evaluation and treatment of depression, PTSD and substance use disorders. Over a dozen major medical, family and patient advocacy organizations have already endorsed this collaborative effort. In addition, the APA is a proud founding partner of "Give an Hour." This volunteer organization provides professional mental health and substance use disorder services through a network of professionals who volunteer their services for an hour a week to active and returning military, National Guard, veterans and their families. "Give an Hour" has been utilized as a portal for care for those who fear the stigma of seeking services within the VA or DoD structure.

#### ***Scientific Data and Information Available to Physicians***

Over the past decade, the relationship between medicine and industry, including pharmaceutical manufacturers and medical device companies, has been under increased public scrutiny. Patients need to be able to rely on the objective recommendations of their physicians. In turn, physicians must be able to rely on the objectivity of research as it pertains to the safe and effective use of medications and medical devices.

Recognizing the necessity of managing potential conflicts of interest, the APA has been proactive in examining our relationships with the pharmaceutical industry. We have taken considerable pains to implement safeguards to reduce the risk of a conflict of interest between the industry and the provision of Continuing Medical Education. In fact, the APA received a commendation and a 6 year accreditation for outstanding compliance with accreditations rules and regulations—2004–2010 from the Accreditation Council for Continuing Medical Education.

The APA also has a Scientific Program Committee (SPC) which is responsible for all decisions concerning the content and format of the APA Annual Meeting, including editorial responsibility for the peer review, selection and presentation of the scientific and clinical content of the Annual Meeting. The committee reviews all submissions for scientific and clinical merit, including those symposia seeking industry support. Members of this committee must also submit disclosure forms and recuse themselves from discussions that might involve a perceived conflict.

In March 2009, the APA's Board of Trustees voted to phase out industry-supported education programs and industry-supported meals served at the APA scientific meetings. As far as we know, the APA is the first professional medical specialty to end industry-sponsored symposia. As a result of the Board action, at our 2009 scientific meeting, only 11 of over 500 programs offered were supported by the pharmaceutical industry. I do want the Committee to note that the overwhelming majority of our educational activities at our annual meetings are developed by APA members as well as the National Institutes of Mental Health, National Institute on Drug Abuse and the National Institute of Alcohol Abuse and Alcoholism.

The American Psychiatric Association has long understood the need for a comprehensive disclosure policy based on clarity and transparency, particularly in the areas of publishing, research and education. APA recognizes that the ultimate success of its education enterprise rests on the public's (and its members') trust and confidence that the educational content is based on accepted scientific information free of any perceived marketing bias. Similarly, the success of our research enterprise rests on the public's trust and confidence that the research is conducted and presented in an unbiased manner.

We at the APA are hopeful that today's hearing and testimony will help promote access to information, encourage expanded support for research, and enhance the ability of returning military and their families to advocate effectively for the treatment they need and deserve.

Thank you for the opportunity to testify. I would be pleased to answer your questions.

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**Prepared Statement of Commander Donald J. Farber, Esq., USN (Ret.)  
San Rafael, CA**

**Introduction and Background**

Thank you, Mr. Chairman. My name is Don Farber. I am a Navy veteran, 25 years in the line; half that time sea duty. For the past 17 years, I have practiced law in San Rafael, California—with a large portion of my practice representing victims of antidepressant suicide. I have gathered information on antidepressants and suicide over the years, including:

- Deposing pharmaceutical CEO's, FDA officials, pharmacists, industry psychiatrists, and treating physicians;
- Reviewing many of industry's so called "trade secrets" on antidepressants and suicide—documents the public and the FDA never see;
- Acting as a co-lead counsel from 2002–2006 in Federal court, Los Angeles, on the Plaintiffs' Steering Committee on a mass tort case involving Paxil and 3,000 plaintiffs who alleged addiction from the drug;
- Addressing the last three (3) advisory committee hearings on antidepressants and suicide convened by FDA.

**A "Religious War"**

The antidepressant suicide debate has been ongoing since Prozac entered the market in 1988—the FDA's having received 350 reports of completed suicides by Prozac patients by early 1991. The debate has always been intense, one medical historian quoted as calling it a "religious war."<sup>1</sup> My testimony today excludes the related issue of third party violence which may relate from antidepressants, such as the rising number of unexplained school, workplace, and shopping mall massacres.

**Of Course, They Do!**

Do antidepressants cause suicide? Of course they do! Antidepressant manufacturers would not secretly settle wrongful death lawsuits for large sums that they do if these were just nuisance suits. In antidepressant clinical trials going back to the 1980's, the manufacturers' own principal investigators have assessed several hundred suicide related adverse events as "caused" by the antidepressant.

Antidepressant manufacturers cannot credibly deny their medications cause suicide. Their voluntarily adopted "Warning" labels entitled "Clinical Worsening and Suicide Risk," on their medications translate to a meaningful conclusion. By Federal regulation, the companies' cannot issue these "Warnings" unless there is reasonable evidence of a QUOTE causal association UNQUOTE between the drug and suicidality. In short, the companies—with their labels—legally acknowledge causation despite their continuing overtures to the contrary.

**No Clinical Trials on the Subject—Ever!**

Looking to this Committee's focus on hopeful solutions to the suicide problem, if there is one point I'd like to emphasize today, it is this. A major scientific gap exists in the 20 year antidepressant suicide debate. There has never been a prospective trial designed to test the link between the antidepressants and suicidality. Do not take my word for this. I leave with the Committee my work product in the packet—citing 27 sources affirming what I just reported ("Work Product"). The irony is that antidepressant enthusiasts, before the debate started going against them, criticized plaintiffs' experts as "junk scientists" for opining on medication induced suicide. What is "junk science" is the implication real science exists to deny antidepressant suicidality when nary a scientific trial has ever been conducted to make that determination.

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<sup>1</sup>Quoting University of Toronto medical historian Professor Edward Shorter, by Benedict Carey in *New York Times*, December 13, 2006 article "Panel to Debate Antidepressant Warnings."

### 20 Years of “Ethics”—or Self Preservation?

Why no testing? One theory for the historical failure to test is because the companies fear the likely results. Documenting the scientific link between antidepressants and suicide would significantly erode consumer and provider confidence in the medications, even more so than the events of 2004 when the FDA first acted on the subject. It is noteworthy that the FDA has not invoked its powers under the Food, Drug & Cosmetic Act (“FDCA”) to require antidepressant manufacturers to specifically test for suicide. While safety is a threshold requirement for any drug approval, “two well controlled trials” demonstrating efficacy are all that is required under FDCA to get the drug on the market. Safety is more of a subjective call, and is a requirement the FDA can often satisfy by adequate labeling. Over the years industry has offered shifting explanations for its “no testing” posture in antidepressant suicide:

- a. Early on they claimed was no reason to test because the preliminary data, through meta-analyses and the like, indicated there was no suicide problem. That excuse went away early last decade when data on pediatric and young adult populations showed a high suicidality rate.
- b. Then they claimed that a prospective randomized clinical trial (“RCT”) to test a suicide hypothesis was not practical because it would entail too large a test population. That excuse became questionable when it was shown that a “challenge/dechallenge” protocol could be designed with only a few hundred patients in each treatment arm, with only a slight decrease in the confidence interval to detect the problem.
- c. The next excuse was that it would be unethical to specifically test for suicide, given that placebo, or sugar pill treatment in a clinical trial for a patient known to be suicidal would breach medical ethics, such as the Nuremberg Code. That turned out questionable, as well, when it was pointed out that “placebo” is routinely used in psychotropic drug trials endorsed by the FDA, that European countries traditionally restricted placebo testing as a matter of course, and that in any case, a non-medication treatment arm involving therapy would avert any prohibition based upon non-treatment of an at risk patient.
- d. The final excuse is one from a manufacturer of a major SSRI who, having avoided testing for 20 years, simply claimed it was not QUOTE “methodologically possible to design and conduct a scientifically reliable clinical study that would yield greater scientific understanding between . . . (the drug) . . . and suicide than now exists.”

In 1990 at the height of the initial Prozac controversy, the FDA, itself, requested Eli Lilly to perform such testing. (See *“EliLillyFDAMemo”*.) The FDA backed off after Lilly produced a 1991 meta-analysis, an analysis later highly criticized for its gaps in the data, showing Prozac had no statistical significance with suicidality. In later times, a senior FDA official, contrary to its original persuasive powers to get Eli Lilly to agree to the testing, seemed to reverse itself. In a 2004 interview the FDA’s Director of Medical Policy, Dr. Robert Temple, in charge in 1990 when his office persuaded Lilly to test, told PBS:

“Nobody is going to let you do a placebo control long-term trial to see if there are more suicides in one group than another because that would involve leaving people who are grossly depressed off therapy. I don’t think anybody would do such a trial.”<sup>2</sup>

Dr. Temple’s gratuitous concession was as unnecessary as it was counter-productive. FDA has more than enough tools in its arsenal to ensure/persuade industry to do the testing. In 2003 the FDA banned the dietary supplement Ephedra, doing so only after the highly publicized death of Baltimore Orioles pitcher Steve Bechler who took the supplement before succumbing. Ephedra’s 155 deaths reported to the FDA when the drug was banned were dwarfed by Prozac’s 350 completed suicides reported a decade earlier—which the FDA summarily dismissed at the time as anecdotal. Another FDA legal enforcement tool short of banning, if the affected company does not participate in making its drug safe, is to declare the drug misbranded and prosecute. This could properly occur if the company refused to comply with an FDA labeling request to place in the labeling the high incidence of suicide events and the company’s failure to have tested for suicidality. The essence is that the Federal Government has the power, indirectly if not directly, to compel companies wishing to market antidepressants to conduct specific suicide testing. While manufacturers can

<sup>2</sup>May 28, 2004 *PBS Newshour*, Interview Dr. Robert Temple by PBS Correspondent Susan Dentzer.

contest such FDA actions in court, the judiciary gives great deference to the FDA's mission of ensuring drug safety and enforcement actions in support. Since 2004 consensus in the research community, save the pharmaceutical industry, is that focused antidepressant suicide testing was long past due. Dr. Temple's interview notwithstanding, FDA officials themselves, including Dr. Janet Woodcock and Dr. Thomas Laughren, are on record stating prospective testing on the antidepressant suicide issue is needed.<sup>3</sup>

#### **Antidepressant Suicide Reports—From Health Care Providers!**

Ephedra's adverse event data at the time of its banning were minor compared to antidepressants. Prozac, Zoloft, and Paxil, the first three (3) SSRIs ("selective serotonin reuptake inhibitor") on the market combined for 638 reported deaths between the period November 1, 1997 and the time FDA banned Ephedra on December 30, 2003.<sup>4</sup> The FDA's "Adverse Event Data System" (AERS) and its pre-1997 predecessor system recording "MedWatch" reports of adverse events constitute merely a drop in the bucket of the overall drug induced adverse events occurring in the general population. Except for pharmaceutical companies and other selective entities, reporters of "MedWatch" submissions do so voluntarily. Adverse events filed with AERS constitute, depending on what expert you talk to, from 1 percent to 10 percent of the actual adverse events occurring throughout the country. AERS filing is not proof that the reported drug caused the adverse event, especially when consumers and lay people file the reports. However it is commonly accepted that health care providers, already burdened by substantial medical paperwork, file "MedWatch" submissions to the FDA because they believe there may be causation in the particular patient. Filings of antidepressant adverse events are voluminous. Prozac, Zoloft, and Paxil "MedWatch" reports constituted 20,142 filings from 1997 to 2009. Fifty-five percent (55%) were originated by health care providers. Two thousand four hundred fifteen (2,415) suicide attempts by antidepressant patients were reported in that time frame, of which 64 percent were reported by health care providers. Of that total, eight hundred three ("803") were completed suicides.

#### **FDA Issued First Suicide Warnings in 2004**

After many years of dismissing the antidepressant suicide problem, the Food & Drug Administration, confronted the issue anew in 2004. That year the Agency, after advisory committee hearings, directed the issuance of generalized suicide warnings for adults taking antidepressants, and "black box" warnings for patients under 25. The FDA's database did not show statistical significance in suicidality causation for adults between 25–64 years of age. That, however, is not proof antidepressants do not cause suicides in that group. The FDA's data comprising 100,000 adult patients from placebo controlled trials only going back to the early 1980's is hampered by the significant vacuum I referred to earlier—incomplete data from old trials never designed to link antidepressants and suicidality. An "either or" approach on antidepressant suicide causation, which antidepressant advocates selectively now apply to the 25–64 age group, is misleading as well as simplistic.

#### **"Statistical Significance"—As Used in the Debate—Is Not Very Helpful**

Industry traditionally has relied upon the concept of "statistical significance" to debunk causation. The fact that the pediatric and young adult patient pools shows statistical significance between antidepressants and suicidality despite the limited scope of nature of data for all populations suggests, according to experts of all stripes, the increased sensitivity of youth to antidepressants. The antidepressant suicide risk, when and where it presents itself, cannot be accurately detected and measured with the swoop of the broad brush. The FDA's suicide warning highlights what are believed to be the medication's high risk periods, stating that close obser-

<sup>3</sup>FDA Transcript of Psychopharmacological Drugs Advisory Committee December 13, 2006, page 456 line 12 through 457 line 17, and Transcript of Hearing Subcommittee on Oversight & Investigations of Committee on Energy & Commerce, September 23, 2004, 2nd session, Serial No. 108–125 ("FDA's Role in Protecting the Public Health Examining FDA's Review of Safety and Efficacy Concerns in Antidepressant Use by Children" Tab 38, page 368, 369. e.g. "(At CDER meeting) . . . there was general agreement that more studies would be desirable. . . . Dr. Woodcock suggested that a trial was needed to examine the emergence of behavioral toxicity in children and adolescents treated with antidepressants. She added that *the focus of the trial should not be efficacy.*")

<sup>4</sup>On November 1, 1997, FDA commenced AERS recording in a new computer system. All reported adverse events to the FDA prior to that date were accounted for in a separate system, and remain segregated. The "350" Prozac completed suicides reported earlier are thus not compiled in AERS.

vation for suicidality should occur **“during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.”** Suicidality can then abate, giving way to what antidepressants advocates call the “therapeutic” effect of the medications. Most experts testifying for plaintiffs in antidepressant suicide cases do not contend they are per se opposed to the medications or wish them banned. On the contrary, they prescribe antidepressants for carefully screened patients and monitor them for suicidality in accordance with the FDA warning.

### **Antidepressants Both Cause and Prevent Suicides**

Just last August, seven (7) FDA authors, including the Director of Medical Policy, published in the *British Medical Journal* their conclusion, a correct one in my view, stating “Antidepressant drugs can have two separate effects: an undesirable effect in some patients that promotes suicidal ideation or suicidal behavior and a therapeutic effect in others.”<sup>5</sup> Stated succinctly, and I paraphrase: Antidepressants both cause and prevent suicides!

Most of my plaintiff experts in antidepressant suicide lawsuits agree with this in terms of the short term trials that the databases reflect. Long term adverse side effects are another issue. With some patients driven to suicide by antidepressant induction, other patients, including those suffering from Major Depressive Disorder (“MDD”) and otherwise statistically bound for suicide, yet saved by the effect of antidepressants at least in the short term, the effect is a statistical dead heat when viewed in the large numbers of these many, short term trials.

### **Saturated Propaganda and True Believers!**

Then why are we still debating this? Because of twenty (20) years of saturated propaganda. Antidepressant suicide risk has been and remains suppressed by basically two factions: (1) the pharmaceutical industry and (2) organized psychiatry. No “conspiracies” here—it is pure self interest.

In industry’s case, the products sell. *Reuters* reports antidepressant use doubled in a decade, to \$9.6 billion in U.S. sales in 2008. Any loss of consumer and provider confidence due to a documented suicide risk cuts directly into sales. Universities and professors depending on outside research money take pharmaceutical funds to test antidepressants—and other drugs—executing non-disclosure agreements to obtain the pharmaceutical contracts. And ghost writing! The favorable results of the drug trials get written up by the drug company—while the negative trials are quelled. The draft to report the favorable results is turned over to the professor who, after a few minor changes, becomes the lead author on the article which is submitted to a prominent medical journal. After publication, the next day the news of this effective drug is published in the *New York Times* or *Wall Street Journal*. The net result of what was implied to the public as credible science by independent academics was actually carefully choreographed data by a drug company. Stung by criticism, companies have attempted to defuse the issue by claiming they have posted on their Web sites, the results of all their clinical trials, “whether positive or negative.” While these postings have accurately represented whether efficacy results were “positive or negative,” they continue to suppress overall suicidal data. The “causation” assessments by the principal investigators mentioned above are censored out of the Web sites. Nowhere, for example, on GlaxoSmithKline’s Web site does it disclose that 42 patients out of the 2,963 patients taking the drug during pre-marketing clinical trials attempted suicide, a “frequent” occurrence of this serious event.

### **“America is not Maoist China”**

Organized psychiatry suppresses awareness of the antidepressant suicide risk for another reason. They are true believers. Organizations like the *American Psychiatric Association* (“APA”) and the *American College of Neuropsychopharmacology* (“ACNP”)<sup>6</sup> are examples. I also include the National Institute of Mental Health

<sup>5</sup> BMJ (*British Medical Journal*) 2009; 339:b2880 Published 11 August 2009.

<sup>6</sup> On January 21, 2004, ACNP ([www.ACNP.org](http://www.ACNP.org)) . . . attempted a preemptive strike against the FDA and the Agency’s plan to review pediatric antidepressant suicide data February 2, 2004. Not in possession of the FDA’s then newly obtained antidepressant data showing an association with pediatric suicidality, the ACNP in its 22 page release highlighted sections in its report entitled “Weak Evidence Links SSRIs to Suicidal Behavior in Youth” and “No Significant Increase in Suicidal Behavior in Clinical Trials of Youth.” ACNP’s lack of updated data was hardly of concern to the organization. The report acknowledges “because the Task Force did not

Continued

(“NIMH”) in this grouping. Organized psychiatry is very professional, does a lot of superb work in mental health, and cares for their patients. Their opposition to suicide warnings while in good faith, is misguided. The true believers insist antidepressant suicide Warnings scare patients away from their medications—causing more suicides in the long run. One industry sponsored statistician echoing this concern, writing in 2007 stated: “If the intent of the pediatric black box warning was to save lives, the warning failed, and in fact it may have had the opposite effect; more children and adolescents have committed suicide since it was introduced.” A medical commentator for the American Enterprise Institute criticizing the FDA’s implementation of the “black box” was surprisingly candid in asserting that societal impact of the warning trumped all, and that individual suicides are not the question.<sup>7</sup> The Committee should take note of the invidious nature of this rationale, which lurks throughout the pro-antidepressant lexicon. Even if it were true that Warnings add to the Nation’s suicides, which I doubt, the notion that keeping individual patients in the dark about antidepressant suicide risk for the overall good of society is Maoist China, not the United States of America where individual informed consent is central to medical ethics. More frightening than organized psychiatry’s opposition to warnings out of patient concern is that the attitude, if it carried the day, would have denied risk information to fellow physicians. It is here, e.g. primary care, where the majority of antidepressants are prescribed and label information counts. No rationale can justify withholding medical risk information from fellow providers. While the “Warnings” issue is settled history, its core issue addresses us once again as the Veterans Administration (“VA”) and Department of Defense (“DoD”) deal with rising suicides in their constituent populations.

#### **Lack of “Completed Suicides” Is Nothing to Brag About**

A retort now universally put forth by antidepressant advocates who opposed the FDA’s warnings is that there were no “completed suicides” within the 4,100 pediatric patients comprising the clinical trials that spurred the “black box” warning. Taken from a controlled clinical trial environment of psychiatric monitoring, the absence of completed suicides gives little solace when, with 109<sup>8</sup> “possibly suicide related” events out of the 4,100, causation of suicidality from the medication is established. Downplaying the fact of no “completed suicides” in the short term pediatric trials is revealing as one notes how far industry has moved the goalposts as more and more revelations on the adverse effects of the medications have surfaced with each passing year. The claim itself manifests a degree of desperation. One can imagine the ridicule a tire manufacturer would receive testifying before Congress if acknowledging his company’s deficient tires have caused a large number of highway accidents, but he didn’t view it as a big problem because most of the accidents were not fatal. This Committee should treat the “no suicides” claim in these short term trials with the same curiosity.

#### **Antidepressant Advocates—Playing “Politics” Themselves**

Industry and organized psychiatry claim, usually subtly, that the FDA caved in to politics and media, in issuing the warnings. One APA headline proclaimed “The FDA May Have Overreacted.”<sup>9</sup> These swipes at the FDA have no basis in fact. The 15–8 advisory committee vote recommending the “black box” was cast entirely by independent experts. It should be pointed out that industry and organized psychiatry use politics and lobbying on the matter as much as anyone. That was demonstrated during the 2004 hearings. From 1990 onward both groups fought vigorously to dissuade the FDA from instituting any suicide warnings for antidepressants. In early 2004 when FDA’s preliminary antidepressant data on children

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*have access to a substantial amount of unpublished data, including detailed findings held by drug sponsors, this report is preliminary.”* ACNP’s attempt to ward off FDA action failed with the Agency’s imposition of suicide warnings based on the Feb. 2nd hearing. Additionally, the FDA’s ultimate determination of the data showed serious lapses in the ACNP’s proclamation. (Source: “Preliminary Report of the Task Force on SSRIs and Suicidal Behavior in Youth.” January 21, 2004. The ten (10) authors of the preliminary report had substantial ties to industry. One author of this report is an Investigator assisting the U.S. Army in its current study to assess rising Army suicides.

<sup>7</sup>“Is it possible, then, that SSRIs have precipitated some actual suicides? Yes . . . But the larger question the FDA must answer for the public is whether these medications have prevented more suicidal activity than they have caused. Almost surely they have.” *“The Rush to Black Label (or blackball) SSRIs.”* September 30, 2004, by Sally Satel, MD, <http://www.aei.org/article/21316>. . . .”

<sup>8</sup>See page 157, bottom line, FDA “Psychopharmacological Drugs Advisory Committee” transcript, September 13, 2004.

<sup>9</sup>“Psychiatric News” May 4, 2007, <http://pn.psychiatryonline.org/content/42/9/1.1.full>.



showed causality with suicidality, both groups continued their past argument that the sky would fall if the Agency imposed suicide warnings. This time, however, on March 22, 2004 the FDA went the other way, issuing the generalized suicide warnings for both children and adults. The Agency, at the same time, farmed the data out for a second opinion. It simultaneously announced it would convene additional hearings when the re-evaluation was complete. The re-evaluation was completed in the summer of 2004, confirming the causation in children. With verification of the risk now placed before the advisory committee, the FDA, among other options, placed the “black box” warning option, the highest form of drug risk warning, before the committee for a vote. Confronting the looming “black box,” industry and organized psychiatry in preparing their presentations executed an about-face.<sup>10</sup> Rather than decry the generalized suicide “Warning” issued March 23, 2004 as contrary to their long held views, both groups pivoted quickly to make it appear the recently instituted generalized suicide warning was something they always supported. The sky will fall argument was now directed to the “black box” option. The tactic failed. The committee voted 15–8 to impose the “black box” in regard to the children’s risk, and it was implemented by the FDA on October 15, 2004. The 2004 hearings further illustrated how Psychiatry differs from General Medicine on the matter of the antidepressant warnings. Non-psychiatrists on the advisory committee voted 10–3 in favor of the black box. Psychiatrists split 5–5. Psychiatry’s opposition flew in the face of the fact that non-psychiatrists dispense the great majority of antidepressant prescriptions, about 70 percent by many accounts, with non-psychiatrists generally supporting the warnings. Since the implementation of the “black box” in 2004, both industry and organized psychiatry have lobbied vigorously to remove the boxed label.

#### **In the Debate—Who to Believe?**

I do not contend that the antidepressant skeptics’ voices should dominate this discussion. Both antidepressant benefit and risk information should be weighed proportionately for treatment, but when investigating suicides, it is a risk-driven inquiry only. For honest brokers pursuing the issue, such as this Committee, VA, and DoD—it is necessary that history and credibility of the voices speaking on the antidepressants be objectively evaluated. Going back centuries, one would not place great credence on the “flat Earth” advocates after Columbus and Magellan proved the world to be round. The same analogies might be drawn from the history of the antidepressant debate. There were those from the early and mid 90’s, after Prozac came on the scene, calling attention to the antidepressant suicide issue—names in psychiatry like Peter Breggin, David Healy, and Joseph Glenmullen. There were others, the majority from industry and organized psychiatry, who vigorously promoted the medications and went out of their way to discredit these voices who were saying “not so fast.” The “flat Earth” advocates from the early 90’s are still around—and still on the same side of the issue, now claiming, that the FDA’s “black box” warnings have increased suicides nationally. I am not here to name names or criticize personally those who have a contrary view to mine. After all, I’m only a lawyer opining on what certainly involves medical and scientific issues. But lawyers, as well as the public, look at the evidence and make judgments—both in the jury docket and in our daily lives. It is thus more than fair to point out these antidepressant enthusiasts were wrong from the start, proven wrong by a demonstrated statistical significance in suicidality in pediatric populations determined in 2004, and wrong again in 2006 when statistical significance was shown with young adults. History has shown the skeptics were right from the beginning—and should in this search for truth command at least as much deference as those Investigators now participating in the process who were on the wrong side of events that the FDA decided.

#### **Lurking Beneath the Polite Exterior—NIMH v FDA**

Where does the strategic situation stand today? As much as the FDA has moved the ball since 2004, the antidepressant suicide issue remains stuck in the quicksand.

<sup>10</sup>At the initial February 2, 2004 hearing, the APA representative declined to offer recommendations for labeling based on the new data and further admonished the FDA on the antidepressant suicide issue concerning children, stating “we are concerned that the publicity surrounding this issue may frighten some parents and discourage them from seeking help for their children. . . .” (FDA PDAC Transcript 2/2/04 Page 226 line 25 thru Page 227 line 3). After the FDA issued the generalized suicide warnings March 22, 2004 and the “black box” option was before the panel on September 13, 2004, the APA representative told panelists: “(W)e support the continuation of the current FDA warnings with respect to antidepressants. We believe the language is appropriate and consistent with our current knowledge, understanding and scientific data.” (FDA PDAC Transcript (FDA PDAC Transcript 9/13/04, bottom page 300, top of page 301).

Lurking beneath the surface of the antidepressant suicide debate are polar opposite positions of two Federal agencies: the Food & Drug Administration (“FDA”), and National Institute of Mental Health (“NIMH”). This opposition is not, for comity purposes, openly acknowledged and can be explained, in part, by the agencies’ different statutory missions.

This Committee should note the sharp distinction between the antidepressant suicide warnings emanating from the FDA, and the continued suppression of the antidepressant suicide risk by the NIMH. One would not expect NIMH to give medication induced suicide equal billing with a “take your meds” approach in psychotropic therapy. On the other hand, NIMH is obliged to be accurate in its public pronouncements. That has not always been the case in regard to antidepressants, and unfortunately remains so in some applications. Examples are useful. On September 20, 1991 NIMH was instrumental in the FDA’s decision to deny suicide warnings to the public in regard to Prozac, erroneously framing the labeling issue in terms of banning antidepressants, urging the FDA voting panelists on that day “instead of trying to withhold these drugs, there should be much more aggressive effort to make . . . (antidepressants) . . . even more widely available to the appropriate patients.”<sup>11</sup> Banning Prozac was never on the table, the FDA having rejected that option weeks earlier (“*APANewsReleaseProzac*”). NIMH should not suppress awareness of the risk as pointed out by the FDA, and should give representative information on the limited effectiveness of antidepressants, articles of which have increased substantially in the last few years. Today one is hard pressed to find existence of the FDA’s suicide warnings on the NIMH Web site. One finds, instead, a skewed selection of literature on the Institute’s Web site, mostly all strongly endorsing antidepressants and omitting mention of the articles in the scientific literature citing the drawbacks. In May 2008, I notified the Director, NIMH that the Institute’s publication “Depression,” distributed to the public misrepresented, by under-statement, the breadth of the FDA’s suicide warning by omitting the fact adults were included in the FDA’s warning (*FarberLtrtoNIMH*). Responding to my letter, NIMH simply misstated the facts, again, by asserting its publication was issued before the FDA’s issuance of the warning (*NIMHLtrtoFarber*). NIMH continues in 2010 to misrepresent the FDA’s suicide warning (*NIMHWebsite & NIMHLtrtoFarber*).

#### **FDA Suicide Warnings Are Detailed and Balanced**

Since 2004, FDA “suicide warnings” on antidepressants have been detailed and balanced. In 2007 the FDA was fair enough on the issue to ensure the labeling reflected that failure to treat depression, impliedly by antidepressants, could be hazardous as well. NIMH, by contrast, continues its longstanding policy of silence on the antidepressant suicide risk. NIMH further highlights articles criticizing the FDA’s suicide warnings. I praised the Director for the good work the Institute does—but the skewed coverage of antidepressants has to be troubling for citizens expecting neutrality and objectivity from NIMH. The FDA’s directed suicide warning is excellent, entailing monitoring of symptoms and followup, including advising monitoring by caretakers and family members to be alert for symptoms of suicidality (*Feb2010FDAAntidepressantWarnings*).

#### **Antidepressant Suicide Monitoring**

For veterans and servicemembers, I fear this 3rd party monitoring is not being done—it certainly won’t be unless the VA and the command structure recognize the value of the FDA warning, and implement it in a way appropriate to the veterans’ setting. The setting of a VA clinic, and any combat zone, obviously poses unique issues for considering such 3rd party monitoring. Patient privacy and the “macho” persona are also issues in mental health treatment that have to be confronted in treating veterans and active military. Whatever the difficulties, the Veterans Administration and DoD will be doing their members a disservice if risky drugs are administered to patients without the safeguards that patients in private practice receive at the recommendation of FDA. In medical malpractice cases, physicians who don’t warn patients of the potential dangers of a drug as recommended by the FDA are generally considered to violate the standard of care.

#### **NIMH Tags Along—But Still Silent**

When the turbulence of 2004 over pediatric data arose and the FDA had to change its policy and issue an antidepressant suicide warning, and again in 2006 when young adults were added to the “black box,” the NIMH was effectively forced

<sup>11</sup>FDA Transcript of Psychopharmacological Drugs’ Advisory Committee September 20, 1991, Page 177 Lines 1–7.

to tag along. In November 2006, the NIMH issued five (5) grants to study the anti-depressant suicide situation, including adult suicide (*NIMHPressRelease061113*). Presumably these grants were a byproduct of the numerous pleas heard during the 2004 FDA hearings that the cited scientific vacuum be rectified. Notwithstanding what transpired before 2006—or since, this prolonged gap and NIMH silence continues to exist in an area which arguably it has responsibility to lead (*NIMHEmail*). The lack of progress in this 20-year problem is unsatisfactory in public health, regardless of which agency or agencies have lagged.

#### VA (and DoD) on “Suicide”—Fish Out of Water?

My current observation on the issue of veterans’ and military suicides leaves me concerned. In dealing with rising numbers of suicides, VA and DoD appear to be relying on NIMH to lead them to enlightenment. Noted on the Institute’s Web site is the Army’s memorandum of agreement and frequent references to the issue of veterans’ suicides. It is natural that NIMH would be a source of Federal assistance given that neither DoD nor VA, despite huge constituencies for treatment and certain specialties in research, e.g. combat stress and prosthetics, have never been institutional leaders in drug safety or suicide. Traditionally, the military has medically discharged members with serious mental health problems. In 2004, I learned from *Navy Times* of the large numbers of suicides in the Pacific Fleet. Stating the background and relevant facts on antidepressant suicide litigation, I wrote a letter to the Commander in Chief of the Pacific Fleet with specific recommendations (*FarberCINCPACFLT*). The issue was turned over to Navy medical bureaucrats in Washington, where it died a sudden death; at least no one ever followed up with me. While in theory a NIMH partnership is the correct call for VA and DoD to make in alleviating the very serious problem of rising veterans’ and active duty suicides, for reasons I’ve stated I fear NIMH will not be robust in sufficiently highlighting antidepressant risk from benefit, and that investigative avenues to determine the full causes of the rising rates may be bypassed. Maybe antidepressants are responsible for half the suicides—or maybe just a few, or possibly none. Whatever it is, it is scientifically unacceptable and a breach of duty to approach this complicated problem pretending the issue of antidepressant induced suicide does not exist. Mr. Chairman, your leadership here today ensures that question won’t be swept under the rug—as it was for so long.

#### Conclusion

My two recommendations to the Committee are:

1. Direct the VA to conduct independent antidepressant suicide testing through one or more neutral, third parties, and
2. Direct the VA to ensure all psychotropic drug labeling warnings and precautions are made available to all patients.

Thank you for the privilege of testifying before this Committee.

Respectfully,

Donald J. Farber

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#### Prepared Statement of Ira Katz, M.D., Ph.D., Deputy Chief Officer, Mental Health Services, Office of Patient Care Services, Veterans Health Administration, U.S. Department of Veterans Affairs

Mr. Chairman, Mr. Ranking Member, and Members of the Committee:

Thank you for the opportunity to appear today to discuss the Department of Veterans Affairs’ (VA) response to the mental health needs of America’s veterans.

VA has responded aggressively to address previously identified gaps in mental health care by expanding our mental health budgets significantly. In fiscal year (FY) 2010, VA’s budget for mental health services reached \$4.8 billion, while the amount included in the President’s budget for FY 2011 is \$5.2 billion. Both of these figures represent dramatic increases from the \$2.04 billion obligated in FY 2001. VA has increased the number of mental health staff in its system by more than 5,000 over the last 3 years. During the past 2 years, VA trained over 2,500 staff members to provide psychotherapies with the strongest evidence for successful outcomes for post traumatic stress disorder (PTSD), depression, and other conditions and we require that all facilities make these therapies available to any eligible veteran who may benefit.

VA is working closely with our colleagues at the Department of Defense (DoD) to improve the quality of care for veterans and servicemembers alike. Since October 2009, VA and DoD have held two major conferences related to the mental health needs of veterans and servicemembers. In FY 2010 and FY 2011, we will expand inpatient, residential, and outpatient mental health programs with an emphasis on integrating mental health services with primary and specialty care.

With its emphasis on providing care management for depression and making evidence-based psychotherapy available for all veterans who need it, VA is ensuring that planning for treatment of mental health conditions includes attention to the benefits as well as the risks of the full range of effective interventions. Making these treatments available responds to the principle that when there is evidence for the effectiveness of a number of different treatment strategies that can be effective, the choice of treatment should be based on the veteran's values and preferences, as well as the clinical judgment of the provider.

My testimony makes four major points: first, appropriate use of psychotherapeutic medications is a key component of overall mental health care, but medications, like all treatments, can be associated with risks as well as benefits; second, VA has systems to monitor for adverse effects associated with medication use and programs to enhance the safety of pharmacological treatments; third, VA's mental health programs have been designed both to optimize the safety of psychopharmacological treatments and to provide effective alternative strategies for treatment; and fourth, VA's mental health and suicide prevention activities are effective and evidence-based. The data demonstrate that young adult veterans are coming to VA for their mental health needs, and those veterans who may be vulnerable to suicidality as an adverse effect of antidepressant medications have lower suicide rates when they come to VA for health care.

#### *Effectiveness and Safety of Psychopharmacological Treatments*

It has been somewhat over 50 years since the benefits of psychopharmacological treatments for serious mental illnesses were established, and during that time there has been a steady accumulation of scientific evidence for the effectiveness of medications for the treatment of mental disorders, for limiting the severity and duration of episodes of illness, and for preventing relapses and recurrences. Reviews of the evidence have confirmed these findings, which have been translated into recommendations for clinicians in the VA-DoD Clinical Practice Guidelines for Major Depressive Disorder, Post Traumatic Stress Disorder, Psychoses, and Substance Use Disorder, as well as guidelines for the treatment of mental health conditions supported by other U.S. Government agencies, agencies of other nations, professional societies, and scientific organizations. Today, the use of medications as a key component of mental health care is as well established as treating infectious diseases with antibiotics, cancer with chemotherapy, or rheumatological conditions with anti-inflammatory agents; in sum, the effectiveness of this treatment modality has been established beyond any reasonable doubt. There are, of course, many questions that can and should be raised, to include: when medications should be used and when other therapies should be used instead or in addition; how decisions should be made about dosage and duration; how therapy should be monitored; and how treatment should be modified when adverse effects are observed.

The accumulating evidence about the effectiveness of psychopharmacological treatment has been accompanied by increasing knowledge about side effects and adverse reactions. In recent years, there has been concern about suicidality as a possible adverse effect of approved medications used to treat conditions as diverse as depression, anxiety, bipolar disease, psychoses, attention deficit disorder, sleep disturbances, migraine, Parkinson's disease, and others. For each of these, the associations between suicide and medications have been difficult to evaluate because, for each, medications have been demonstrated to be effective for the treatment of conditions that are, themselves, risk factors for suicide. In most contexts, this can make it difficult to sort out what effects may be due to medication and what to the underlying condition. This is a phenomenon known as "indication bias;" it is a reflection of the principle that medications are prescribed for individuals who are already at increased risk for suicide. However, suggestions that antidepressant medications may lead to increased risks of suicide-related behaviors in adolescents and young adults were derived from randomized clinical trials where the research design allows the separation of the effects of antidepressant medications from those of depression.

Although findings from clinical trials on antidepressants and increased risks of suicide cannot be explained by indication bias, these relationships are complex. They are based on increases in suicidal ideation and related behaviors, rather than death. Moreover, when investigators looked across the lifespan, they found that in-

creases in suicidal behaviors in younger individuals were offset by decreases in older adults. Finally, the findings from randomized clinical trials have not been reinforced through evidence from observations on the relationships between antidepressant prescribing and suicide rates across time or geographic areas. Although there is still debate about whether the available evidence demonstrates decreases in suicide rates with increased prescribing of newer antidepressants, there are no suggestions that increased medication use leads to increased risks of suicide.

Nevertheless, the Food and Drug Administration (FDA) viewed the findings from randomized clinical trials as sufficient to require a boxed warning in the product labeling of all antidepressant medications. The warning includes language stating that:

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of [insert established name] or any other antidepressant in a child, adolescent or young adult must balance this risk with the clinical need. Short term studies did not show an increase in the risk of suicidality with antidepressant compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressant compared to placebo in adults aged 65 and older. . . .

The language in the boxed warning also notes that use of antidepressants is, in general, associated with both risks and benefits. The important clinical issue is not about whether these medications have a place in mental health care, but rather about how they should be used. The FDA's boxed warning states:

Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior . . .

Other research provides evidence that certain medications may have specific effects decreasing the risk of suicide. A randomized clinical trial found that clozapine had a demonstrated impact reducing suicidality when compared with another atypical antipsychotic medication. This led FDA to approve the use of clozapine for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorders. Findings from other research suggest that lithium, rather than mood-stabilizing anticonvulsants, may be associated with decreased rates of suicide for people with bipolar disorder. Still other research demonstrates decreased rates of suicide and death from accidental overdoses in people with opiate addiction who are treated with methadone. All of these findings represent important leads for guiding clinical practice.

VA's research programs sponsor scientific investigations on the effect of medications for mental health conditions including depression, substance abuse, anxiety disorders, PTSD, sleep disturbances and psychotic disorders. In these studies of pharmacological treatments for mental health conditions, safety plans are in place to respond to patient needs emergently when suicide ideation arises during a research study. VA has well established reporting plans for adverse events in research to inform oversight bodies in a timely manner (VHA Handbook 1058.01), and VA's Pharmacy Benefits Management program keeps clinicians conducting research well informed about medication label changes. Effective February 1, 2010, VA's Office of Research and Development entered into a new Memorandum of Agreement with the VA National Suicide Prevention Hotline; this agreement delineates the exact procedure for research personnel to use when a veteran participating in a research program needs help for suicidal thoughts or actions. Studies are currently being evaluated to determine how this will complement research safety plans already in place.

Although the issue raised in this hearing is a broad one, the importance of depression as a risk factor for suicide, and the high rates of utilization of serotonin-reuptake inhibitors and other antidepressant medications, makes questions about these medications a major public health concern. Moreover, with the ongoing wars in Afghanistan and Iraq, there are substantial numbers of young veterans returning home, many of whom may have mental health conditions. The effects of antidepressant medications are very relevant to this important component of the populations served by VA.

#### *Monitoring Adverse Drug Events*

VA recognizes that the use of any medication can be associated with a risk for adverse events. In response to this basic principle, VA has developed a comprehen-

sive system to identify potential adverse drug effects (ADEs), and to provide information as quickly as possible to clinicians and providers. An ADE is defined as an unintended effect of a drug that occurs secondary to drug administration.

Post-marketing drug surveillance is vital for recognizing ADEs and reporting them to FDA. A cornerstone of post-marketing surveillance is collecting and evaluating reports of ADEs through voluntary reporting by health care professionals. The safety profile of any drug or pharmaceutical agent evolves over time as new information is discovered when health care providers offer it to larger populations and sub-groups not previously studied during clinical trials. Because the electronic medical record is able to link prescription data to clinical outcomes at the patient level, VA is uniquely able to identify and track drug safety issues. VA has the only national system for electronic reporting of ADEs through its innovative VA Adverse Drug Event Reporting System (VA ADERS). By analyzing this computerized database, VA is able to identify drug safety signals, assess the significance of external drug safety issues in our own patients, and rapidly track trends of known drug safety issues.

VA's Center for Medication Safety (VA MedSAFE) is a national, comprehensive pharmaco-vigilance program that emphasizes the safe and appropriate use of medications. VA MedSAFE utilizes various methods and tools, including passive and active surveillance, to continuously monitor for potential ADEs, including the use of VA ADERS as previously described. In many instances, VA MedSAFE directly and promptly notifies providers across VA's health care system if patients are at risk. VA, DoD and FDA have a memorandum of understanding (MOU) that allows close collaboration on specific post-marketing surveillance efforts and other drug and vaccine safety projects conducted through FDA's newly established Sentinel Initiative and its Office of Surveillance and Epidemiology.

Evaluating preventable ADEs, providing interventions to decrease preventable ADEs, and educating the field on best practices all reduce the likelihood of ADEs. By conducting and promoting medication safety projects at the regional and national levels, VA provides safe and effective pharmaceutical care to veterans. Through the national roll-up system and data analysis provided by VA MedSAFE, each facility and VISN (Veterans Integrated Service Network) can benchmark themselves against national trends. We are unaware of any other health care system with as robust and well-developed a system for tracking, assessing, and acting on drug-related safety issues within their patient population.

VA provides consumer medication information sheets on each new and renewed prescription. VA is highly engaged with patient education on medications with local VA medical centers developing policy for teams of clinicians to provide medication education, involving physicians, nurse practitioners, physician assistants, clinical pharmacy specialists, pharmacists, nurses, and other allied health care providers. Clinical Pharmacy Specialists and clinical pharmacists are key members of the health care team and can assist in optimizing drug therapy and improving medication safety for outpatients.

Medication Reconciliation, a Joint Commission National Patient Safety Goal, is a process which mitigates the risk of ADEs that occur at transitions of care by addressing discrepancies between a patient's accounting of medication use and the medication lists in the medical record every time a medication is dispensed, changed, or added to the medication regimen. The VA Medication Reconciliation Initiative, launched in December 2008, is tasked with facilitating safe, high quality, effective, and above all, veteran-centered medication reconciliation throughout the VA system. This multi-disciplinary effort includes a VA Medication Reconciliation Toolkit, Educational Video, Facility Monitor, External Peer Review Process, and patient informational Web site called "Medications: Play it Safe!" on the My HealthVet Web site. This initiative's workgroups continue to improve patient and staff resources and tools to improve documentation and monitoring of this process. In the coming months, VA will continue to bring together innovators from VA with those from DoD and the private sector to establish a world-class medication reconciliation program for veterans and to provide guidance for this challenging endeavor.

As part of these programs, VA has been concerned about increases in suicidal ideation and other symptoms of suicidality as adverse drug effects. VA has provided guidance to its facilities addressing concerns about antidepressants, anticonvulsants, retinoids, propoxyphene, ziconotide, tetrabenazine, interferon, neuraminidase inhibitors, leukotriene inhibitors, aripiprazole, and paliperidone.

Also, the Serious Mental Illness Treatment Research and Evaluation Center (SMITREC) conducts ongoing analyses of risk factors for veterans' suicides and shares its findings to the field. So far, VA has distributed new information on risks specifically in VA's population related to mental health conditions, traumatic brain

injury, and pain. Currently, SMITREC is collaborating with VA MedSAFE to conduct a broad-based, exploratory evaluation of the associations of medications with suicide. The goals of these analyses will be to generate hypotheses to guide further research about potential side effects; they are being conducted to ensure that the full resources of the VA as a national health care system are used to detect all possible risks to veterans. Still another activity, the PTSD Mentorship program, led by the National Center for PTSD, provides training for PTSD specialty care staff from all VA medical centers and includes an emphasis on evidence-based pharmacological treatment for PTSD and a focus on avoiding poly-pharmacy.

*Safe Use of Psychopharmacological Agents and Available Alternative Treatments*

VA has been making significant enhancements to its mental health services since 2005, through the VA Comprehensive Mental Health Strategic Plan and special purpose funds available through the Mental Health Enhancement Initiative. VA's enhanced mental health activities include outreach to help those in need to access services, a comprehensive program of treatment and rehabilitation for those with mental health conditions, and programs established specifically to care for those at high risk of suicide. To reduce the stigma of seeking care and to improve access, VA has integrated mental health into primary care settings to provide much of the care that is needed for those with the most common mental health conditions. In parallel with the implementation of these programs, VA has been modifying its specialty mental health care services to emphasize psychosocial as well as pharmacological treatments and to focus on principles of rehabilitation and recovery.

In addition to the care offered in medical facilities and clinics, VA's Vet Centers provide outreach and readjustment counseling services to returning war veterans of all eras. It is well-established that rehabilitation for war-related PTSD, Substance Use Disorder, and other military-related readjustment problems, along with the treatment of the physical wounds of war, is central to VA's continuum of health care programs specific to the needs of war veterans. The Vet Center service mission goes beyond medical care in providing a holistic mix of services designed to treat the veteran as a whole person in his or her community setting. Vet Centers provide an alternative to traditional mental health care that helps many combat veterans overcome the stigma and fear related to accessing professional assistance for military-related problems. Vet Centers are staffed by interdisciplinary teams that include psychologists, nurses and social workers, many of whom are veteran peers.

Vet Centers provide professional readjustment counseling for war-related psychological readjustment problems, including PTSD counseling. Other readjustment problems may include family relationship problems, lack of adequate employment, lack of educational achievement, social alienation and lack of career goals, homelessness and lack of adequate resources, and other psychological problems such as Depression and/or Substance Use Disorder. Vet Centers also provide military-related sexual trauma counseling, bereavement counseling, employment counseling and job referrals, preventive health care information, and referrals to other VA and non-VA medical and benefits facilities.

To promote suicide prevention, VA established a strong partnership with the Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) to operate a Veterans Call Center as part of the National Suicide Prevention Lifeline. VA also has appointed suicide prevention coordinators and care managers at each VAMC and the largest community-based outpatient clinics. Altogether, VA employs over 400 staff members who focus specifically on suicide prevention.

During 2009, the VA Call Center received approximately 10,000 calls per month, approximately 20 percent of all calls to the National Suicide Prevention Lifeline. These calls led to 3,364 rescues of those determined to be at imminent risk for suicide and 12,403 referrals to VA Suicide Prevention Coordinators at local facilities. In 2009, the VA Call Center received calls from 1,429 active duty servicemembers, a little more than 1 percent of all calls. To address the needs of the active duty population, VA worked with SAMHSA to modify the introductory message for Lifeline, developed MOUs with DoD, and established processes for facilitating rescues, including collaborations with the armed services in Iraq. Also during 2009, the hotline services were supplemented with an Internet chat line that has been receiving more than 20 contacts a day.

The Lifeline and VA Call Center may be the most visible components of VA's suicide prevention programs, but the Suicide Prevention Coordinators are equally important. Both the VA Call Center and providers at their own facilities notify the Suicide Prevention Coordinators about veterans at risk for suicide. The Coordinators then work to ensure the identified veterans receive appropriate care, coordinate services designed specifically to respond to the needs of veterans at high risk, pro-

vide education and training about suicide prevention to staff at their facilities, and conduct outreach and training in their communities. Other components of VA's programs include a panel to coordinate messaging to the public as well as two Centers of Excellence charged with conducting research on suicide prevention: one, in Canandaigua, focused on public health strategies, and one in Denver, focused on clinical approaches.

In 2009, VA approved the *Handbook on Uniform Mental Health Services in VA Medical Centers and Clinics* to define what mental health services should be available to all enrolled veterans who need them, no matter where they receive care, and to sustain the enhancements made in recent years. One important set of requirements in the Handbook was designed to ensure that psychopharmacological treatment is conducted using evidence-based strategies to optimize effectiveness and safety. Another set was designed to ensure that evidence-based psychotherapies are available for veterans who could benefit from them and that meaningful focused between effective alternative treatments are available.

VA has established programs to support the principle, specified in FDA's boxed warning, that "(p)atients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior." The purpose of the boxed warning is not to create barriers for the use of these medications for the treatment of depression or PTSD. Instead, it is to promote awareness that these medications are associated with risks, as well as benefits, and that treatment requires monitoring.

Also, based on its Comprehensive Mental Health Strategic Plan, VA has enhanced access to mental health services by requiring that mental health services must be integrated into primary care services. To ensure veterans are monitored appropriately while they are receiving mental health services, including treatment with psychotherapeutic medications, VA requires that these integrated care programs include evidence-based care management.

Care management for depression includes repeated contacts with patients to educate them about depression, medications, and other treatment, as well as to provide evaluations of both therapeutic outcomes and adverse effects. The benefits of the frequent contact program relate to increased patient-engagement in care. Also, information from patient monitoring is translated into decision-support for providers about when they should modify treatment. Two programs that are used frequently in VA primary care settings are Translating Initiatives in Depression into Effective Solutions (TIDES) and the Behavioral Health Laboratory (BHL), both of which are evidence-based interventions supported by extensive research. Studies on care management for depression in primary care settings have demonstrated that these interventions can decrease both depression and suicidal ideation in older adults. This led to recognition of care management for late life depression as a best practice for suicide prevention.

For several years, VA has provided training to clinical mental health staff to ensure that there are therapists in each facility who are able to provide evidence-based psychotherapies for the treatment of depression and PTSD as alternatives to pharmacological treatment or as a course of combined treatment. The initiative to make these psychotherapies broadly available within VA is relevant to concerns about medication safety, but the program was not developed as a result of those concerns. VA implemented the broad use of evidence-based psychotherapies in response to evidence that for many patients, specific forms of psychotherapy are the most effective and evidence-based of all treatments. Specifically, the Institute of Medicine report on treatment for PTSD emphasized findings that exposure-based psychotherapies, including Prolonged Exposure Therapy and Cognitive Processing Therapy, were the best-established of all treatments for PTSD. Other specific psychotherapies included in VA's programs include Cognitive Behavioral Therapy and Acceptance and Commitment Therapy for depression and Skills Training and Family Psycho-Education for schizophrenia. VA is adding other treatments such as Problem Solving for Depression, Cognitive Behavioral Therapy and Contingency Management for Substance Use Disorder, and behavioral strategies for managing both pain and insomnia.

#### *Focusing on the Evidence*

As stewards of the public interest and bearing the responsibility for caring for America's veterans, VA conducts ongoing analyses of its programs and continually asks itself how they can be improved. VA's mental health enhancements were designed to implement evidence-based practices. Early in this process, VA conducted exploratory analyses of the associations between the rates of suicide and the quality of mental health services, evaluating both on a facility-by-facility basis. The findings demonstrated statistically significant associations with two quality measures even after controlling for other differences between facilities. These findings led VA to



adopt specific requirements for followup care after hospital discharge, and to require depression care management. Most generally, the findings support the conclusion that high quality mental health care can prevent suicide.

One way to evaluate the impact of VA mental health care, with its use of medications as well as other forms of treatment, is to evaluate suicide rates. However, before addressing this issue, it is important to consider who accesses VA health care. For this, it is useful to refer to findings on those veterans returning from Afghanistan and Iraq who participated in the Post-Deployment Health Re-Assessment (PDHRA) program administered by DoD. Between February 2008 and September 2009, approximately 119,000 returning veterans completed PDHRA assessments using the most recent version of DoD's form. Of the more than 101,000 who screened negative for PTSD, 43,681 came to VA for health care services and 57,476 did not. Translating this finding into statistical language, the odds of coming to VA for those who screened negative were about 0.8:1. Among 17,853 who screened positive for PTSD, 12,674 came to VA for health care services and 5,179 did not; in other words, the odds of coming to VA for those who screened positive were about 2.4:1. These findings demonstrate that veterans screening positive for PTSD were substantially more likely to come to VA for care. Findings about depression were similar. Both sets of findings support earlier evidence that those veterans who come to VA are those who are more likely to need care and to be at higher risk for suicide. The increased risk factors for suicide among those who came to VA is often referred to as a case mix difference.

Working with the Centers for Disease Control and Prevention's National Violent Death Reporting System, SMITREC recently calculated rates of suicide for all veterans, including those using VA health care services and those who do not. This analysis included data from 16 States for individuals aged 18–29, 30–64, and 65 and older for the years 2005, 2006, and 2007 (during the period of VA's mental health enhancement process). The year 2005 marked the beginning of enhancement, while the year 2007 is the most recent one for which data are available.

Suicide rates for veterans using VA health care services aged 30–64, and those 65 and above were higher than rates for non-users, and they remained higher from 2005 to 2007, probably a reflection of the case mix discussed above. However, findings for those aged 18–29 were quite different. In 2005, younger veterans who came to VA for health care services were 16 percent more likely to die from suicide than those who did not. However, by 2006, those younger veterans who came to VA were 27 percent less likely to die from suicide, and by 2007, they were 30 percent less likely. This difference appears to reflect a benefit of VA's enhancement of its mental health programs, specifically for those young veterans who are most likely to have returned from deployment and to be new to the system.

It is particularly important to look at suicide rates among the youngest veterans (those aged 18–24) who are thought to be most vulnerable to suicidality as an adverse effect of antidepressant medications. Because the number of veterans from the 16 States in this group is relatively low, the rates are, for statistical reasons, variable. Nevertheless, they demonstrate important effects. In 2005, 2006, and 2007, respectively, those who came to VA were 56, 73, and 67 percent less likely to die from suicide. Those who utilized VA services were, to some extent, protected from suicide with an effect that appeared to increase during the time of VA's mental health enhancements.

#### *Conclusion*

VA as a system is committed to detecting and decreasing adverse drug effects and improving the quality and availability of mental health care to veterans. VA's mental health enhancements have included major initiatives to increase the use of evidence-based psychotherapy for the treatment of PTSD and depression, as well as to enhance the safe use of psychotherapeutic medications. VA recognizes the concerns raised by FDA and others about the use of antidepressant medications among young adults as a potentially vulnerable population, but it has found that the risk of suicide is lower among the young adult veterans who come to VA for care and that the rates appear to be dropping. VA firmly believes that each veteran has earned an individual determination of the best treatment and routine followup for his or her specific condition, and its clinical guidelines support this endeavor.

The concerns about risks of suicide are appropriate concerns. VA has conducted evaluations to determine whether they are reflected in increased rates of suicide in those young adult veterans who receive VA care. The answer is that these veterans are, in fact, at decreased risk for suicide. Thank you again for the opportunity to appear, and my colleagues and I are available to address any questions from the Committee.

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**Prepared Statement of Brigadier General Loree K. Sutton, M.D.,  
Director, Defense Centers of Excellence for Psychological Health and  
Traumatic Brain Injury, Special Assistant to the Assistant Secretary of  
Defense for Health Affairs, U.S. Department of Defense**

**Introduction**

Chairman Filner, Mr. Buyer, distinguished Members of the Committee; thank you for the opportunity to appear here today to talk to you about the Department of Defense's (DoD) efforts to reduce the number of suicides across our force.

On behalf of DoD, I want to take this opportunity to thank you for your continued, strong support and demonstrated commitment to our servicemembers, veterans, and their families.

Over the last 9 years, a new era of combat emerged, where counterinsurgency and asymmetric warfare are the norm. This shift continues to place a great amount of strain on our most important resource, our servicemembers. Despite the operational challenges facing them and their families, they remain incredibly resilient, motivated, and well-trained. The Department recognizes the need to provide the resources and programs necessary to maintain their resilience and motivation. Our core messages tell our servicemembers and their families that they are not alone; treatment works; the earlier the intervention the better; and reaching out is an act of courage and strength.

The Department also recognizes that the total number and rate of suicides continue to rise and this is of deep concern at all leadership levels. Today, I will share with the Committee our current efforts to reduce the number of suicides across the force, and the role of medication and suicides.

Suicide has a multitude of causes, and no simple solution. There are many potential areas for intervention, and it is difficult to pinpoint the best approach because each suicide is unique. Recognizing this, DoD is tackling the challenge using a multi-pronged strategy involving comprehensive prevention education, research, and outreach. We believe in fostering a holistic approach to treatment, leveraging primary care for early recognition and intervention, and when needed, providing innovative specialty care. The areas of focus to reduce risk include: (1) conducting data collection and analysis to detect contributing risk factors; (2) facilitating partnerships across DoD, Federal agencies, and civilian organizations to increase collaboration and communication; (3) reducing stigma and increasing access to resources to provide needed care; and (4) using research to close gaps and identify best practices.

**Data Surveillance**

Quality data collection and analysis are critical components behind effective prevention efforts. The Department made great strides over the last 12 months on gathering critical information to understand the complexity of factors leading to suicide and ways to prevent such tragedies from occurring within our communities. Data collected by the DoD Suicide Event Report (DoDSER) tell us that we must continue to educate our population and build programs, as there continue to be multiple opportunities to intervene. For example, we are learning that 30 percent of individuals who died by suicide communicated their potential self harm; 49 percent had been seen in a medical/support clinic/program within 30 days of suicide; and 26 percent sought broadly defined mental health resources.

Historically, the Services used unique suicide surveillance systems. In January 2008, the National Center for Telehealth and Technology (T2), a Defense Centers of Excellence (DCoE) component center, launched the DoDSER Annual Report. The DoDSER Annual Report was developed to standardize data collection and reporting. Pulling data from all branches of the military, it captures over 250 data-points per suicide with details, summaries, and analyses of a wide range of potential contributing factors. DoDSER Annual Report data include specific demographics, suicide event details, treatment, and military history, among others. The variables are designed to map directly to the Centers for Disease Control and Prevention's National Violent Death Reporting System to support direct comparisons between military and civilian populations.

By standardizing data and reporting, DoD tracks and analyzes suicide data and contributing risk factors proactively to inform and improve future prevention, intervention, and treatment services. The DoDSER Annual Report is revised annually based on input from the Services. The data facilitate the review and evaluation of the effectiveness of suicide prevention initiatives and their execution over time. DoDSER represents the strides DoD has taken to better understand what some of the underlying factors are for suicide. The Department uses this tool to inform current efforts and initiatives.

According to the Armed Forces Medical Examiner System (AFMES), in January 2010 there were 24 confirmed suicides, all in Regular Components within the DoD. In calendar year 2009, AFMES reported that there were 312 confirmed suicides, with 286 confirmed in Regular Components and 26 confirmed in the Reserve Components. Demographic risk factors include: male, caucasian, E-1 to E-4, younger than 25 years old, GED or less than high school education, divorced, and in the Active Duty Component. Other factors associated with suicide, which are consistent with data from civilian populations, are: substance abuse, relationship issues, and legal, administrative (Article 15), and financial problems. Although the impact of deployment is still under investigation, a majority of suicides do not occur in the theaters of operation. Sixteen percent of suicides occurred in Iraq or Afghanistan. Despite the knowledge gained and data collected, it is important to resist oversimplifying or generalizing statistics. Each suicide is as different as a person is unique.

According to AFMES, there were 26 confirmed suicides in calendar year 2009 among the Reserve Components, which include all active Guard and Reserves. Due to the unique nature of their service, there are challenges associated with capturing all suicide completions, preparatory behavior and self harm without intent to die among National Guard and Reserve populations when they are not on active or activated status. To address this issue, DoD is examining ways to utilize information gathered from existing tracking and reporting systems including, but not limited to, insurance and benefit data. The DoD continues to support National Guard and Reserve populations through numerous initiatives to increase outreach, care, and resources on all fronts.

The numbers also tell us that prevention is not enough, as 36 percent of military suicides had a history of a mental disorder. The integrated efforts of prevention, intervention, and treatment are essential to DoD's approach to tackle the challenge of suicide.

#### **Facilitating Partnerships**

Continued collaboration with the Department of Veterans Affairs (VA) and other Federal, private, and academic organizations is a key part of DoD's overall strategy.

Conferences serve as dissemination and outreach platforms by providing local and regional coordinators with innovative ideas to implement within their communities and providing DoD and VA with the opportunity to gather feedback on communities' needs. The annual DoD/VA Suicide Prevention Conference provides such a forum. With over 900 attendees, the 2010 conference shared practical applications, results from research and pilot studies, guidance from senior DoD and VA leaders on the way forward, and testimonies emphasizing the importance of seeking help.

We work closely with our partners at the VA to ensure that the transition out of service and into VA care is seamless and that servicemembers, veterans, and families receive the care they deserve. The DCoE coordinates information and resources with VA's National Suicide Prevention Lifeline (1-800-273-TALK), and National Resource Directory. As part of this partnership, DCoE worked with VA and the Substance Abuse and Mental Health Services Administration (SAMHSA) in December of 2009 to modify the introductory message on the Lifeline, so that callers are instructed to press "1" if they are a United States military veteran or Active Duty Servicemember (ADSM) or are calling about one. This expansion increases the scope of services that are available to ADSMs who may be in crisis.

Collaborative care is an example of an immediate solution that DoD is aggressively implementing. According to DoDSER data, 36 percent of completed suicides had a history of a mental health condition. Providing mental health services in conjunction with primary care is an important part of our prevention strategy because early detection and intervention is a key to preventing suicide behaviors. Each Service is developing collaborative care models based on recommendations from a National Institute of Mental Health (NIMH) study. The DCoE collaborates with the Services to integrate the best practices from these models to develop consistent standards across DoD. DCoE is currently implementing a controlled trial study at 6 sites and 18 clinics of collaborative primary care to inform future efforts.

In August 2009, the DoD Suicide Prevention Task Force was established under the purview of the Defense Health Board. The goal of the task force is to provide recommendations to legislative and administrative bodies on suicide prevention within the military.

#### **Reducing Stigma**

The Department recognizes the importance of eliminating the toxic threat of stigma by transforming its culture from reactionary to a more proactive environment by engaging leadership to encourage transparency, accountability, candor, and respect. The DoD is promoting awareness among leaders and urging them to lead by

example in matters related to health and well-being. In addition, changes in policies and messages to all levels help create a safe culture to seek help. One significant change was the revision of question 21 on the questionnaire for security clearances on whether a servicemember has sought mental or behavioral help in the past year. DoD believes that servicemembers should not have to deny themselves the care they need and deserve out of fear of repercussions. Our efforts to combat stigma will continue alongside our efforts to provide the best prevention, intervention and treatment options.

Additionally, DoD is undergoing a cultural transformation to push care closer to the servicemembers and their families. An emphasis on early intervention for antecedent issues such as post traumatic stress, depression, and substance abuse can help address needs before they develop into bigger issues that could contribute to suicides. This population based approach enables DoD to engage multiple audiences including peers, families, units, and communities to support suicide prevention, risk reduction, and overall health promotion. The Services also have programs to address needs before they develop into issues that must be addressed in a specialty care setting.

DCoE helps combat stigma through the Real Warriors Campaign, a public education initiative that reinforces the notion that reaching out is a sign of strength. Under the theme of “Real Warriors, Real Battles, Real Strengths,” this effort provides concrete examples of servicemembers who sought care for psychological health issues and are maintaining a successful military career. While primarily focused on stigma, the Real Warriors Campaign is actively engaged in the fight against military suicide in a number of ways:

- The Web site prominently displays the National Suicide Prevention Lifeline on every page;
- Two video profiles of servicemembers involved in the campaign openly discuss their struggles with suicidal ideation from a position of strength and optimism having reached out for care that is working; and
- The site allows servicemembers, veterans, families and health professionals to confidentially reach out to health consultants around the clock through the Real Warriors Live Chat feature or by calling the DCoE Outreach Center.

The Campaign’s message boards include numerous posts from servicemembers who share their coping strategies for dealing with suicidal ideation. The site includes content that focuses on suicide prevention and substance abuse. Short, documentary-style videos illustrate the resilience exhibited by servicemembers, their families, and caregivers.

Since the Real Warriors Campaign launched in May 2009, the Web site, [www.realwarriors.net](http://www.realwarriors.net), saw more than 45,500 unique visitors from 127 countries, with more than 69,128 visits and 450,000 page views. The DoD believes that stigma can be defeated by encouraging and supporting servicemembers to reach out when help is needed.

### **Research**

A critical component of DoD’s strategy is advancing research. As part of DoD’s research portfolio, the RAND Center for Military Health Policy Research is reviewing and cataloging suicide prevention programs across the Services with recommendations for enhancements of current programs. The results will be released March 2010 and disseminated to inform future program development.

A pilot study that showed promise in the civilian sector is the Caring Letters Program. In a randomized clinical trial, sending brief letters of concern and reminders of treatment to patients admitted for suicide attempt, ideation, or for a psychiatric condition was shown to dramatically reduce the risk of death by suicide. In an effort to determine the applicability to military populations, the National Center for Tele-Health and Technology (T2) is piloting a program at Ft. Lewis, Washington. The goals of the Caring Letters Pilot are to (1) test the feasibility of expanding the program to other military treatment facilities, (2) collect preliminary outcome data, and (3) evaluate the method of letter transmittal (email vs. postal mail). Since its inception in July 2009, 81 letters have been sent. Efforts are currently underway to plan a multi-site randomized control trial.

### **Department of Defense Initiatives**

Many programs are currently in place to raise awareness among servicemembers, train civilian providers supporting our servicemembers and communities, and increase leadership involvement in behavioral health efforts. The programs are on all levels, from the national level down into local communities. These initiatives, including programs that provide face-to-face support or online support, demonstrate

DoD's multi-pronged approach and commitment to ensuring servicemembers and families have access to the best resources. Some examples of these efforts are detailed below:

Each Service has its own suicide prevention initiatives tailored to its culture. In November 2007, DoD established the DCoE to offer a central coordinating point for activities related to psychological health concerns and traumatic brain injuries. DCoE focuses on the full continuum of care and prevention to enhance coordination among the Services, Federal agencies, and civilian organizations. DCoE works to identify best practices and disseminate practical resources to affected communities. In this effort, emphasis is placed on building resilience, supporting recovery, and promoting reintegration to ensure a comprehensive, multi-faceted, and proactive approach in promoting health and well-being.

The Suicide Prevention and Risk Reduction Committee (SPARRC), chaired by DCoE, provides a forum for inter-Service and VA partnership and coordination. Members include Suicide Prevention Program Managers from the Services and representatives from the National Guard Bureau, Reserve Affairs, VA, Office of Armed Forces Medical Examiner, T2, Substance Abuse and Mental Health Services Administration, and others. This committee is the main venue for ensuring collaboration and consistency in systemwide communication related to suicide, risk reduction policy initiatives, and suicide surveillance metrics across the military. A SPARRC Web site is currently in development to serve as a "clearinghouse" for suicide prevention information, contacts, innovative approaches, and tools.

Additionally, the DCoE Outreach Center coordinates with Military OneSource, accessible by phone at 1-800-342-9647. Licensed mental health consultants are available to listen, answer questions, and refer callers to a wide range of services 24 hours a day, 7 days a week, 365 days a year. Military OneSource provides services on a range of other topics including education, relocation, and parenting.

Another DoD program that encourages seeking care is inTransition, which provides a bridge of support for servicemembers while they are transitioning between health care systems or providers. The program assigns credentialed "Supercoaches" on a one-on-one basis to servicemembers in transition. These "Supercoaches" provide support, encouragement, and promote continued use of behavioral health services.

In an effort to increase access to resources and align with modern communication platforms, DoD is harnessing technology and social media tools. Afterdeployment.org, an interactive Web site developed by T2, provides servicemembers and families behavioral health information using an anonymous platform. This mental wellness resource is designed to help servicemembers and families manage the challenges faced after a deployment. In addition, Afterdeployment.org launched a series of free podcasts, available on iTunes, discussing a variety of mental health issues affecting servicemembers and families. Since the rollout in August 2008, Afterdeployment.org has seen 86,083 visits to its Web site. Afterdeployment.org is currently developing both a mobile version of the site and a mobile application. The portability will allow access to resources regardless of location.

Telebehavioral health refers to use of telecommunications and information technology for clinical and non-clinical behavioral health care services. Telebehavioral health may include the use of videoconferencing, Web-based cameras, email and telephone. T2 is exploring ways to supply timely telebehavioral health services to servicemembers in theater and during health screenings immediately upon return to the continental United States. The use of technology provides servicemembers and their families access to psychological health care even in the most extreme and/or remote circumstances.

#### **Medication and Suicide Risk**

The Department supports the use of psychopharmacological treatments as a key component of mental health care. Scientific evidence over the past several decades points to the role of medications in limiting the severity and duration of illness as well as for preventing relapses and recurrences. These findings have been translated into recommendations for clinicians in the VA-DoD Clinical Practice Guidelines for Major Depressive Disorder, Post Traumatic Stress Disorder, Psychoses and Substance Use Disorder. These guidelines are updated periodically as required to reflect the most current knowledge concerning each of these conditions. Recognizing that all medications carry potential risks as well as benefits, clinicians must exercise their judgment in applying these guidelines and determining the most effective use of medications, other therapies which include Cognitive Behavioral Therapy, Cognitive Processing Therapy and/or Prolonged Exposure treatment, or a combination of medication and therapy. Therapy must be monitored, with careful attention to diagnosis, dosing, clinical response and potential adverse events.

In recent years, antidepressant medications, particularly the use of Selective Serotonin Reuptake Inhibitors (SSRIs), have been closely evaluated for the increased risk of suicide-related behaviors in adolescents and young adults associated with their use. In recognition of this risk, the FDA requires a “black box” warning in the product labeling of all antidepressant medications that advises clinicians to closely monitor any worsening in depression, emergence of suicidal thinking or behavior, or unusual changes in behavior, such as sleeplessness, agitation, or withdrawal from social situations. Close monitoring is especially important during the first 4 weeks of treatment. The FDA also recognizes that depression and other psychiatric disorders are themselves associated with increased risks for suicide.

Accordingly, the Department uses multiple tools to address the identified risk for antidepressant as well as other medications, as scientific evidence reaches the threshold for action. These methods include dissemination of safety alerts to clinicians, patient information sheets, pharmacy monitoring for harmful combinations of prescribed medications, adherence to the Joint Commission standards governing medication reconciliation, compliance with the reporting of adverse events, increasingly sophisticated use of pharmacotherapeutic analysis as well as training and education programs in evidence-based modalities reflecting the most current clinical practice guidelines.

The DoDSER data base, while still maturing, provides an unprecedented repository of Service suicide surveillance data that will continue to inform our efforts. Further, we look forward to the payoff from continued research investments.

### **Way Forward**

Suicide is a problem that needs solutions now. DoD is focused on rapidly translating best practices into applicable tools for servicemembers and families. At the same time, DoD continues to improve on collaborative relationships across the Services and with national experts, collecting data, and in research efforts that will accelerate improvements in current services and programs as well as spur new innovations. In addition, DoD will also continue to evolve and leverage our population-based system to push innovations in prevention and care toward the servicemember and family.

DoD’s current initiatives to address the challenges placed on servicemembers and their families are progressing, but we recognize that there is still much to be done. In order to build on our current efforts and successfully shift to a model of population-based care, we identified the following areas of additional focus.

An issue of increasing concern is suicides of military family members and how to support surviving families. At this point in time, DoD does not track suicides of military family members. However, DoD recognizes the importance of engaging and supporting this population, as their sacrifices deserve our recognition. The DoD Suicide Prevention Task Force met this year with surviving families at the Tragedy Assistance Program for Survivors (TAPS) Seminar. The DoD Task Force will provide recommendations to the Secretary of Defense and Congress. Efforts will be focused on increasing outreach to families; providing families with more education and training to recognize the signs of suicidal behavior and where to seek help; and supporting families after a suicide event. In addition, for calendar year 2010, SPARRC partnered with TAPS to form a subcommittee to identify additional needs of families and to recommend concrete solutions.

Postvention, which refers to all activities and response after a suicide event, is another area of growing attention. The goals of postvention include: (1) promote healing, (2) reduce risk of contagion, and (3) identify those at risk and connect them to help. Postvention is also viewed as a form of prevention for survivors. This year, DoD will work with the Services to promote consistent postvention protocols across programs.

Connect/Frameworks Suicide Postvention Program is a civilian program that utilizes evidence-supported protocols to promote an integrated community-based response to suicides. Postvention protocols and guidelines include topics such as discussing cause and method of death; how to address needs of families; memorial service activities; and media coverage and messaging.

In addition to prevention, intervention, and treatment, DoD is shifting attention to increasing resilience. DoD promotes a holistic approach that optimizes the physical, psychological, and spiritual components of the human condition. The DoD is also piloting resilience programs in military settings to determine applicability and effectiveness within military populations. While the impact of deployment on suicide is still under investigation, it cannot be denied that an era of high operational tempo and persistent conflict increases pressure on our warriors. A comprehensive approach to enhancing resilience actively confronts the increasing stressors servicemembers face in this environment.

2010 will also provide DoD further opportunities to demonstrate a public health model of prevention, by supporting peer-to-peer programs in the Services and continuing to increase the number of mental health providers in communities. DoD is actively engaged in hiring more mental health providers and providing them with quality and continued training.

#### **Conclusion**

Through our united and concerted efforts, we can continue making a change for the better. DoD recognizes the need to provide the resources and programs necessary to maintain the resilience and motivation of our servicemembers and families. We will continue to emphasize education as we deliver our core messages. “You are not alone; treatment works; the earlier the intervention the better; and reaching out is an act of courage and strength.”

We are devoted to this effort and will continue to work aggressively to prevent the unnecessary loss of life.

With the Committee’s continued assistance and support, we will ensure our brave men and women in uniform and their families have access to the resources they require.

On behalf of the DoD, thank you for the opportunity to highlight these vital issues. I look forward to your questions.

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#### **Statement of Bart P. Billings, Ph.D., Carlsbad, CA (Psychologist and Author)**

##### **I. Role of Psychiatric Medications in Suicide**

If you were the parent of a son or daughter serving in the military, would you want your child being prescribed medication, on the battlefield or off, which contained a black box warning that states:

##### **Suicidality and Antidepressant Drugs**

**Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. . . .**

A medication guide appears at the end of the label. The label states, “The prescriber or health professional should instruct patients, their families, and their caregivers to read the medication guide and should assist them in understanding its contents.”

The medication guide gives specific guidance about identifying danger signs:

**Call a health care provider right away if you or your family member has any of the following symptoms especially if they are new, worse, or worry you:**

- Thoughts about suicide or dying
- attempts to commit suicide
- new or worsening depression
- new or worsening anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worsening irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

**Identical or nearly identical warnings and information can be found in all antidepressant labels.** The strongest warning pertains to children and young adults up to age 24, which includes many young military personnel.

From 2002 through 2008, there has been nearly a doubling of psychiatric medications prescribed to our military personnel and their families. At the same time, there has been a surge in the number of suicides among servicemembers and their family members that appears to correlate directly with the increased use of psychiatric medication.

Stop and think about the fact that military personnel, who carry a weapon 24 hours a day, 7 days a week, for a year deployment, can be given a medication that has a black box warning, indicating a potential side effect can be suicide as well as aggressive, angry and violent behavior that can lead to homicide. If a medical practitioner prescribed this type of medication in the civilian community, to a patient who constantly carried a loaded weapon (had a permit to do so) and had extensive training on how to use this weapon, they could likely be charged with malpractice and possibly lose their license to practice medicine. If there was a suicide or homicide by this patient, directly related to this prescription, then the practitioner could be criminally charged.

When discussing this issue with several civilian private practice physicians, they stated that they would not prescribe psychiatric medications to this type of patient but would refer the patient for counseling. This is not the case with many Veterans Administration (VA) psychiatrists, who in most cases prescribe psychiatric medications to the veterans they treat. I was recently at a professional conference at a local college where a VA psychiatrist admitted openly that he prescribed psychiatric medication to 98 percent of the patients who he treated at his clinic located in North County, San Diego.

In 2008, the *New York Times* reported Dr. Ira Katz, head of mental health services in the VA, wrote an email to his staff stating: The VA should be quiet about the rate of suicide attempts with veterans receiving VA services. It should be noted that about 1,000 suicide attempts a month were reported in veterans seen at VA facilities. Again, one must look at the relationship between extensive numbers of psychiatric medication being prescribed at the VA and the large number of suicides and attempted suicides by veterans receiving services at the VA.

For the past 27 years, I have been living within 15 minutes from Camp Pendleton Marine Base, which is a major staging area for marines sent into battle and returning from battle. My proximity to one of the largest marine bases in the world has allowed me to see firsthand what many young military personnel and their families experience. I have seen military personnel as patients, as an expert doing evaluations for legal cases involving marines and as a member of an advisory board at Palomar Community College providing scholarships to military personnel and their families. I have spoken with marines at various social functions as well as through service clubs and charity events. This exposure has helped me to conclude that one of the biggest fears that a marine has in discussing his personal combat stress reactions to others is that he will be medicated.

In 2007, a reporter, Rick Rogers from the *San Diego Union Tribune*, published a story stating that more marines died at Camp Pendleton from suicide, homicide and motorcycle accidents (34 percent increase in motorcycle deaths between 2007 and 2008) than marines deployed from Camp Pendleton who died in combat.

This same reporter, previous to this article, reported that marines and other military personnel were being sent into combat while on psychiatric medication. He was one of the first reporters in the country to report on this policy, developed by the chief psychiatrists in all military services. An article in *Time* magazine a few years ago discussed the medication of our military in depth and identified, by name, the leading proponents of endorsing the use of psychiatric medication on the battlefield. Principally Colonel Cameron Ritchie of the Army and Captain William Nash of the Navy.

At a past educational conference that I was invited to 3 years ago, as a VIP at Camp Pendleton, I had an opportunity to ask the Commanding General of the Camp Pendleton Marine Base what he thought about Mr. Rogers article regarding marines being sent into combat while on psychiatric medication. His response was similar to many other combat commanders I have spoken with, who have been educated by military psychiatrists. He stated that mental health diseases should be treated like any physical disease, and that would be by administering medication. He stated that if you had an infectious disease, you would get an antibiotic and if you had a mental disease, psychiatric medication could be similarly administered. When I mentioned that the side effects of antibiotics had no black box warning of possible suicide and psychiatric medication did, he was quick to state he never took medication himself and wouldn't do so.

The questions that need to be asked:

- How can medical practitioners in the military and the VA get away with what, in the civilian community, could be considered malpractice and in certain cases criminal?
- Why are military mental health psychiatrists or their disciples, who initially recommended the use of these types of medication to their mental health subordinates, who are located on the battlefield, still in positions of leadership and



funded, with the responsibility to explain the causes of continued escalation of suicides in the military?

- Why hasn't there been a change in mental health leadership who has consistently failed to stop the drastic increase in suicides and homicides in the military?
- Why haven't there been widely published post-mortem reports on all suicides and homicides, both on the battlefield and at home, clearly identifying if the victim was on psychiatric medications?
- Does anyone believe that military mental health staff who advocated initially using psychiatric medication, will ever do research that demonstrates that the same medications they recommended be used on our military personnel has direct side effects that can lead to suicide and homicide?

Hopefully some, if not all of these questions can be answered in testimony provided at these congressional hearings.

I don't believe the current increase in suicides and homicides in the military is a coincidence, based on my personal observations, as well as other professionals' observations and writings on the subject. A recent text, "*Medication Madness*," written by a world renowned psychiatrist, Peter Breggin, M.D., on adverse reactions to medications, discusses in depth the science and end results of adverse reactions to psychiatric medications. This text should be read by anyone taking or prescribing medication. I have personally spoken with psychiatrists, who work with military personnel, who have informed me they changed the way they currently treat their patients (reducing their use of medication) after hearing Dr. Breggin speak about adverse effects of psychiatric medication.

At the 17th Annual International Military and Civilian Combat Stress Conference in May 2009, everyone attending the conference heard an Army social worker state that the use of psychiatric medication on the battlefield was rampant. She had completed two 1-year tours of duty in Iraq and Afghanistan and estimated that 90 percent of the U.S. combatants have used, at one time or other, psychiatric medications. She explained that they are being handed out, not only by physicians but also by physicians assistants, nurses, medics and even from soldier to soldier. She was told by various psychiatrists, while deployed, to support medicating troops and in one instance that her services on the battlefield were useless since she could not prescribe medication.

At the same combat stress conference, an Army Lieutenant Colonel Commander described how some of his troops, after returning to Germany from Iraq, were given psychiatric medications and how their behavior deteriorated after receiving the medications.

Prescriptions for all TRICARE beneficiaries, according to a Department of Defense (DoD) claims database (attachment 1 and 2), indicate that in 2002 a total of 3,739,914 prescriptions for antidepressants and antipsychotics were issued. In 2008 the number of these prescriptions rose to 6,413,035 (attachment 1 and 2).

Figures for 2009 are not available at this time but based on the steady progression of increased amounts of medications prescribed, one would assume the total prescriptions, to date, would be over 7 million.

In 2009, the number of suicides in the military surpassed the civilian death rate from suicide. The suicide death rate for military personnel was 20.2 per 100,000 while the civilian death rate was 19.2 per 100,000. Veterans between the ages of 20 to 24 had a suicide death rate of 22.9 per 100,000, which is 4 times higher than non-vets the same age. It should also be noted that statistics indicate that there are 10 failed attempts at suicide for each actual completed suicide.

This is the first time in decades that military suicides are at the current level. Presently we now have the highest level of suicides in the military that we have seen in three decades. Since 2001 there have been 2,100 suicides in the military, triple the number of troops that have died in Afghanistan and half of all U.S. deaths in Iraq. The correlation of increased suicides, as well as homicides, in the military, and the increased use of medications, with a side effect of suicide, irritability, hostility and aggressiveness does not appear to be a coincidence, but a direct link to adverse reactions a person may experience when taking these medications.

A recent study was performed in Sweden (attachment 3):

Rickard Ljung, M.D., Ph.D., Charlotte Björkenstam, M.Sc. and Emma Björkenstam, B.Sc; Ethnic Differences in Antidepressant Treatment Preceding Suicide in Sweden, *Psychiatric Services* 59:116–a–117, January 2008 <http://ps.psychiatryonline.org/cgi/content/full/59/1/116-a> Janne Larsson, reporter—investigating psychiatry, Sweden <mailto:janne.olv.larsson@telia.com>.

This study linked a direct relationship between people taking antidepressants or antipsychotic medications and suicide.

**“Thus it can be said that 561 (45 percent) of ALL male and female 1,255 persons (18–84) who committed suicide in Sweden 2006 had filled a prescription for antidepressant drugs OR neuroleptics (not at all counting other psychiatric drugs) within 180 days before their suicide.”**

Overall conclusions of the study indicated that approximately 46 percent of people taking these medications committed suicide. The study found a direct link between the use of psychiatric medication as described above and suicide.

There are many other studies that cite similar and even more significant findings, but since I don't consider myself an expert in the science of these medications, I will defer all questions in regard to the science behind these medications to Peter Breggin, M.D., who will provide extensive testimony in this area. Dr. Breggin has a prestigious background with the National Institute of Mental Health (NIMH) and elsewhere, where he researched the science of the medications we are discussing.

Also information on the Internet Web site [www.ssristories.com](http://www.ssristories.com) lists hundreds of civilian and military cases of death, suicide, attempted suicide, etc. that are linked to psychiatric medication. It identifies such cases of sudden death in soldiers taking a combination of psychiatric medications, the May 11th, 2009 Iraq mental health clinic shooting where 5 soldiers were killed by a soldier on psychiatric medication.

On the other side of the coin, I have not observed significant long-term studies that have ever shown any psychiatric medication to be effective in treating Post Traumatic Stress Disorder (PTSD), for which significant prescriptions in the military are written. I am not saying that the FDA hasn't seen research presented to them by pharmaceutical companies, that allowed them to approve these medications for treating PTSD, but am concerned that these studies were less than one would desire to approve treating all our military as well as their families. When positive results are reported, they are typically short-term, not long-term effects.

## II. National Tri-Service Combat Stress Conference

As a retired military officer and founder and director of the longest running combat stress conference in the world, I have had the opportunity to talk with numerous active and reserve military personnel and their families. I have also heard presentations from experts from throughout the world on stress reactions to combat. As a clinical psychologist and mental health professional for over 42 years, I have had the opportunity to see patients while in the military (33 years, 9 months in USAR), as well as in my civilian practice. These experiences have also allowed me to teach classes on combat stress reactions in the military as well as in the civilian community.

I have been honored with military awards (attachment 4) and my work has been lauded by DoD officials for developing the International Military and Civilian Combat Stress Conference, as well as other programs (attachment 5, 6, 7 and 8).

As a military and as a civilian psychologist, I have had an opportunity to develop firsthand opinions regarding, not only the relationship between psychiatric medications and suicide, but other adverse reactions our military personnel experiences that interfere with their performance on the battlefield and when returning home to their families.

My overall observations and clinical experience leads me to state, emphatically, that integrative treatment approaches in treating combat stress and related problems is more effective in the long run, than prescribing drugs, both as a force multiplier and a money saver.

Integrative approaches—such as individual counseling, bio-feedback, guided imagery, progressive relaxation, peer counseling, cognitive-behavioral therapy, virtual reality therapy, implosive therapy, hypnosis, etc. have little or no adverse reactions and there is research that shows them to be effective both short-term and long-term. It should be noted that during the first Persian Gulf War, combat stress chambers were successfully used to reduce stress. This is more that can be said currently of psychiatric medication. A recent book written in 2007 by a world-renowned psychologist, Stanley Krippner, Ph.D. and his associate, Daryl S. Paulson, Ph.D. titled *“Haunted by Combat,”* as well as an epilogue to this text presently being published in the 2010 paperback, gives extensive examples and findings as to the success of providing integrative mental health treatment protocols.

If one considers that the average cost of a prescription for an antidepressant or antipsychotic can cost anywhere from \$25 to \$50 each, then the cost the DoD is billed for so-called mental health prescriptions should likely exceed \$2 billion a year. This level of funding could pay for all the mental health professionals needed to pro-

vide the integrative treatment programs our military personnel and their families need, with no fear of adverse reactions and every expectation of success. If implemented, there are strong indications that the suicide rate would drop dramatically, as well as the increasing number of soldiers being diagnosed with PTSD and other reactions to combat stress.

During the first Persian Gulf War, I was in a medical unit, the 6252nd U.S. Army Reserve Hospital, which deployed most of its military personnel. Upon returning after the war ended, I observed many varied problems among the soldiers. These problems consisted of emotional difficulties, marital difficulties, financial problems, general health problems, legal problems, family problems, spiritual problems, etc.

What was striking at the time was that most of these problems could have been minimized or completely avoided if the soldiers were better prepared prior to deployment. With the assistance of the Commanding General of the 6252nd and the staff of our Combat Stress Company, I developed a readiness protocol to address all of the issues one had to deal with prior to and when actually deployed, as well as when returning home. We came up with a 20-minute interviewing manual that, with minimal training, one could administer to each member of a military unit.

The soldier would respond for themselves as well as for their family. The program was called the Human Assistance Rapid Response Team (HARRT—brochure attachment 9 and 10). Members of the Combat Stress Company administered the instrument to military units with significant success. Readiness problems improved and returning prematurely from deployment dropped. The HARRT program also identified Suicide Ideation and Homicide Ideation.

Out of the HARRT program, a 2-day conference (attachment 11) was born to teach how the HARRT program could be utilized and improved. This conference led to an annual National Tri-Service Combat Stress Conference held for 15 years at Camp Pendleton Marine Base in California. Today this conference, which is held the first week of May, is going into its 18th year and has been re-named The Annual International Military and Civilian Combat Stress Conference.

In December 1997, I was invited to the Pentagon by Brigadier General Richard Lynch to address the Army Reserve Forces Policy Committee's Mobilization Subcommittee in regard to the HARRT program. The committee was made up of seven Major Generals with command experience. After my presentation of the HARRT program, Major General Donald F. Campbell, chairman of the committee, stated that the total committee supported the implementation of the HARRT program (attachment 12). Major General Campbell stated in his letter **"As chairman of that mobilization subcommittee, I am pleased that our decision to support your program has assisted you in your commitment to pursue your goal of fully implementing the HARRT program with all our military services, both Active and Reserve."**

Major General Hennis, who was one of the committee members of the above-mentioned panel and a Commanding General for the National Guard in one of our southern States, requested at the committee meeting that the HARRT program be first fully implemented for all members of the National Guard in his State. Since there was no followup funding from the DoD to fully implement the HARRT program, this request could not be followed up on at the time. This lack of funding and followup from DoD was repeated on other occasions resulting in the underutilization of an admittedly viable program. In another instance, a National Guard Special Forces unit in California specifically contacted me to perform the HARRT interviews on all their members prior to deployment. Since there was no funding and orders to honor their request received from DoD, the request could not be implemented. The Special Forces commander was upset and disappointed his request could not be honored and had to deploy knowing his unit could have been better prepared to depart.

On May 28, 1999, I was invited to visit the Department of the Army's Office of the Surgeon General. As a result of the visit, a letter was written (attachment 2) commentating favorably on the Combat Stress Conference, the Prisoner of War Conference and the HARRT program. A comment in the letter specific to the HARRT program is as follows: **"It is reasonable to expect that this program alone will directly benefit hundreds of thousands of servicemembers and their families."** This comment was related to a then recent DoD directive 6490.5, instructing all military organizations to implement Combat Stress programs.

From 1997 and later in 1999, when the HARRT program and Combat Stress Conferences were initially supported by the above-mentioned DoD organizations at the Pentagon, there has been little followup by DoD to fully follow through and implement these viable Combat Stress educational and preventative programs. This lack of followup has predictably resulted in many hardships for military personnel as well as their families. No one knows how many suicides and homicides could have

been averted if these, admittedly quality Combat Stress programs could have been fully implemented back in 1997 or 1999. Instead the DoD has supported the extensive use of psychiatric medication, which appears to have worsened the problems of combat stress, which can be readily measured by the increases in suicide and homicide in the military.

In 2005, the military command, from the Tri-Service Combat Stress Conference founding organization (6252 USAH), stated it did not have the staff or funding to continue the Tri-Service Combat Stress Conference and asked myself and other retired officers if we could continue the conference privately, with no military funding or support. This request was shocking, due to the fact that the need for combat stress training was elevated since the beginning of the War on Terrorism. This lack of support for combat stress training was consistent with the lack of DoD followup mentioned above. This challenge to continue the training conference was taken up by a few dedicated retired officers and today the conference still continues and is now the longest running and in my mind, one of the best conferences held in the world on combat stress. It should be noted that in 1999, when I visited the DoD to discuss the conference, I suggested that the DoD take over the conference due to the important nature of the content and the fact that when I retired I was fearful the conference would not continue. I was told that I was doing a good job both verbally and in writing but that they were not interested in assuming leadership of the conference.

To date, the International Civilian and Military Combat Stress Conference has trained thousands of military and civilian personnel on how to effectively deal with combat stress related problems. It has also motivated other military and civilian groups to start their own conferences on combat stress. It is considered by many to be the gold standard of all combat stress conferences, as demonstrated by the many world-renowned military and civilian instructors and Federal and State legislative people who have attended and have given presentations over the years.

(For conference history and previous instructors see [www.tservsc.bizhosting.com](http://www.tservsc.bizhosting.com)). At the onset of the current War on Terrorism, many expert presenters at the Combat Stress Conference warned that military personnel should not be medicated when on the battlefields or when eventually returning home. The overall consensus of presenters, as well as people attending the conference, was that integrative treatment was the most effective way of dealing with combat stress issues. I would estimate that only 2 percent of people attending the conference advocated medicating soldiers. This 2 percent consisted primarily of psychiatrists. It should be noted that most psychiatrists are primarily trained to administer medication and generally don't have the training to provide integrative treatment. This lack of exposure to integrative treatment can be traced back to the medical schools that train psychiatrists. An example of this was when I recently questioned, at a conference where he was a presenter, a chief psychiatrist who worked in a VA clinic. He stated at this public forum that he medicates 98 percent of the veterans he sees as patients. This is not an isolated instance based on common psychiatry practice standards.

I have personally seen military personnel as patients, who explained that they were given antidepressants on the battlefield to simply try to stop smoking. One marine explained to me that when he returned back home, he could find no indication in his medical record that he was ever given psychiatric medication. He experienced cognitive problems from the first time he was given the medication and when he complained to the medical staff, he was given even more psychiatric medication. It wasn't until he, on his own, took himself off the medication after 2 years that he returned to normal functioning. This marine was interviewed by me and California Assemblyperson Mary Salas' (Chair of Assembly Veterans Committee) Chief of Staff, Francisco Estrada, to evaluate veteran's services in California. This is not an isolated case since I have encountered many military personnel with the same experiences. The use of the psychiatric medications is prevalent on the battlefield, where it is being dispensed not only by medical doctors but also by physician's assistants, medics, soldier to soldier, etc.

#### **SUMMARY AND RECOMMENDATIONS**

Since the War on Terrorism began, there has been a steady increase in suicide and homicide in the military. There has also been a steady increase in the number of psychiatric medications purchased by DoD and prescribed to military personnel and their families. Research and the FDA (black box warning) have revealed that there is a direct relationship between the use of psychiatric medication and suicide. The black box warnings on the actual medication label also describe the link between the medication and suicide, as well as other cognitive effects, which can also trigger homicidal behavior.

There have been integrative treatment training programs, as well as actual treatment protocols, available since the end of the first Persian Gulf War that have been effective in treating and identifying residual effects of combat stress, i.e. the Human Assistance Rapid Response Team (HARRT), Tri-Service Combat Stress Conference. These programs have been underutilized and underfunded in favor of widespread use of psychiatric medications with the result being increases in military suicide and homicide.

A solution to the ongoing and increasing problems with suicide and homicide is not more medication but more integrative treatment programs administered by trained mental health providers, as well as military leadership personnel.

The full implementation of the HARRT program as a readiness tool, as well as its use as an instrument to identify potential suicide and homicide ideation is advisable. The HARRT program was recognized by DoD personnel as a valuable tool, as far back as 1997 and 1999, with recommendations at that time to fully implement the program.

Also DoD should recognize that all military personnel in combat experience Post Traumatic Stress (PTS)—notice there is not a “D” at the end. PTS for military personnel is a normal reaction to being in an abnormal environment, the battlefield. PTS becomes a disorder (D) when the soldier (term referring to individuals in all military organizations), does not learn ways of dealing with the PTS and how to normalize themselves. If this normalization process does not occur, then the soldier can develop a disorder and the PTS can become Post Traumatic Stress Disorder (PTSD).

It is critical that the DoD become aware of the difference between PTS and PTSD. If DoD can recognize that psychiatric medication has not been effective in treating combat stress, than a natural conclusion would be to turn their focus and finances to methods that have been approved and worked in the past to various degrees and expanding these programs.

**One program that should be strongly considered for implementation by DoD should be a mandatory one (1) hour a day program for thirty (30) days for all military personnel returning from combat zones.** This mandatory 1 hour a day, of structured mental training (MT), administered by trained staff, using a militarywide standardized approach, will help all returning soldiers realize that they are having normal reactions from being in an abnormal battlefield environment. By learning methods of dealing with abnormal experiences and developing coping approaches through integrative treatment methods, they can return to normal functioning. There will no longer be a need for soldiers to hide what they are experiencing since all individuals, by attending mandatory MT programs, will realize that they are all human beings, in a similar situation, subjected to the same stresses and similar experiences.

Cutting back on the extensive use of psychiatric medication and implementing integrative programs such as the HARRT program, MT programs and similar programs throughout the military, could lead to strong expectations for significant decreases in PTSD, suicide and homicide in the military. This decrease would result in more soldiers being available for deployment, reduction in family and personal hardships and a reduction in psychiatric disability moneys being spent, while in the military as well as when the soldier returns to civilian life after discharge.

