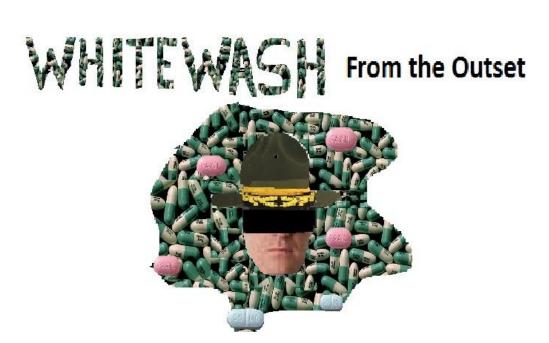
Fort Hood Shootings--April 2, 2014



Authored by Donald J. Farber, Attorney at Law ©2014 May 20, 2014

For 15 years Donald J. Farber has represented clients in actions involving antidepressant induced side effects. He has testified as an expert witness on the marketing of antidepressants and before the House of Representatives and FDA public hearings on evidence gathered during litigation on antidepressant induced suicide. In 2002 he met with senior FDA officials with allegations and evidence that antidepressant suicidal risk was being suppressed by certain drug companies. The FDA investigated the allegations and, as a result of the agency's findings, conducted hearings which resulted in the antidepressant suicide warnings that the FDA ordered in 2004. Farber served as a surface warfare officer in the U.S. Navy for 25 years, with 13 years sea duty

*** *** *** *** ***

How can the Army be accused of whitewash when the results and findings of Fort Hood are still pending? That is a fair question, but the premise is wrong. The Army's findings on Fort Hood were determined long ago.

At the live news conference following the April 2nd Fort Hood shootings, on scene commander Lieutenant General Michael Milley was asked this follow up question by the

reporter who had just solicited from him that the shooter was on medications: "Like SSRIs¹ or other antidepressants, things of that nature?" Milley answered "Yes he was."²

The next day in Washington Secretary of the Army John McHugh and Army Chief of Staff Raymond Odierno briefed the Senate Armed Services Committee on the shootings. McHugh reported Specialist Ivan Lopez had been "undergoing a variety of treatment and diagnoses for mental health conditions ranging from depression to anxiety to some sleep disturbance...(and)...was prescribed a number of drugs...including Ambien" a short term sleep aid.³

No media outlet reported Milley's antidepressant revelation. The few outlets that ventured to identify medication dutifully followed McHugh's cue, mentioning only "Ambien."

Those thinking the Secretary's choice of a sleep aid to associate with the shooter instead of a Prozac, Zoloft, or Paxil was an innocuous inadvertence stemming from fast moving events between Texas and Washington—think again!

The Secretary's choice of the sleep aid but not the antidepressant was as predictable as it was diversionary. One pondering McHugh's aversion to antidepressants need merely be reminded the Army has sacred policy cows to protect as it undergoes yet another investigation of violence amidst record suicides.

McHugh identifying only Ambien was particularly incongruous given General Milley's statement hours earlier indicating the shooter had been undergoing treatment for depression and anxiety. Both are psychiatric disorders for which the SSRI Paxil, for example, is FDA indicated. Ambien has no FDA authorized indication for either.

Identifying a sleeping pill instead of a drug required by the FDA to carry a "black box" warning for suicidality could not but send a signal to subordinates beginning the Fort Hood investigation that the Army's narrative on its suicide crisis would continue uninterrupted. Amidst its suicide crisis the Army has disregarded antidepressant suicide warnings from the Food & Drug Administration ("FDA") since they were first issued in 2004 and, like Secretary McHugh, won't touch the subject whenever suicide or violence erupts in the ranks.

The Army's suicide rate rose dramatically starting in 2005, exceeding the civilian rate beginning in 2008⁴. "Suicide rates double(d) among U.S. soldiers between 2004 and 2009." The service experienced 325 completed suicides in 2012 and 301 in 2013.⁶

Army History

¹ "Selective Serotonin Reuptake Inhibitor" type antidepressant, and includes Prozac, Zoloft, and Paxil.

² Fox News Live Coverage of Fort Hood News Conference April 2, 2014

³ Transcript April 3, 2014 Senate Armed Forces Committee Hearing

⁴ Army—Health Protection, Risk Reduction, Suicide Prevention, Report 2010 (hereafter "Army 2010 Suicide Report") page 11

⁵ BMJ 2014;348:g1987 doi: 10.1136/bmj.g1987 (Published 6 March 2014)

⁶ Official home page of the U.S. Army, Army News Service, February 3, 2014, http://www.army.mil/article/119301

Americans know from history what government, including the U.S. Army, is capable of undertaking if allowed to its own devices without oversight. This has included the Army's occasional sordid history of human experimentation and ethical lapses in medically related matters. One need look no further than the U.S. Supreme Court in U.S. v Stanly (483 U.S. 669 (1987)) in documenting what the Army has perpetrated on unknowing individuals in the name of science. The Army secretly administered LSD into Master Sergeant James Stanly when he was assigned to Aberdeen Proving Grounds to test its effects on human subjects, causing Stanley hallucinations, incoherence, memory loss, and impairment of military performance. His marriage dissolved because of the personality changes wrought by the LSD.⁷ The online encyclopedia lists a multitude of government and Army projects in history with unethical underpinnings, insightful reading for those placing unconditional faith that government will not at times intentionally abuse the rights of citizens through unbridled exercise of executive powers.⁸

Understanding the bureaucratic mindset and the history of U.S. involvement in Iraq and Afghanistan aids in unraveling the Army's sensitivity to the subject of psychotropic medications. A top down hierarchy, Army medicine adapted well to the exigencies of combat casualties in Iraq and Afghanistan, admirably saving countless lives and aiding the battle wounded to restore their lives. The matter of mental health and psychotropic medications in the Army and the other services, on the other hand, is a horse of a different color.

The Army became enamored with antidepressants much like the rest of the nation. SSRI use ascended rapidly in the nation as Prozac led the way in 1988, with Zoloft and Paxil soon following. It didn't take long for the Army to jump on the bandwagon. Aggressive use of antidepressants and antianxiety medications (anxiolytics) started in the 1990s as antidepressant manufacturers, citing strong endorsements from medical organizations like the American Psychiatric Association ("APA") successfully lobbied the Department of Defense ("DOD") to stock pharmacies and implement use of psychiatric medications, particularly antidepressants and anxiolytics, as a staple of military medicine. What sold in civilian life took hold in the military, including casual dispensing for minor stresses and mood swings by troop physicians without training in psychiatry. The FDA's first antidepressant suicide warning was issued in 2004 in part because of the overly casual approach with which physicians dispensed the drugs with minimal screening to determine actual psychiatric need. In the nation of the part of the property of the overly casual approach with which physicians dispensed the drugs with minimal screening to determine actual psychiatric need.

Drugging with psychiatric medications became a routine aspect of military medicine in which it was intended to facilitate overall force readiness—in short, drugging soldiers to get them out of the barracks and out on patrol! While the infantry generals running the Army hardly had time to oversee psychotropic medications in their medical corps, their involvement in preparing combat units for deployment and maintaining force structure was a call for all subordinates to fall in line. Army doctors and medics were integral to mobilizing the troops for war zone readiness.

Army Doctors and Haircuts

Army doctors in the field are extensions of the chain of command, implementing top down policies with nearly the zeal of infantry officers. It was not always that way. While medical corps commanders and hospital commanding officers were almost by definition career types, junior doctors

⁷ 97 L Ed 2nd 559.

⁸ http://en.wikipedia.org/wiki/Unethical human experimentation in the United States

⁹ http://apps.who.int/medicinedocs/en

¹⁰ Statement of FDA Psychopharmacologic Drugs' Advisory Committee (hereafter "PDAC") Chairman Matthew Rudorfer, MD to Associated Press, February 3, 2004 in wire story "Child Warnings for Adult Antidepressants Advised": "We want to put a speed bump in the road...the...(antidepressant)... warnings as they exist in the current labeling are not adequate or are not being taken seriously."

out in the field were not. A few decades ago the Army physician in the field was a short time reservist, needed a haircut, and was more sympathetic to enlisted gripes than unit discipline or orders from on high. The TV series MASH was not entirely fictional in that respect.

The all-volunteer force changed that. The 1972 establishment of the military's own medical school, i.e. Uniformed Services University of the Health Sciences ("USU") and the end of the draft the next year set a new direction in the medical corps of all the uniformed services.

The 2014 Army physician served in the military before s/he took the Hippocratic Oath, went to medical school at USU, and stays in the service longer than the colleague of a generation ago.

The Sacred Cows

One such sacred cow is the widespread and compelled use of psychiatric medications as a cornerstone of Army medicine. Twenty (20%) percent of Army soldiers were on antidepressants in 2010, according to House testimony by a general officer. The Army sees that as no big deal, the Medical Corps witness shrugging off the percentage because that is: "what you see in the general population." The analogy may be pure rationalization. CBS News reports "13 percent of the overall population... (are)...on antidepressants." Health news from San Francisco Gate reported 11% of Americans over twelve take antidepressants.... 13

Even assuming the civilian figures correct, the ordinary citizen may not view "the general population" as the desirable standard for our troops. In what Army leaders rightly herald as "the best Army in the world," the healthy and motivated American youth meeting the enlistment standard and desiring to serve wouldn't need brain altering drugs to do what earlier generation of soldiers did as a matter of course.

While one would not expect any Army physician to acknowledge subordinating any patient's care to service policy, the reality is that the medication policy, unstated though it is, serves force needs more than patients' stated needs and depends on Army physicians for implementation.

That the modern generation of soldiers must be forced fed psychiatric drugs at the same rate as the collective disabled, elderly, mentally incapacitated, incarcerated, felons, and drug and alcohol abusers is troubling to that ordinary citizen. Americans believing their sons and daughters are qualified in their own right to defend their country without the stimulating—or blunting—effect of antidepressants have to be concerned where the leadership has taken the American Army and its soldiers under the mantle of readiness.

Why the High Dosing?

http://sfgate.com/health/article/Antidepressants-nation-s-top-prescription-4034392.php

¹¹ Testimony of Brigadier General L.K. Sutton, Medical Corps, U.S. Army, February 24, 2010 before the House Committee on Veterans Affairs, "Exploring the Relationship Between Medication and Veteran Suicide," Serial No. 111-62;

¹² http://cbsnews.com/news/study-shows--70-percent-of-Americans-take-prescription-drugs-

¹³ SFGate "Antidepressants—nation's top prescription" by Kathryn Roethel,

¹⁴ Chief of Staff, U.S. Army, testimony before House Armed Services Committee September 18, 2013

In a sentence--the Army remains stuck in the 1990's, the halcyon era of antidepressants. 15

Stuck in the 1990's speaks of bureaucracy in general and Army inertia in the face of major antidepressant developments shedding light on the medication's drawbacks. The halcyon era occasioned uncontested glee sparked by rising SSRI sales and pharmaceutical marketing that the new antidepressants not only "worked," but that Prozac, the "miracle drug" would end depression forever. SSRI makers marketed their products in the 1990's under the guise depression was just a chemical imbalance in the brain and that their pills would restore the balance. The claim was never proven; yet the media spread it uncritically. It took a decade for critical researchers to verify it as a combination of market hyperbole and unwitting journalism. One SSRI manufacturer published information in 1995 that its drug outperformed placebo in preventing suicidality. The actual results were just the opposite. But the Army kept on dispensing its troops the medications without pause, actually increasing usage.

Were SSRI efficacy viewed as positively today as in the 1990s, there would arguably be justification for the Army to work through the suicide revelations without undue disruption. Such would not be incompatible with medical ethics given other safeguards providers work through. Indeed the American Psychiatric Association ("APA") remains a strong proponent of antidepressants under appropriate treatment conditions. The Army's bureaucratic nature, however, has not come to grips with updated knowledge on antidepressants as it has been revealed in recent years both in the media and scientific literature.

¹⁵ Sales for the top 3 antidepressants, all SSRIs, in 1999, totaled approximately \$6.5 billion; Prozac \$2.4 million (http://money.cnn.com/magazines/fortunes); Zoloft \$2.034,000 (http://www.uic.edu/classes/actg); Paxil \$2.052,800, http://www.gsk.com/content/dam/GSK/globals/annual-report-2000.pdf.

¹⁶ New York Times, June 30, 2002 by Erica Goode, "Antidepressants Life Clouds, but lose 'miracle drug' Label."

¹⁷ SmithKline Beecham Pharmaceuticals, in its promotional booklet PX5522 of July 1997 "Paxil...Patient Question & Answer Guide" asks "What Causes Depression?" then answering, in part, "Too often in the past, depression was mistakenly considered a sign of emotional weakness. The fact is depression is an illness with biological causes...Depression is *not* a weakness or a personality flaw...Research has shown that that the symptoms of depression are related to an imbalance of important natural substances called *neurotransmitters*, which act as 'messengers' between nerve cells in the brain...*Paxil* relieves the symptoms of depression by Increasing the amount of serotonin available to nerve cells in the brain." Numerous experts debunked this claim (infra), but most significantly the Paxil project director at SmithKline Beecham when Paxil was FDA approved, though first testifying on the chemical imbalance theory as causative of depression that "many people believe that, and I guess I believe it to some extent as well," later upon questioning on whether the "chemical imbalance" came before or after the depression, testified he thought "both are equally speculative. We don't really know the cause of depression or what is the underlying pathophysiology in depression. If we knew, we would have much more variability in the ways of managing and treating the illness." (From deposition of Geoffrey Dunbar, MD, September 14, 2005 in Civil Action No. 3:05CV25WHB, U.S. District Court, Southern District of Mississippi.

¹⁸ "The Media and the Chemical Imbalance Theory of Depression" by Leo and Lacasse, Soc (2008) 45:35-45, DOI 10.1007/s12115-007-9047-3 (Published online: 28 November 2007).

¹⁹ European Neuropsychopharmacology 5 (1995) 5-13; "Reduction of suicidal thoughts with paroxetine in comparison with reference antidepressants and placebo."

²⁰ The 1995 article, and other GlaxoSmithKline documents, listed "run-in" suicidal data against placebo during the pre-randomization phase, a scientifically fraudulent procedure. The correct result was that Paxil induced far more suicides and suicide attempts than placebo. After much litigation over this falsehood, Senator Charles Grassley, (R, IA), among others, called the FDA's attention to the discrepancy. In a contorted response to Senator Grassley's letter, Glaxo SmithKline made the best case it could to defend its false figures. (See GSK "Press Release" dated February 8, 2008 "GlaxoSmithKline Responds to Letter from Senator Grassley Regarding Paxil").

Even mainstream psychiatry, originally indignant that the FDA issued black box antidepressant suicide warnings that upset the APA's talking points that suicide warnings scare away patients who need the medications the most, has come around to acknowledge the wisdom of suicide "Warnings." That includes briefing patients directly in the case of adults, and family members or caretakers in the case of minors and the infirm. It also includes briefing 3rd party observers to monitor patients for suicidal symptoms during the early stages of antidepressant usage and upon dosage changes. Third party observance protects the patients experiencing the suicidal and other dangerous side effects but whose mental state cannot rationally process events. Both the patients and 3rd party observers are instructed to notify the health care provider immediately if any of the cited symptoms are observed. In the case of competent adults, the patient for privacy reasons may veto the physician's recommendation that a 3rd party be advised to monitor, but rarely do patients object.

The APA remains opposed to the "black box" warning, arguing it deters treatment.²²

Surprise: Antidepressants Don't Work

Harvard psychologist Irving Kirsch, PhD, has almost single handedly destroyed the 20 year myth that antidepressants work. Before qualifying this more accurate than inaccurate statement, it is noted that unlike all other commentators in recent history Kirsch accessed via Freedom of Information ("FOI") previously unpublished trial data submitted to the FDA by antidepressant manufacturers seeking licenses, and along with colleagues published findings of that review in 2008.²³ The qualifier to this paragraph's first sentence is that Kirsch's study confirms pharmaceutical claims that antidepressants are effective in treating severe depression, but not the lesser the forms of "mild" and "moderate" depression.

In 2012 *Sixty Minutes* ran a segment on Kirsch and his research. Leslie Stahl explained Kirsch's findings: "if you're moderately depressed or mildly depressed, a sugar pill would do just as good."²⁴

Not unexpectedly Kirsch came under fire from antidepressant advocates, a given over the years when anyone raises a red flag questioning the medications. They took swipes at

6

²¹ The APA's representative to the FDA's Feb. 2, 2004 PDAC, David Fassler, MD, stated at that forum: "(W)e are concerned that the publicity...(about antidepressant induced suicidality)...surrounding this issue may frighten some parents and discourage them from seeking help for their children. This would be a real tragedy since the reality is that we really can help most of these kids." (From *PDAC 2/2/04 transcript*, page 226 line 25 to page 227 line 5). Dr. Fassler again appeared at the follow on PDAC September 13, 2004 following the FDA's March 22, 2004 public health advisory ordering suicide warnings for adults as well as children. At the 9/13/04 forum, Fassler stated: "(W)e 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, understanding and scientific data." (From PDAC 9/13/04 transcript, pp 300-301).

²² In response to concerns like the APAs, in its addition of young adults to the BBW on May 2 2007, the FDA ordered that the BBW include the statement that failure to obtain treatment for depression also may cause suicidality, and that antidepressants showed a positive result for adults over 65.

²³ Kirsch I, Deacon BJ, Huedo-Medina TB, Scoborio A, Moore, TJ, Johnson BT, PLoS Med 2008 Feb; 5(2):e45;

²⁴ http://www.cbsnews.com/news/inside-60-minutes-placebo-story/

Kirsch for spearing their sacred cow, charging that he and his colleagues never proved that antidepressants don't work. Kirsch's pushed back at his critics, stating that what they alleged was "absolutely true...what we have shown is that the data upon which drug approval was based does not show clinical significance...Possibility is a long way from fact...The onus should not be on critics to demonstrate that a treatment in ineffective, but rather for proponents to demonstrate that it is."²⁵

Kirsch should be mandatory reading for Army physicians casually passing out antidepressants. It seems highly likely that the vast majority of Army soldiers to whom antidepressants are prescribed, if suffering depression at all, were not suffering severe depression which is, technically more akin to "major depressive disorder" ("MDD"). While outsiders such as this writer have no access to such medical information, it is likely the Army doesn't either, including the individual physicians who actually treated the patients at the time unless the medical documentation was more detailed than is usually the case.

The overwhelming majority of civilian physicians, 79%, prescribing antidepressants are primary care physicians ("PCP").²⁶ This 79 percent figure is probably higher in the Army given the relative unavailability of psychiatrists out in the field.

Given large patient loads, PCP's administering sick call routinely diagnose quickly, bypassing the more formalistic clinical depression diagnostic process. War zone sick calls can require improvisation as in the movies, but even in a clinical setting PCPs diagnose and prescribe pills quickly. This does not violate the PCP standard of care, a factor in civilian care. The PCPs ensure the medical charts properly reflect the antidepressant prescribed, an easier process today given portable devices and electronic records. The indication for which treatment is prescribed would be added, e.g. "depressed," "depression," "anxious," "anxiety," often omitting the more refined formality of "severe," "moderate," or "mild" depression or "generalized anxiety disorder."

This writer's information from Army mental health professionals supports the proposition that over prescribing antidepressants and anxiolytics and the lack of monitoring of troops for suicidality after dosage lies with physicians and medics in the field having no specialized psychiatric training. One senior Army psychiatrist insisted off the record he would never prescribe an antidepressant to a patient he couldn't personally monitor, and cringed when relating the difficulties out in the field of monitoring troops for suicidality after they were prescribed antidepressants. The psychiatrist declined offering specifics when asked whether PCPs out in the field were violating the FDA's monitoring recommendations. The animated nature of the response, however, suggested he was aware of physicians in troop units dispensing psychiatric without follow-on observation and that he disapproved of the practice.

The Army has not published, and appears to have intentionally avoided establishing procedures for ensuring troops in field units are monitored for suicidality in a manner compliant with the FDA's antidepressant suicide warnings. In theory the FDA's recommended assignment of a family monitor or caretaker perfectly fits the culture of the military's chain of

²⁵ http://ncbi.nlm.nih.gov/pmc/articles/PMC2582668/, Mcgill J Med Nov 2008; 11(2); 219-222.

²⁶ Yale J Biol Med Jun 2013; 86(2): 139-146 (Published online Jun. 13, 2013)

command. The officers and senior NCOs customarily ensure the health and welfare of the troops that in turn ideally result in a cohesive unit and that morale remains high.

Command assurance that adequate suicide monitoring occur during antidepressant dosing is problematic. The military culture at the senior level is deferential to command discretion. Issuing standardized monitoring instructions to subordinate commanders is shunned for fear of alienating leadership morale. The other side of that coin is that without such directives, it is inevitable that a large percentage of local commanders will simply ignore the FDA's guidance, not out of spite, but of unawareness of antidepressant dangers.

In the Army's 2010 suicide report lamenting the crisis the service was struggling through, emphasis was placed on leadership and looking out for the troops. While not stating it directly, the report strongly suggested the Army's highest generals believe the suicide crisis is simply failed leadership—in combination, of course, with the long wars.²⁷ That the Army itself may be at fault for policy failure, one can assume, was never under discussion.

In the broad sense, however, the Army's emphasis on leadership is outstanding advice in any case. Positive leadership could probably marginally improve the Army's obvious suicide problem.

Good leadership in the Army has as its equivalent the dynamic that occurs during antidepressant clinical trials. In these usually several week trials sponsored by pharmaceutical company to test their drugs, the mere presence and attention of the psychiatrist investigator directed to the participating patient, calling this in the vernacular the "love and attention" factor, pays positive dividends to the mental health of the participants. As a general matter, patients in clinical trials do not commit suicide. Completed suicides, by the numbers, occur when the victim(s) are not directly and frequently monitored either by health care providers, family, or caretakers. The greatest number of suicides, by far, have occurred in the normal course of routine antidepressant distribution where no one expected the patient to suffer the ultimate fate, including when the indication for which antidepressant therapy was prescribed was not depression. That the placebo effect is so positive in depression clinical trials to render antidepressant efficacy clinically insignificant may be that the "love and attention" is nothing more than the uplifting nature to the patient of a positive physician-patient relationship. 29

While the Army's emphasis on leadership can only be positive, its elephant in the room attitude posture on antidepressants has a substantially negative effect to wipe away whatever

²⁷ Army 2010 Suicide Report, page 4: "Lost Art of Leadership in Garrison—The Army's institutional policies, processes, and programs have not kept pace with changes resulting from nearly a decade at war...Leaders are consciously and admittedly taking risk by not enforcing good order and discipline."

²⁸ In the FDA's review of adult antidepressant trials for psychiatric indications, only eight (8) completed suicides occurred among 77,382 participating patients, a crude rate of ".0001" (see Table 19, page 47 FDA "Clinical Review: Relationship Between Antidepressant Drugs and Suicidality in Adults" November 16, 2006.) In the FDA's review of pediatric trials, there were no completed suicides in the 24 trials involving over 4,000 patients (*PDAC Transcript Feb. 2, 2004*, by FDA official Thomas Laughren, MD, page 254 line 16)

²⁹ See "Placebo Effects on Pharmacotherapy Outcomes in Major Depression" *Psychiatric Times,* September 15, 2007, by Aimee M. Hunter, PhD, e.g. "the beliefs and expectations of the patient and physician/clinician, as well as the nature of the patient-physician relationship, are of primary importance in the treatment context."

gain it may otherwise accrue with caring leadership. General leadership presence does not compensate for misguided leadership. The Army's failure to ensure platoon leaders and first sergeants are brought into 3rd party status in accordance with the FDA's guidance on monitoring troops for suicidality during antidepressant therapy remains the Army's Achilles heel in its sincere, but ineffective efforts to overcome its scourge of suicides.

It would be a mistake to presume the exigencies of the war zone is the only circumstance in which liberal antidepressant dispensing occurs and danger lurks. Prescribing for battle fatigue symptoms, obviously, occurs under those conditions. Numbers wise, however, the Army's casual dispensing practice is worldwide and applies in non-combat areas with the same risk. In U.S. and overseas based units, including the Active Reserve and National Guard, treatment is provided by physicians without psychiatric training with no professional limitations on their status to administer antidepressants and anxiolytics freely.

The internecine struggles ongoing within the Army may well speak to a major factor contributing to if not responsible for the suicide crisis. The Army is not unique in terms of divergences between psychiatrists and PCPs. The same phenomena occurs in civilian medicine. What makes the Army's situation problematic is the difference in the sheer numbers of field physicians in the Army and the lethal combination with a 20% dosage rate of antidepressants. For better or worse, the Army's suicides at the end of the day are added up accurately and counted against the service.

Unlike civilian society, however, the U.S. Army has the authority, rhetorically speaking, to muster all doctors on the parade grounds, read the riot act to them, and order compliance. The Army "MEDCOM" (Headquarters, Army Medical Command) theoretically has that mission. As a practical matter, however, large bureaucracies resist change with the Army, viewed by many, as the most bureaucratic of all the military services. It may simply be too much for the Secretary of the Army, the infantry generals, and the medical generals to unravel and correct the Army's out of control system of coercive medication and to order troop monitoring for signs of suicide after dosing is ordered.

In the meantime the Army would be well advised to require troop physicians to read Dr. Kirsch's updated findings that antidepressants, in most cases, don't work. That would be a good start at turning the corner away from the Army's antidepressant dispensing machines.

The Cubbyhole in the Pentagon!

Until suicides escalated sharply in 2005, mental health in the Army was on few radar screens. Even fewer paid heed to psychiatric medications. Such was within the exclusive domain of medical bureaucrats and a smattering of military psychiatrists. Virtually no oversight or interest on the matter was shown by the infantry generals who run the Army from another wing of the Pentagon.

The antidepressant world changed in 2003, the same year as the Iraq invasion. In 2003-2007 when the FDA was engaged tumultuousness regulatory events concerning antidepressant induced suicide, the Army and Pentagon's priorities focused on the wars in Iraq and Afghanistan. Psychotropic medications were on auto pilot.

Increased Psychotropic Drugs to Meet Combat Numbers

The Army has not released medication figures for antidepressants and anxiolytics, but it appears psychiatric drugging rose significantly as force requirements confronted dwindling troop availability in Iraq and Afghanistan. We can't backtrack from the 20% antidepressant dosage rate in 2010, but it appears dosage rates rose with the Iraq war. The marked rise in prescribed opiates and amphetamines starting in 2005 would appear to bear that out.³⁰ The 20% rate, in any case, is where the debate is grounded.

In 2005 the year the Army's suicide rate rose dramatically as National Guard troops were recalled to active duty to provide 8 of the Army's 15 combat brigades in Iraq.³¹ The Army's 2010 suicide report called attention to the problem whereby field deployment prescriptions handed out to troops could not be accounted for and were considered susceptible to drug abuse by troops exchanging pills for kicks and getting high.³² The report showed near paranoid tracking by unannounced testing of what the Army considered drugs of abuse though they were prescription drugs, e.g. amphetamines, oxycodone, opiates.³³ This was entirely appropriate and necessary for discipline, our use of "paranoid" merely contrasting the Army's ostensible indifference over the far more dangerous antidepressant.

In 2003 civilian patients and their physicians began to respond negatively to disclosures of suicidal and other antidepressant side effects reported in the press. As a result, in the civilian world "the use of antidepressants fell sharply in 2003 and 2004."³⁴ "(T)he markets for these drugs grew sluggish in 2005, following the...(FDA's)...adoption in 2004 of warning labels indicating that the drug may cause suicidal thoughts in children and adolescents."³⁵ Army troops read newspapers too. Many became reluctant to take antidepressants and anxiolytics; others resisted but eventually succumbed under pressure, and others resisted to the point of being processed for discharge.

The Army reacted by doubling down. The generals took the position that those resisting the medications, especially soldiers with disciplinary history, were malingering to evade war time deployment.

Decline in antidepressant use has since rebounded since the downward trend associated with the commencement of suicide warnings. According to the latest Center for Disease Control data published in 2013, antidepressants as a class are the third most prescribed class in the U.S., following cardiovascular and cholesterol lowering drugs.³⁶

"PTSD"

³⁰ Army 2010 Suicide Report, page 55

³¹ http://nationalguardmagazine.com/article..."The Guard Surge in Iraq" by Bog Haskell

³² Army Health Promotion, Risk Reduction, Suicide Prevention, 2010 (Hereafter "Army 2010 Suicide Report) top of page 36

³³ Army 2010 Suicide Report, page 55

³⁴ "Antidepressants and Suicide" British Medical Journal, Editorial, BMJ 2008;336:515

³⁵ CNNMoney.com "The antidepressants to watch in '06" by Aaron Smith, January 4, 2006.

³⁶ http://www.cdc.gov/nchs/data/hus/hus13.pdf page 22 of "Health, United States, 2013"

The Army's other sacred cow is PTSD ("post-traumatic stress disorder"). If the Army didn't have PTSD to explain its suicides and violence, it would have to invent it. "PTSD" commands the spotlight from every angle. General Milley was so anxious in his April 2nd news conference to get the Army's nomination of PTSD as a cause of the rampage that he effectively predicted the diagnosis in advance. This was after the shooter was already dead and diagnosed earlier, apparently, with depression and anxiety.³⁷

If sounding slightly facetious to make a serious point on a serious issue detracts from understanding my attempt to characterize the Army's diversionary tactic, I'll try to restate it with pinpoint accuracy. The Army's basis for explaining over 2,000 suicides since 2005 lies with soldiers' mental health issues aggravated by 13 years of war.³⁸ The theory sounds enticing, one element undisputedly true. Enamored with the theme, one that invokes emotionalism and patriotism and counts on citizens' gratitude for the service's 13 years of continuous sacrifice, the Army in putting forth this disjointed theory has hedged it bets.

A Disjointed Theory: "13 years of continuous war"

The problem with the theory is that individual soldiers commit suicides—not staffs or command centers.

Few doubt that the Army Chief of Staff's civilian secretary at the Pentagon hearing shouts of panic and anger from her 3 or 4 different bosses over these 13 years issuing war time orders was probably a nervous wreck 5 years into the war. But that's not how the methodology goes in figuring military suicides. Individual service members, one by one, and each's status at any given time over the past 13 years is what is material to individual soldier suicides.

A media outlet accepting the Army's theory hook, line, and sinker was *USA Today*. The paper attributed to "scientists" a long held view that it was the overall strain on the Army during the war years that contributed to the suicides, not merely individual soldiers who had been in and out of combat.³⁹ The "scientists" the paper quoted were NIMH civilians and contractors retained by the Army for the STARRS project, addressed below. One understands Army uniformed psychiatrists, as well, played a role in STARRS but it is not thought they were inclined to counter the Army's theory which—practically speaking, reflects the vested interests

³⁷ Fox News coverage of live news conference April 2, 2014, General Miley's responses to questions: "he was currently under diagnosis for PTSD, but <u>he had not yet been diagnosed with PTSD</u>.".... "he was <u>not diagnosed as of today with PTSD</u>, and that is a lengthy process to be confirmed..." "he was undergoing behavior health and psychiatric treatment for depression and anxiety and a variety of other psychological and psychiatric issues..." "I don't know if he was diagnosed in the clinical sense; there are reports that he self-reported a traumatic brain injury, previously coming back from the Iraq War..."

³⁸ Army Suicide Report 2010: Page 1 succinctly summarizes the Army's theory on its suicides: "(T)he alarming rate of suicides in the Army...No one could have foreseen the impact of...(thirteen)....years of war on our leaders and Soldiers." The original 2110 report stated "9" years to war (from 2001). Figure "thirteen" was inserted in keeping with Army's theory.

³⁹ "Scientists have long speculated that the fast-paced tempo the Army was under at home and abroad during the war years was an overall strain that contributed to suicides and that deaths were not just a factor of combat duty." *USA Today* by Gregg Zoroya, March 3, 2014 "Study: High Suicide Rates for soldiers in, out of war."

of Army psychiatry more so than any other Army branch.

That civilians, psychiatrists or otherwise, comprehend wartime combat and its effect on those who serve through it reminds classic movie fans of a scene from the movie of Herman Wouk's epic novel *The Caine Mutiny*. The prosecution's psychiatrist, new to the Navy, testified as an expert that Captain Queeg, played by Humphrey Bogart, was perfectly sane and should not have been relieved by the executive officer of command on the bridge of the *Caine* during the deadly typhoon. The executive officer's lawyer Barney Greenwald, a grounded pilot played by Jose Ferrer, attacked the psychiatrists' credibility with ferocious determination. Greenwald mocked the psychiatrist's competence to render that opinion without having ever been to sea and having never witnessed the pressures of combat required of a ship's captain. The executive officer, played by Van Johnson, was acquitted following Bogart's renowned unraveling on the witness stand while shaking the little steel balls in his hand. Wouk's tale, purely fictional of course, was as compelling as it was entertaining in the context of serious dialogue regarding the credibility of civilian psychiatrists venturing opinions on the effects of war and combat stress without having heard the tocsins call to battle.

More importantly the numbers don't match up. The narrative that wartime deployments in combination with mental health problems is causing of the record number of suicides has been debunked by cold hard facts. Numbers showed Army National Guard and Army Reserve suicides nearly doubled from 2009 to 2010, and that about half of those soldiers who killed themselves never deployed to a combat zone. The futile nature of the Army's narrative is aptly illustrated by then Army Vice Chief of Staff General Peter Chiarelli who commented at the time: "if you think you know the one thing that causes people to commit suicide, please let us know, because we don't know what it is."

Wishful thinking shouldn't make it so either. Chiarelli, a top Army combat officer over decades who has tasted the ravages of war led Army voices in maintaining it is continuous years of war that unlocks the mystery of the suicide epidemic. Chiarelli doesn't have the same problem as the psychiatrist in *Caine Mutiny*, but that he could not offer more than gut instinct as the basis for his opinion has to be seen as lacking persuasiveness. General Chiarelli stated

⁴⁰ "Suppose the requirements of command were many times as severe as you believe them to be—wouldn't even this mild sickness disable Queeg?" "That's absurdly hypothetical, because..." "Is it? Have you ever had sea duty, Doctor?" "No" "Have you ever been to sea?" "No." (Wouk then adds without quotes:..."Bird was losing his self-possessed look.") "How long have you been in the Navy?" "Five months—no, six, I guess, now..." "Have you had any dealings with ships' captains before this case?" "No." "On what do you base your estimate of the stresses of command?" "Well, my general knowledge..." "Do you think command requires a highly gifted, exceptional person?" "Well, no—" "It doesn't?" "Not highly gifted, no. Adequate responses, fairly good intelligence, and sufficient training and experience, but—" "Is that enough equipment for, say, a skilled psychiatrist?" "Well, not exactly—that is, it's a different field—" "In other words, it takes more ability to be a psychiatrist than the captain of a naval vessel?" (The lawyer looked toward...(the president of the court martial panel, a line captain)). "Doctor, you have admitted Commander Queeg is sick, which is more than Dr. Lundeen did. The only remaining question is, how sick. You don't think he's sick enough to be disabled for command. I suggest that since evidently you don't know much about the requirements of command, you may be wrong in your conclusion." The Caine Mutiny by Herman Wouk, pp 450-451

⁴¹ Washington Post, January 19, 2011, "Army Sees Suicide Decline Overall, Increase Among Guard and Reserve Soldiers," by Greg Jaffe.

⁴² Ibid Jan. 19th Washington Post

to the press it would be wrong to blame the suicides on the war--but then--proceeded to blame the suicides on the war.⁴³

After retirement Chiarelli, the Army's second in command 2008-2012 and who personally directed and signed the Army's 2010 suicide report showed frustration at the lack of progress in solving the problem. He called criticism of the Army, and presumably himself as well, "scapegoating" for the fact civilian suicides, in his view, presented the same problem to the country as Army suicides, but that civilian suicides did not receive the same public focus.⁴⁴ Interviewed by the networks after the April 2nd Fort Hood shooting, Chiarelli was sticking with his narrative that general mental health problems in the Army and the wars are responsible.

Recent *USA Today* coverage further noted the above data were not helpful to the Army's argument, that "while suicide rates...(for those who served in Afghanistan and Iraq)...more than doubled from 2004 to 2009 to more than 30-per-100,000, the trend among those who never deployed nearly tripled to between 25- and 30-percent per 100,000...Rates for civilian(s)...remained steady at 19 per 100,000."⁴⁵

The April 2nd Fort Hood News Conference

Why PTSD was the focus of General Milley's news conference when reporters' questions were posed to him and not "depression" or "anxiety" illustrates two obvious truths. One is the herd mentality of the media and its copycat syndrome of what Rush Limbaugh calls the "drive by media." PTSD is a living example of group think in the media, feeding the psychic prevalent in Congress as well. P_T_S_D is a staccato phrase, implying one who utters it, must know what s/he's talking about given its authoritative ring—not bad for a disorder that didn't exist until 1980.⁴⁶

Stress in Iraq/Afghanistan Greater than Iwo Jima and Battle of the Bulge?

Nobody has challenged the Army why its theory on Iraq and Afghanistan veterans committing suicide in record numbers due to prolonged operational tempos does not—and did not apply to World War II, Korean War, and Vietnam veterans. It is necessary to belabor the point—as the Army has apparently so forgotten the struggles of earlier generations.

There were 292,131 American battle deaths in World War II.⁴⁷ Korean War U.S. battle deaths were 33,629.⁴⁸ In the 9 year Vietnam War, 47,318 American service members were

13

⁴³ New York Times, July 29, 2010, "Pentagon Report Places Blame for Suicides" by Elisabeth Bumiller: "'For us to blame this thing just on the war would be wrong,' Gen. Peter W. Chiarellii...said at a news conference...'That's not what we're trying to do here.' Nonetheless...Chiarelli said that he believed...that the overall Army suicide rate had been driven up by the 21 percent of suicides committed by soldiers with multiple deployments, 'That has just always been my concern, that they may be it, that may be the reason,' he said 'but I don't have any data that I can tie that to.'"

⁴⁴ http://www.politico.com/news/stories/0912/81413.html

⁴⁵ USA Today March 3, 2014 et al by Gregg Zoroya

⁴⁶ http://www.ptsd.va.gov/professional/ "PTSD History and Overview"

⁴⁷ The World Almanac and Book of Facts, 1985, Newspaper Enterprise Association, Inc. page 340

⁴⁸ Ibid

killed.49

Deaths of U.S. service members in Iraq totaled 4,489, and in Afghanistan through May, 2014 totaled 2,320.⁵⁰

In World War II in the North African campaign in February, 1943, German Field Marshall Erwin Rommel at the two mile wide Kasserine Pass handed the U.S. its first defeat of the war "inflicted devastating casualties on the U.S. forces ...more than 1,000 American soldiers were killed ... and hundreds were taken prisoner..."51 The Allies suffered "about 70,000 casualties" in North Africa before Rommel was defeated and the Axis surrendered on May 12, 1943.⁵² The invasion of Sicily, and the boot of Italy followed. There were 60,000 allied casualties in the Italian campaign,⁵³ including 29,200 in the bloody 4 month Anzio campaign, 16,200 of which were Americans (5,500 killed in action, 17,500 wounded, and 4,500 prisoners or missing).⁵⁴ "In April and May 1944, the Allied air forces lost nearly 12,000 men and over 2,000 aircraft in operations paving the way for D-Day."55 Rome was liberated two days before troops landed on Normandy. Allied casualties on D-Day "have been generally estimated at 10,000...(with recent verification that there were)...2.499 Americans killed on June 6, 1944 in Operation Overlord."⁵⁶ The Normandy invasion saw over 209,000 Allied casualties.⁵⁷ The remains of 9,386 American war dead are entombed at Normandy.⁵⁸ On December 16, 1944 the Germans attacked in the wintry cold of the Ardennes forest to drive a spear between American and British armies. After 40 days and Hitler's gamble having failed, American casualties in the Battle of the Bulge totaled 89,500, killed in action 19,500, captured or missing 23,000.⁵⁹ After VE Day in April 1945, action shifted to the Pacific" but the Pacific theater was yet to see its deadliest days."60

In the intense Pacific campaigns following the attack on Pearl Harbor and the loss of the Philippines, ground forces of the U.S. Army and U.S. Marines fought island hopping campaigns the likes of Guadalcanal, New Guinea, Tarawa, the Gilbert and Marshalls, Guam, Kwajalein, Saipan, Truk, Tinian, Peleliu, Philippines and Leyte Gulf, Iwo Jima, and Okinawa and others over a 3-4 year period.

In the Bataan death march in 1942 following the fall of Manila, "the exact figures are unknown, but it is believed thousands of troops died because of the brutality of their captors, who starved and beat the marchers, and bayoneted those too weak to walk." On August 7,

⁴⁹ Ibid.

⁵⁰ www.defense.gov/new/casualty.pdt

⁵¹ http:///www.history.com/this-day-in-history/battle-of-the Kasserine-pass

⁵² www.u-s-history.com/pages /h1727.html

⁵³ www.battlefieldhistorian.com/italian_campaign-1945-1945.asp

⁵⁴ www.history.army.mil/broachures/anzio/72-19.htm

⁵⁵ www.ddaymuseum.co.uk/d-day/d-day-and-the-battle-of-Normandy

⁵⁶ Ibid

⁵⁷ Ibid

⁵⁸ Ibid

⁵⁹ En.wikipedia.org/wiki/Battle-of-the-Bulge

⁶⁰ www.pbs.org/wgbh/americanexperience/features/general-article/pacific-major battles

⁶¹ www.history.com/topics/world-war-II/bataan-death-march

1942, the First Marine Division landed on the beaches of Guadalcanal in the Solomon Islands, setting the stage for one of the most pivotal and contested pieces of real estate in the history of the world. The 25th Infantry Division later joined forces with the Marines. Jungle disease was deadly in the malaria infested swamps, as the combatants fought hand to hand with bayonets. Hostilities ended February 9, 1943 as the Japanese abandoned the island. "Allied losses numbered around 7,100 men, 29 ships, and 615 aircraft."

The New Guinea campaign from 1943-1944 saw 12,000 American casualties, less than the 17,107 suffered by the Australians.⁶³ In the bloody 4 day invasion of Tarawa, "American losses were a costly 978 killed and 2,188 wounded."64 In the 3 month Gilbert and Marshall's campaign in which U.S. Marines were supported by naval forces, American dead or missing totaled 3,300 with 4,830 wounded.⁶⁵ In the Mariana and Peleliu campaign in mid-1944, U.S. forces executed landings on Saipan, Guam, and Tinian. U.S. killed in action totaled 9,500.66 "More than 15,000 Americans were killed or wounded" retaking Leyte in October, 1944, fulfilling General MacArthur's pledge "I Shall Return." In the battle to retake Luzon and liberate Manila in January, 1945, "MacArthur's Sixth Army suffered 38,000 individuals killed or wounded."68 In the 5 week battle of the tiny atoll of Iwo Jima ending on March 26, 1945 "as many as 7,000 Americans were dead and 24,000 wounded...almost 6,000 of those killed were U.S. Marines."⁶⁹ Following Iwo Jima, U.S. forces attacked Okinawa, 350 miles from the Japanese homeland. "U.S. Marines and Army troops fought a bloody battle of attrition against an enemy concealed in intricate underground defense systems...When the island was finally secured, more than 12,000 U.S. soldiers and Navy personnel were dead or missing and more than 36,000 were wounded."⁷⁰

Troop comforts and military life in general have changed. Those continuously deployed in World War II without seeing their families did not have Email or Skype to communicate with their loved ones.

It would seem under the Army's theory and its civilian mental health experts opining the same, that suicides would seemingly have risen modestly near the end of these wars. There were over 12,000,000 Americans serving in the military in 1945, the last year of World War II.⁷¹ That never happened as can be noted in the graph on the next page. As can be seen in the graph, not only did national suicides not spike at all, but both eras experienced the lowest rate of suicides every experienced. Military suicides were so minimal, no records or writings on the subject were recorded until 1981.

⁶² www.militaryhistory.about.com/od/worldwarii/a/battle-of-guadalcanal_2.htm

⁶³ www.history.army.mil/brochures/new-guinea/ng.htm

⁶⁴ www.militaryhistory.about.com/od/worldwarii/p/World-War-II-battle-of-tarawa.htm

⁶⁵ www.en.wikipedia.org//wiki/Gilbert and Marshall Islands campaign

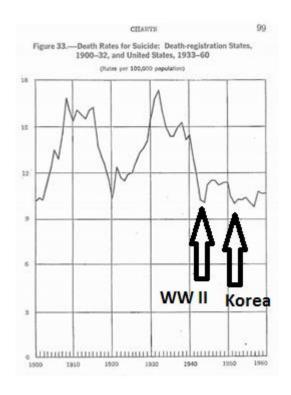
⁶⁶ www.en.wikipedia.org/wiki/Mariana and Palau Islands campaign

⁶⁷ www.pbs.org/wgbh/americanexperience/features/general-article/pacific-major-battles

⁶⁹ www.pbs.org/wgbh/americanexperience/features/general-article/pacific-major battles

⁷⁰ www.pbs.org/wgbh/americanexperience/features/general-article/pacific-major battles

⁷¹ www.nationalww2museum.org/learn/education/for-students.ww2-history/ww2-by-the-numbers/us-military.html



Vietnam Undercuts Army's Theory Too

The Vietnam War presents perplexing, and certainly tragic issues in regard to suicide. There is no question that Vietnam veterans, as time has passed, are in one of the highest demographics for suicide. The Army's theory for its high current rate of suicides, however, rests with the active duty scenario and that scenario will remain our focus. That said, the Army's theory is significantly undercut by the Vietnam War experience. The Army's 2010 suicide report in which the "9" continuous years of wartime footing were cited does not persuade given the 10 years of the U.S. Army in Vietnam between 1965-1975. Active duty suicides during the Vietnam era were not archived. If there was any spike in Army suicides during that war heavily covered by the reporters in the field, they seemingly would have been reported. The Army's justification for its narrative, however, is that it let its guard down on "good order and discipline" in Iraq and Afghanistan as a result of the continuous years of war. This seeming mea culpa, interesting in any case, is added to by the 2010 report that implied the troops were extremely unhappy by their involuntary extensions in Iraq, People can relate to that, e.g. the troops were

_

⁷² www.abcnews.go.com/Health/Vietnam-vets-highest-rates-suicide-alongside-baby boomers/story?id=19100593, "Suicide Rate Spikes in Vietnam Vets Who Won't Seek Help" by Susan Donaldson James via Good Morning America

⁷³ "At the result of the protracted and intense operational tempo, the Army has lost its former situational awareness and understanding of good order of discipline within its ranks." Army 2110 Suicide Report, page 1.
⁷⁴ The Army, rightfully proud over extending its stretched force into two theaters, proceeded to explain why Army troops were disenchanted, i.e. presumably turning to suicide: "On the other hand, we must now face the unintended consequences of leading an expeditionary Army that included involuntary enlistment extensions, accelerate promotions, extended deployment rotations, reduced dwell time and potentially diverted focus from leading and caring for Soldiers in the post, camp, and station environment." Introduction, page iii under signature of General Peter W. Chiarelli.

unhappy and they bitched. That is where the Army logic ends however. The Army's implication is that the next step was troops killing themselves in record numbers. Two factors immediately resurface to undercut the scenario. Those who served in Vietnam will remind anyone that the "good order and discipline" problems the Army cited in 2010 as occurring in Iraq and Afghanistan were at least as bad in Vietnam, and probably much, much worse. Open use of dope, ignoring orders, and fragging officers all occurred in Vietnam. The major fact differentiating then and now is the conscription Army in Vietnam versus the all-volunteer Army in recent times. The more the Army and its civilian theoreticians venture that 13 years of continuous explain the suicides, they, the Army at least, should be reminded to go back and look at the Vietnam archives.

Blaming the Troops

The Army's theory that its suicide crisis is attributable to 13 years of continuous war casts dispersion, unwittingly no doubt, on the current generation of soldiers. Many would consider it degrading to suggest that this generation of soldiers are not as mentally resilient as their predecessors in Bataan or the Battle of the Bulge.

Let us be clear. It is Army thinking, not the thinking of its critics,' that raises the specter of generational inadequacy in coping with lengthy war. The Army, of course, would reject that characterization, but it is the essence of what the Army is maintaining. There is unanimous agreement that the modern service member should be encouraged to seek mental health treatment when troubled and that doing so should not be detrimental to the career. But neither enlightened policy nor the soldiers' responses to that policy relates to the Army's theory that 13 years of war has produced this suicide crisis. The Army's theory states simply this generation of soldiers is more subject to wartime stresses than previous generations. With no data available to prove it, the logic behind this theory is equally lacking.

The policy failure of unrestrained antidepressants and the resultant suicide crisis has been aggravated by Army leadership *turning* on its troops to explain the problem rather than looking inward. The Army changed its tune from its troops being "the best and the brightest" a mere decade ago to a force that in the Army's 2010 suicide report is one of drug and alcohol abusers, high risk soldiers, spouse beaters, and felons? Such people problems that the Army now cites are not questioned. They exist. They always existed; it is only since the suicide crisis rapidly evolved that Army leadership has pointed its fingers at what it essentially says now are its problem soldiers.

No one diminishes the prolonged stresses of the current Army and its soldiers that Iraq

⁷⁵ Recruiting video for Army volunteers to "Tactical Operation Center," http://www.goarmy.com/army-videos.vid-f05b1968-24ef-4f55-92c0-1c4d93ba500b.autostart.html

⁷⁶ Army 2010 Suicide Report, See "Contents" pp I thru vii, "High Risk Behavior" (page 50); "Illicit Drug Use" (page 54) "Reporting criminal behavior" (page 58); "High Risk Population" (page 68); "Increased Crimes" (page 71); "Felony Crimes" (page 73); "Sexual Offense" (page 78) "Soldiers who committed spouse abuse and child abuse/neglect in the last 6 years has increased has increased by 177%." (page 80);

and Afghanistan have presented. Developing the theme that World War II, Korean War, and Vietnam soldiers, on the other hand, had fewer personal stresses and "mental health" problems resulting in the mass increase in Army suicides of today is unpersuasive to those observers who place military history in perspective and understand the dynamic of the times.

Of course there are great differences between 50 years ago and now. The troops back then were not fed antidepressants. Those today--are!

Congress

No challenge from Congress or the media has resulted from the Army's narrative that its suicides and violence are attributable to 13 years of continuous war and the mental health problems of its soldiers and families associated with it.

The mood in the Congress is to avoid at any cost any discussion that the All Volunteer Force ("AVF") is a failure and that some aspects of a draft are required to keep up with U.S. defense obligations around the globe. Neither has Congress shown any inkling to challenge the Army on its suicide narrative. Thus, a grateful nation mourns its fallen warriors and respects the military for defending the country at this time of crisis. Period—done!

Pro defense Republicans defer to the generals and admirals as a matter of philosophy except when they feel the uniformed military is doing the administration's bidding in weakening the military. Army suicides do not fit that criteria.

Democrats in Congress are not challenging the Army on its suicide theory either. Such could imply criticism of President Obama's defense policies; Democrats are not about to do that. That the uptick in suicides began in the Bush administration is inconsequential to the principle.

The April 2nd Fort Hood shootings presented the Democrats an opportunity to do what they do well; "never let a serious crisis go to waste." Senator Richard Durbin (D, IL) practices the principle faithfully. On April 9, 2014 Durbin chaired the Senate's defense subcommittee hearing budgetary requests from the surgeon generals of the military services. A longtime opponent of military spending and Bush's strong defense policies, he was one of 23 Democrat senators who voted against the original Iraq action and later opposed the successful Iraq surge. He never served in uniform, though graduating from college in 1966 his draft number for the next 9 years of the Vietnam War apparently was never called. On April 9th Senator Durbin could not have been more exuberant. He praised the military, conveying to the Army surgeon general his condolences to the Fort Hood victims and vowing his sub-committee's support for all the mental health funding that the Army, and other services need to deal with mental health problems as were demonstrated at Fort Hood. Durbin's discomfort with U.S. military superiority apparently extended to war winning generals as well. He took a swipe at General George Patton, rehashing the movie *Patton* and the slapping incident where actor George C. Scott slapped the soldier who had excused himself from battle for suffering the shakes and

18

⁷⁷ Spoken by President Obama's Chief of Staff Rahm Emmanuel, now mayor of Chicago, on the CNBC TV show The *Wall Street Journal Report* on February 9, 2009.

sought refuge in the medics' tent alongside the bloodied wounded. Durbin stated it was marvelous that the U.S. military has come so far since Patton to understand the mental health problems soldiers face in battle. He vowed he and his subcommittee would give the Army whatever support it needed to deal with mental health problems that plaque the services and played out so tragically at Fort Hood.

Game, set, and match for the Army. The service didn't even have to ask for money or defend its narrative. It was simply a done deal. More soberly, there is little likelihood Congress and politicians like Senator Durbin will ever challenge the Army generals in their "PTSD" and mental health narratives to explain suicides and violence. One hopes a House or Senate maverick will start thinking out of the box; that seems possible, but it hasn't happened yet. In the meantime the degree of political capital being expended by both political parties to curry favor with the military trumps any collateral issue, however serious, that arises in DOD.

Media

The media blackout on antidepressant induced violence is similar to the dynamic in Congress. Wire services like AP and Reuters invariably repeat the government releases, venturing nowhere near the territory of what used to be critical journalism. There is no marked difference among TV, cable, and the print media. Media, particularly TV, has the added factor of strong pharmaceutical influences through advertising revenues, the effect of which discourages news executives from running stories going against the grain of their sponsors' products. Occasional TV specials as well as individual print articles have been run which raises the issue of antidepressant risk. The ideological divide among the media has no effect on the allowance that all outlets give military leaders.

The afternoon and evening TV news covers only the major, breaking stories of the day from Washington and around the world. Whether its NBC or Fox News, there has been no challenge to the Army's narrative on Fort Hood simply as a matter of limited time and that media's business model.

Army leaders understand the dynamic. They know that PTSD and the shield of mental health from 13 years of continuous wartime footing gives them unlimited leeway in their attempts to explain away a problem that they cannot otherwise unravel. The Army is not about to tinker with a defense that is working.

FDA and Other Suicide Warnings Disregarded

The Army obviously understands knows the FDA's overall role in the federal apparatus, and invokes that agency's findings on drug alerts when they do not conflict with the service's agendas. No such Army guidance or alert exists on antidepressants and the FDA's warnings to closely monitor patients for suicidality once antidepressant dosing starts. 79

⁷⁸ Citing "FDA recently released new guidance for the sleep medication Ambien," the Army posted the article "Prescription sleeping pills pose morning-after risk for patients," by Katherine Rosario, www.army.mil/article/95407;

⁷⁹ http://accessdata.fda.gov lists the black box warning for antidepressants, its headline "Suicidality and

The Army has been, and continues to defy antidepressant suicide warnings issued by antidepressant manufacturers, the FDA, and independent researchers. The most recent federally funded research published on April 28, 2014 confirmed what the FDA originally published in 2004, and again in 2006. Harvard researcher Matthew Miller and colleagues utilizing data from 162,625 patients between 1998 through 2110, found suicidal behavior was "twice as likely when children and young adults are randomized to antidepressants compared with when they are randomized to placebo."80 Young adults less than 25 are the Army's largest demographic.81

Taking DOD wide figures of 39.6 % of the military population comprising individuals under 25 and applying that to 1,201,146 in the active Army, National Guard, and Army Reserve components, 475,654 patients under 25 for whom the Army prescribes any antidepressant will be prescribed a drug that causes suicidality.⁸²

The FDA's first suicide warning for antidepressants was issued March 22, 2004.83

FDA Public Health Advisory

FDA Public Health Advisory

March 22, 2004

Subject: WORSENING DEPRESSION AND SUICIDALITY IN PATIENTS BEING TREATED WITH ANTIDEPRESSANT MEDICATIONS

Warnings are not issued casually. The legal standard does not simply allow the warning, but "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..."84 The FDA's public statement at an antidepressant hearing emphasized that standard and the process: "we tend to put adverse events in the Warning section when we are pretty sure, when we think we have pretty good

Antidepressant Drugs" stating "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 disorder." The label text amplifies the warning, in part, as follows: "Clinical Worsening and Suicide Risk" "All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of drug therapy, or at times of dose changes, either increases or "Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and non-psychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and other symptoms described above as well as the emergence of suicidality, and to report such symptoms immediately to health care providers..."

⁸⁰ "Antidepressant Dose, Age, and the Risk of Deliberate Self-harm" by Matthew Miller, MD, ScD; Sonja A. Swanson, ScM; Deborah Azrael, PhD; Virginia Pate, PhD; Til Stumer, MD, ScD; JAMA Intern Med.doi:101001/jamainternmed2014.1053 (Published online April 28, 2014).

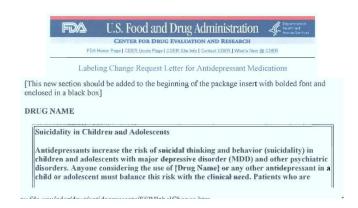
⁸¹ Army 2010 Suicide Report, page 17 figure 7

⁸² http://militaryonesource.mil/12038/MOS/Reports/2012 Demographics Report.PDF

⁸³ FDA Public Health Advisory, March 22, 2004..."Worsening Depression and Suicidality in Patients Being Treated with Antidepressant Medications."

^{84 21} CFR §201.57(c)(6)(i)

evidence that the drug actually does it as opposed to its just being associated with it."⁸⁵ The March 22nd mandate to warn occurred during a review of double blinded randomized control trials ("DBRCT") involving children and adolescents under 18.⁸⁶ DBRCTs are the gold standard for assessing clinical trial results.⁸⁷ The FDA's decision to add adults under that protective umbrella was based on a 28 member expert's panel that heard testimony on all demographics and made that recommendation without age restriction, The FDA's highest form of warning, the "black box" warning ("BBW"), was issued for antidepressants on October 15, 2004 following more analyses of the data that resulted in the March 22, 2004 ordered warning.⁸⁸



The FDA official articulating the agency's position on warnings further articulated the process on BBWs: "A boxed warning...is a judgment...as a general matter...we don't put a description of adverse events in a boxed warning, which is sort of the most stringent warning you can apply in a labeling unless we really believe that the drug is causally related to the adverse event.⁸⁹ Unlike the Army's flirtation with intellectually interesting studies by individual contractors on suicide like STARRS (infra et al), the FDA's data and findings are based exclusively on DBRCT data, the gold standard of scientific research.⁹⁰ The October 15th BBW

⁸⁵ FDA PDAC Transcript February 2, 2004, page 321 2/2/04 (Katz head of section)

⁸⁶ PDAC Transcript February 2, 2004; Presentation by FDA official Thomas Laughren, MD, Slide #6 re 9 drug review, 25 trials, and over 4000 patients

⁸⁷ http://fda.gov/aboutfda/whatwedo/history/overviews/ucm.304485.htm FDA and Clinical Drug Trials: A Short History: "Although several kinds of randomized control trial methodologies can be useful to researchers and regulators, ultimately it was the randomized double blinded placebo controlled experiment which became the standard by which most other experimental standards were judged, and it has often subsequently been referred to as the "gold" standard for clinical trial methodology.

http://fda.gov/downloads/medicaldevices//newsevents/workshopsconferences/ucm240787.pdf by Kathy Jenkins, MD, MPH, San Francisco, CA September 30, 2010, from Jenkins and Gauvreau, Clinical Research Course (November 9, 2009);

⁸⁸ FDA "Labeling Change Request Letter for Antidepressant Medications" dated October 15, 2004 and sent to all antidepressant manufacturers.

⁸⁹ FDA PDAC Transcript February 2, 2004, page 321 lines 16-25

⁹⁰ FDA PDAC Transcript December 13, 2006 on review of adult antidepressant data, Page 32 line 8, i.e. "the search was limited to the double-blind period of the studies."

directive specifically stated: "A causal role for antidepressants in inducing suicidality has been established in pediatric patients." 91

risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. A causal role for antidepressants in inducing suicidality has been established in pediatric patients.

As earlier, adults of all ages remained in the suicide "Warning." Glaxo SmithKline, the manufacturer of the SSRI Paxil and widely prescribed in the Army, issued a "Dear Health Care Professional" letter on May 8, 2006 alerting physicians that statistical significance existed between depressed adult patients taking Paxil and suicidal behavior. Statistical significance is operationally defined as causality. Statistical significance is operationally defined as causality.

Black Box Suicide Warning for Largest Army Group--Under 25!

A further FDA review of data from adult DBRCTs conducted in 2006-2007 and reviewing data from trials conducted in the 1980s through 2006 found, as with children earlier, that antidepressants cause suicidality in adults less than 25 years of age. ⁹⁴ Accordingly, the FDA ordered young adults under 25 be added to the BBW. ⁹⁵

⁹¹ FDA "Labeling Change Request Letter for Antidepressant Medications" dated October 15, 2004

⁹² Glaxo SmithKline "Dear Health Care Professional" letter "May 2006" Page 1, paragraph, i.e. "in the analysis of adults with MDD (all ages), the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo (11/345 (0.32%) versus 1/1978 (0.05%))...This difference was statistically significant."

⁹³ FDA "Joint Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) and the Psychopharmacologic Drugs Advisory Committee (PDAC), July 10, 2008; (Question from Panelist Dr. Pine: "What I heard the FDA to say, and maybe they will restate it, is if association is observed in a randomized, controlled trial, by definition, they have viewed that as a causal association or causality, but maybe you want to restate it." "Dr. Katz (FDA Director, Neuropharmacological Drugs Product Division): No, I think that is right. I think in controlled trials you see a signal, it is statistically significantly different from placebo, that is operationally defined as causality." Transcript pp 274-275.

^{94 &}quot;FDA News May 2, 2007" "FDA Proposes New Warnings about Suicidal Thinking, Behavior in Young Adults."

⁹⁵ FDA May 2, 2007 "Questions and Answers on Antidepressant Use in Children, Adolescents, and Adults," i.e. "FDA is announcing a request to all manufacturers of all antidepressant medications to update the existing "black box" on their product labeling to include warnings about increased risks of suicidal thinking and behavior (suicidality) in young adults 18-24 during initial treatment."



These young soldiers, e.g. under 25, consistently count for 57% of the Army's suicides, the below graph constructed from the Army 2010 suicide report, page 19.

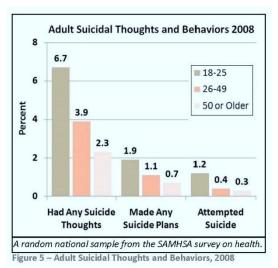
Active Duty Suicide Demographics	Active Duty Army 2009 Demographics	Active Duty Suicide Deaths 2003- 2009	Active Duty Suicide Deaths 2009
Age (Mode)	23 ²¹	21	23
Rank: Jr. Enlisted	45.5%	57.1%	58.3%
Deployment History: One or more	70.9%	69.3%	68.7%

Table 2 - Active Duty Suicide Demographic Data

The under 25 age group by far exceeds in percentage other age groups in the Army experiencing suicide thoughts, having made suicide plans, and having attempted suicide. The graph below is extracted from page 15 of the Army's 2010 Suicide Report. 96

Ī

⁹⁶ Army 2010 Suicide Report, page 15, figure 5.



2010-2014 Army Suicide Study "STARRS"—

Americans can agree if it took \$100 million, or whatever the sum, to spend to rid our troops of the compulsion to kill themselves for reasons unique to the Army, the nation would gladly spend it. The Army's focus to solve its suicide epidemic is illustrated by its dedication to one magic bullet to solve it: STARRS ("Study to Assess Risk & Resilience in Servicemembers"). STARRS manifested Washington thinking in confronting a difficult problem. Kick the can down the road by funding a study.

If you or I were experiencing high suicides in our family and learned that most of our kids who killed themselves did so after taking pills the FDA said caused kids to engage in suicidal behavior, we'd demand focus on that first before venturing into the unknown. Not so the Army—and the National Institute of Mental Health ("NIMH").

In 2010 the Department of Army and NIMH jointly undertook STARRS at the taxpayer cost of \$65 million. The Army's original press release reported cost would be \$50 million. The first fruits of STARRS were released March 3, 2014 through a series of articles. The one scientific fact known about antidepressant induced suicidality from the FDA, i.e. that antidepressants cause suicidality in the Army's most populous demographic, was somehow excluded from the STARRS design. If Congress wishes to investigate a scandal that will take only one hour of testimony to solve, it can start with that.

Excluding antidepressants was not surprising to those who noted the lead author of the study designs was a paid consultant for Eli Lilly, GlaxoSmithKline, and Pfizer, makers of Prozac, Paxil, and Zoloft respectively.

The research community thrives on government grants. One civilian psychologist's impression of STARRS was typical, labeling it "one of the most significant scientific

⁹⁷ http://projectreporter.nih.gov/project info history.cfm?did=8520396&icde=19448101

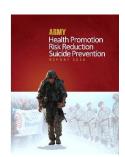
⁹⁸ Stars and Stripes July 28, 2010 "Army Suicide Study to Survey 400,000" by Seth Robson

⁹⁹ "Design of the Army Study to Assess Risk and Resilience in Servicemembers (Army STARRS)" Int J Methods Psychiatr Res 2013 Dec;22(4):267-75 doi: 10.1002/mpr.1401

undertakings in the history of suicide research."¹⁰⁰ It was anything but that. STARRS was designed from the outset to ignore totally the possible role of antidepressants in the suicide epidemic, rendering the project a near scam if its purpose was to find out all possible reasons why soldiers are committing suicide.

With such a muddled approach, it is not surprising that the Army and NIMH are just as perplexed now as when they started as to why soldiers are killing themselves. The conclusion in the March 3rd STARRS release reported: "(T)he root causes for the rise in Army suicides still remain unknown."¹⁰¹

One can be confident the Army and NIMH bureaucrats who put together the STARRS will defend their methodology and the huge expenditure of funds as a worthy project. With the ink barely dry on the March 3rd report showing no results the STARRS contractors are already back at the trough soliciting more taxpayer dollars. While there is more to come from STARRS, one can bet if there were any magic bullets to have been garnered from the studies we would have heard of them by now.



The Army's 2010 Suicide Report

In response to the suicide crisis the Army, in 2010, released a report comprising 352 pages. The Army understood the adverse significance of the Army's traditionally low suicide rate rising to exceed the civilian rate in 2008 and stated that fact in the report. Apparently hoping to put the best face on a bad situation, the Army played loose with the categories. It acknowledged its rate had increased to 20.2 suicides per 100,000 while noting "the civilian demographically adjusted rate typically is about 19.2 per 100,000." In fact the national rate for the 5 preceding years for all ages averaged 11.5 per 100,000. Invoking "demographically adjusted" wording the Army could have been referring to age, race, or gender, or any

¹⁰⁰ Psychiatry 2013 Summer;76(2):126-31. Doi 10.1521/psyc.2013.76.2.126

 $^{^{101}}$ NIMH Press Release, March 3, 2014 "Suicide in the Military: Army-NIH Funded Study Points to Risk and Protective Factors."

¹⁰² The STARRS "researchers conclude: 'These results set the stage for more in-depth analyses aimed at helping the Army target both high-risk soldiers and high-risk situations, as well as at developing, implementing, and evaluating preventive interventions to reverse the rising Army suicide rate.'" *British Medical Journal, BMJ* 2014;348:g1987 doi: 10.1136/bmj.g1987 (Published 6 March 2014)

¹⁰³ Army 2010 Suicide Report, page 11

¹⁰⁴ Army 2010 Suicide Report, page 11

¹⁰⁵ U.S.A. Suicide—Official Final Data, 2005 rate 11.0; 2006 11.1; 2007 11.5; 2008 11.8; 2009 12.0, American Association of Suicidology, http://www.suicidaology.org

combination in arriving at 19.2, each of these factors swing the calculus significantly. Nationally males commit suicide at nearly 4 times the rate of females; white males commit suicide at 2½ times of rate of black males; individuals in the age group 45-54 commit suicide at a higher rate than any other age group. Giving the Army the benefit of the doubt in its representations, its reported figures closely aligned with national "white male" rate of suicide. In its report the Army failed to break out the demographics of its suicides and suicide attempts by age, race, or gender by the 100,000 denominator, leaving readers without the underlying data to make independent calculations.

A Smidgen on Antidepressants

In its report the Army devoted one page to what it called "medication implications" of the suicide problem.¹⁰⁷ The Army's unfamiliarity with the subject matter was manifest throughout the report. In the report the Army touched briefly on the subject of clinical trials. The Army expressed perplexity with the collective results of the trials, all trials conducted by the drug companies and reviewed by the FDA in its comprehensive series of hearings over four years from 2003-2007. The Army report stated "There is contradicting evidence on the association between the use of some antidepressants medications such as...(SSRIs)...and suicidal behavior."108 In the next sentence, the Army acknowledges a 2009 report by the Agency for Healthcare Quality Research and the U.S. Preventive Services Task Force that there was "fair quality evidence" that SSRIs, especially Paxil, increased suicidal behavior in adults age 18-29.¹⁰⁹ Next the Army presented what it apparently thought was breaking news: "However, other research evidence shows the benefit of antidepressant use for the treatment of depression and anxiety, which are known suicide risk factors."¹¹⁰ Acknowledging the 18 to 29 year old demographic fits the "predominant" Army demographic, the report tasked the Army Medical Command ("MEDCOM") to solve the contradiction and "determine those specific medications that will reduce anxiety and depression without increasing suicidal risk." 111

The Army's directive to its subordinate medical command to find medications that cure depression and avoid suicidality could only raise eyebrows. Finding such an antidepressant would be a noteworthy discovery—considering that none exists. Whether the Army is disregarding the U.S. drug regulatory agency (FDA) on antidepressant induced suicidality for reasons of spite over turf or simply institutional incompetence, either ought to be grounds for a probe by Congress.

¹⁰⁶ Rates of suicide for white males between 2005-2009 average 20.5 per 100,000 in accordance with the American Association of Suicidology. (supra)

¹⁰⁷ Army 2010 Suicide Report, page 89

¹⁰⁸ Army 2010 Suicide Report, page 28

¹⁰⁹ The report stated the agencies "...found at least fair quality evidence that second generation antidepressants (mostly SSRI) increased suicidal behavior in adults aged 18 to 29 years, especially those with major depressive disorder and those who received paroxetine' (Paxil)."

¹¹⁰ Army 2010 Suicide Report page 28

¹¹¹ Army 2010 Suicide Report Page 29

Understanding the Army's elephant in the room disregard of antidepressants and its avoidance of speaking openly may have its origin in Army culture. The U.S. Army and its culture have a treasured place in American hearts through history. In the case of its suicide crisis, however, tradition and culture may be working against a solution. Speaking with vocal force to the troops that the old macho character of refusing to seek mental health help is no longer acceptable, for the Army itself there are hints in its 2110 suicide report that it exempts itself from that advice. This report said the Army when faced with a problem can investigate itself and fix what is broken with honest dialogue to mitigate suicides. One can cite the Army's STARRS' effort working with NIMH as positively reaching out to other agencies in seeking help. On the other hand, there is nothing more disingenuous than ignoring the FDA's authoritative data and advice on antidepressants. That is neither "honest dialogue" with its troop leaders nor courageous leadership in confronting the facts.

MEDCOM's 2013 Guidance—Aberdeen Proving Ground All Over Again?

One miscalculates if the view is that Army thinking that tricked Master Sergeant Stanly into agreeing to be a participant in a chemical warfare clothing program and secretly injecting him with LSD ended with that incident. The Army's window dressing on informed consent exhibited with Stanly in 1958 presented itself again on May 21, 2013 with a MEDCOM policy statement for commanders and regional medical commands. The memorandum provides insight on the Army's tactical thinking on antidepressants and is congruent with the service's whitewashing of antidepressant induced suicidality.

The Army's tactical thinking exhibited in the memorandum incorporates antidepressants into the broader subject of drug abuse. Mixing the two as MEDCOM did presented a cogent medical approach to prescription drug abuse. It failed, however, in calling attention to the far more serious problem of suicidality and antidepressant safety.

The MEDCOM memo's stated purpose was to prevent overdose and manage soldiers' "polypharmacy," The Army's injection of antidepressants into this mix was not without

¹¹² Army 2010 Suicide Report, page 2, in part: "firmly demonstrates the Army Senior Leadership's commitment to health promotion, risk reduction, and suicide prevention...it shows that the Army can, when faced with a problem, investigate itself and use those results to fix what it broken...(and)...provides honest dialogue with leaders on our role to work together as a corporate body to mitigate suicides."

¹¹³ Dept. of the Army "Memorandum for Commanders, MEDCOM Regional Medical Commands" dated 21 May 2013 re "Guidance for Managing Polypharmacy and Preventing Medication Overdose in Soldiers Prescribed Psychotropic Medications and Central Nervous System Depressants." (hereafter "MEDCOM memorandum").

some historical bases. SSRIs were originally sold on the basis they not only treated depression, but that they were extraordinarily safe from accidental overdose leading to death. Some SSRIs, particularly those with short half-lives, possess anxiety indications as well that increases the risk of physical dependence and habit forming usage.

MEDCOM's guidance was wrapped in verbiage suggesting Soldiers enjoyed a patients' bill of rights akin to any civilian. MEDCOM's guidance on "Clinical Pharmacy Referral" and "Informed Consent" calls for the patient to be "educated" on the drug treatment being contemplated. The education entails a discussion between the prescribing physician and soldier on the details of the medication, that after hearing the benefits and risks of the proposed treatment and the soldier agrees to proceed, the soldier will then monitor himself or herself for the drug's adverse effects. There are separate provisions that the military pharmacist and physician exchange communications in case records show the soldier is up to no good by abusing refills to get high. The provisions have the enticing appearance of requiring a meeting of the minds between doctor and patient.

There's a catch however. Like Sergeant Stanly at Aberdeen Proving Ground, soldiers signing off on the Army's informed consent form for antidepressants will not have been told the truth that antidepressants cause suicidal behavior in soldiers under 25.

Defying the FDA's scientifically developed findings and recommendation, MEDCOM in a blatantly false statement reported in the memorandum that "it is not known to what extent prescription medications cause suicide or suicidal behavior." It is known. Antidepressants do cause suicidal behavior in young soldiers as the FDA proclaimed.

MEDCOM's inability to tell the truth on antidepressants will solicit the same degree of credibility as that contained on informed consent forms signed by gullible soldiers not told the truth about "Clinical Worsening and Suicide Risk" on the antidepressant labels.

That's how Sergeant Stanley got hooked from LSD. The Army must start telling the truth about antidepressants—if not, the Army through reckless disregard will continue to put its

¹¹⁴ The New York Times Magazine, November 21, 2004, "The Antidepressant Dilemma" page 3 of 10: "Doctors…were wary of tricyclics, the previous generation of antidepressants, because of the risk of overdose. (The difference between an effective dose and a lethal one could be as small as 6 tablets) But it is much harder to OD on SSRIs." E.g. http://www.nytimes.com/2004/11/21/magazine/21TEENS.html

MEDCOM memorandum (supra): "h. <u>Clinical Pharmacy Referral</u>. An appointment during which a comprehensive medication review is performed by a clinical pharmacist on Soldiers meeting the polypharmacy definition. This review includes educating the Solder on the appropriate use of all medication, indication for medication usage, and monitoring for adverse effects. The clinical pharmacist communicates recommendations regarding medication-related problems and non-compliance issues to the Soldier's provider by documenting the medication-related action plan.." "i <u>Informed Consent</u>: Documentation in the patient's medical record indicating that the risks of the treatment plan and/or prescribed therapy have been discussed with the Soldier and that both the provider and Soldier are willing to accept the implied or inherent risks as well as benefits of the treatment plan and/or prescribed therapy."

¹¹⁶ Paragraph 4b of the MEDCOM memorandum states "It is not known to what extent prescription medications cause suicide or suicidal behavior. A high percentage of individuals who attempt suicide or who exhibit suicidal behavior have underlying mental disorders, which are often co-morbid with physical health problems, and are thus expected to be a group with a high likelihood of being prescribed psychotropic and CNSD medications."

soldiers in the throes of death.

What the Army Demonstrates it Cannot or Refuses to Grasp

There is a good reason why Congress assigned drugs to the FDA and ground wars to the Army. That the Army remains oblivious to antidepressant induced suicidality in its 2110 Suicide Report and STARRS may well be explained by its inability to wean off antidepressants as the cornerstone of Army medicine. One might make the case the Army is merely out of its element. On the other hand, some key architects of STARRS from the NIMH side of the ledger were aggressive advocates for antidepressants well before the FDA acted, and criticized the FDA for its "warning" actions. One of the most rigorous promoters of antidepressants over the years, a psychiatrist from Columbia University hired by drug companies as expert witness to testify that antidepressants don't cause suicide, was publicly thanked personally by the STARRS coordinator for his role in the design of the project. Army appreciation is appropriate for all contributors—but the nation cannot appreciate the Army's bias in designing studies ensured to continue the obfuscation of antidepressants in troop suicides.

It took the FDA several years to understand that many of the horrific adverse events occurring with antidepressant patients were the result of the drugs and not the underlying disorder for which the drugs were prescribed. The U.S. regulator finally came to terms with the data beginning in 2004, and in 2009 articulated what the Army has been unable to grasp.

The FDA's Insightful Summary

Those inclined to think the question of antidepressant induced suicide or violence is out of the scientific mainstream should read the FDA's suicide warnings mandated on antidepressant labels. The U.S. drug regulator got it right beginning in 2004 with its label

¹¹⁷ The eleven authors of the STARRS design in concluding their report on the studies stated "The authors would like to thank John Mann...(and others)...for their contributions to the early stages of Army STARRS development." Dr. Mann from Columbia University, a psychiatrist, is one of the most prominent antidepressant promoters in the field of psychiatry. He has appeared as an expert for antidepressant makers in civil cases and testifies that antidepressants cannot cause suicidality; rather they decrease them. Mann has spoken against FDA initiatives to warn of antidepressant induced suicidality. His argument has extended to one that antidepressants can't be risky because where they've been tried, the suicide rate has gone down. ("Those areas of the United States that has the highest prescription rates of SSRIs, both in adults and in children, have had the biggest falls in suicide rate" from Dr. Mann at FDA PDAC September 13, 2004 page 428, lines). Utilizing that Mann argument would seem to confirm that antidepressants are causing Army suicides, given that Army suicides greatly increased only after antidepressant dosage significantly increased. In a 2000 deposition for Pfizer, Mann testified a 1995 scientific literature article "in the Paxil study, they actually showed that suicidal acts were significantly helped by paroxetine relative to placebo." (Deposition of John Mann, MD, in Page 185 lines 16-20, in Miller v Pfizer, US Dist. Ct, KS, case No. 99-2326 KHV). Mann's assurances were false. The article he cited represented one of the most egregious misrepresentations in pharmaceutical history. The article in question was "Reduction of suicidal thoughts with paroxetine in comparison with reference antidepressants and placebo" (European Neuropsychopharmacology 5 (1995) 5-13). Mann did not testify falsely, but his acceptance of industry sponsored data without verification that the data were valid should be noteworthy. As lead author for the American College of Neuropsychopharmacology ("ACNP") in the 1992 ACNP Consensus Statement, that endorsed all SSRIs as effective and safe medications, Mann relied upon the same false figures that were contained in the 1995 article in recommending Paxil for treatment for the public at large.

changes, but later reflected on the dynamic that caused confusion for so many so years. In 2009 these FDA scientists living through the transformational era, recapped to the *British Medical Journal* their research findings from their study of adult trials. The FDA's conclusion "support the idea that antidepressant drugs can have two separate effects: an undesirable effect in some patients that promotes suicidal ideation or suicidal behaviour and a therapeutic effect in others that alleviates depression and reduces any suicidal sequelae from depression.¹¹⁸

What the Army Should Do Now: Commence Psychological Autopsies!

The Army's calculated decision to ignore antidepressants as a factor in its suicide crisis is indefensible. That calculation extends to STARRS, where in expending \$65 million to study troop suicide the Army ensured no focus would be paid to the drug that causes suicidal behavior in soldiers under 25, the group with the most suicides.

The general nature of STARRS was a diversion of ease. It was a project put together that had the effect of making those responsible feel that they were at least trying to solve the suicide crisis. But what was it worth for the Army to determine the actual reason for each soldier's suicide in 2011? 2012? 2013?

Apparently not very much—at least not according to the Army's 2010 suicide report.

The most thorough and accurate process known to determine the cause of a suicide is the psychological autopsy ("PA"). The process combines the traditional county medical examiner's investigation into a questionable death with, in the case of suicide, an examination into why the individual did it. In the PA, no stone is left unturned.

The Army's reaction? It disavows PAs!

Disavowal is not because the service necessarily disputes the claim that PAs are the most accurate process to determine the cause of suicides. Disavowal is based on the Army's contention, <u>one</u>, that it does not have the authority to convene PAs; <u>two</u>, PAs have no value in the many suicides where the manner of death has already been determined; <u>three</u>, that much of the PA's traditional value has been rendered moot by modern technology; <u>four</u>, that even if appropriate, PAs require resources that the Army finds scarce; and <u>five</u>, the suicide crisis is not so bad that the Army requires PAs to solve it.

-

¹¹⁸ BMJ 2009;339:b2880

¹¹⁹ Definition: "A procedure for investigating a person's death by reconstructing what the person thought, felt, and did before death, based on information gathered from personal documents, police reports ,medical and coroner's records, and face to face interviews with families, friends, and others who had contact with the person before death." From Segen's Medical Dictionary, C 2012 Farlex, Inc...See http://medical-dictionary.thefree dictionary/Psychological+Autopsy;Note: the website lists a McGraw Hill Concise Dictionary of Modern Medicine 2002, definition which includes the sentence "a PA focuses on the decedent's intentions relating to his own death, especially suicide..."

The Army professes neither the authority to conduct psychological autopsies nor any interest in conducting them. In its 2110 report the Army, explained that psychological autopsies are conducted "only when approved by AFME...(Armed Forces Medical Examiner)...and have a very narrow and specific function." The Armed Forces identity conveys control by a joint commander under Department of Defense ("DOD") auspices. The suicide report was the Army's and the place to make the argument that it needed more flexibility to convene PAs. Rather than urge DOD to open up the process in light of the present suicide emergency or seek a change in the law, the Army passively sat idly by, clicked it heels and saluted, and defended DOD's hamstringing. Such is the nature of pleasing the boss.

Two, the Army stated the PA has value only "if all other investigative leads have proven futile in determining...(the)...manner of death." If the "manner of death" is a bullet to the head as was the case at Fort Hood with Specialist Lopez, the Army states there is no need for a PA. The Army should have reviewed it notes and gone back to 1988. That was when the Army issued DA Pamphlet 600-24 which stated the correct reasoning for convening PAs. The relevant grounds for ordering a PA following a suicide was not whether or not the mode of death is clear, but whether or not the reason for the decedent's suicide was—and if not, the PA is convened. Fort Hood and Specialist Lopez illustrate the principle with clarity. The manner of death was indisputable; Lopez, in addition to killing others, put a bullet to his head. The real question; indeed the only question in follow up is "why" did Lopez do it. The Army's rationale in its 2110 report defies the basis of PAs.

Three, the Army stated the PAs purpose of determining the decedent's intent has largely been satisfied by the investigator's access to the decedent's inner thoughts by examining the likes of cell phone, social media, and texting history, etc.¹²³ While these mediums exist whereas decades ago they didn't, they do not necessarily depict the reason the decedent did what s/he stated s/he would do, with the effect it is diversionary. The reasoning that "texting" and "Emails," for example, will always reflect fact in establishing intention is simply fallacious. As it was General Chiarelli who signed out this explanation in the 2010 suicide report, he was the same general who told the Washington Post the Army had no idea why its soldiers were committing suicide (see footnote 42).

Four, the Army stated besides, PAs "have limitations...Most significantly, a...(PA)...must be performed by a behavioral health professional with specialty training in psychological forensics, which limits the number of individuals who can conduct them." ¹²⁴ In short, the Army states PAs take too long and there aren't sufficient numbers of mental health

¹²⁰ Army 2110 Suicide Report, page 190

¹²¹ Army 2110 Suicide Report, page 190

¹²² DA 600-24, Chapter 5, 5-1g(1): "Why did the individual do it? When the mode of death is clear and unequivocal, the psychological autopsy can serve to enhance our understanding of the factors the lead to the act. When the mode of death is clear, but that reasons for the manner of dying remain puzzling, the psychological autopsy is the reconstruction of the motivations, philosophy, psychodynamics, and existential crisis of the decedent.

¹²³ Army 2110 Suicide Report, page 190...""The need for psychological autopsies has decreased as a result of improved measures in determining victim intent. For example, media forensics has expanded the Army's investigative capability to examine cell phones, email/texting, web searches and other social/electronic media." ¹²⁴ Army Suicide Report 2010, page 190

professionals to conduct them."¹²⁵ Had the Army desired to get to the core cause of its suicides, it could have funded 325 forensic psychiatrists and paid them \$200,000 a year for the cost of the STARRS \$65 million price tag which did not explain the reason for a single suicide.

Five, the Army saved its most remarkable rationale for rejecting PAs for last, throwing up its hands and conceding that yes, "nevertheless, the...(PA)...provides an investigative tool when other investigative means to determine intent have been exhausted." As one can see, the Army's displeasure with PAs intensifies as its reasoning for rejecting them diminishes. One has to question how many years of 300 plus suicide deaths will it take before the Army concludes all leads are exhausted and PAs become a last resort to find out why.

The Army's rejection of PAs is indefensible under the circumstances. It has all the markings of a conscious effort to muddy the waters to ensure the role of antidepressants is obfuscated in the suicide crisis.

The consensus principle in the scientific literature is that most suicides are multifactorial. The PA penetrates the shell that otherwise pigeon holes conclusions by medical examiners and law enforcement investigators. The latter reflect condensed and narrowly tailored results that are more the products of bureaucratic convenience than determining the "why" of a suicide.

If a soldier's suicide is caused by mental health factors such as depression or PTSD, the psychological autopsy will determine that. If the suicide is caused by antidepressant side effects, the psychological autopsy will determine that too. Mixed motives and factors, too, will be allocated by the mental health specialist conducting the PA in the degree each comparatively caused the suicide.

Many examples can be cited in the PA's ability to distinguish drug effect from other causal factors in suicide. One is akathisia. Professor David Healy identifies akathisia as one of three antidepressant induced conditions that cause suicidality, the other two being emotional blunting and psychotic decompensation. The Army's rejection of PAs ensures antidepressant induced suicides, by design, will continue to be obfuscated in the morass of mental health generalities having little meaning beyond numbers.

Akathisia is subjective inner restlessness. It manifests fidgety movements, swinging of the legs, rocking from foot to foot, pacing to relieve restlessness, and/or the inability to sit or stand still for several minutes. The suicide warning section of antidepressant labeling refers to "akathisia (psychomotor restlessness)." It is sometimes discussed under the subject of

¹²⁶ Army 2010 Suicide Report, page 190

¹²⁵ Army 2010 Report, page 190

¹²⁷ SAFE-T, "Suicide Assessment Five-step Evaluation and Triage" and "Suicide: A Multi-factorial Event" http://www.dcoe.mil/event_docs

¹²⁸ 2010 U.S. Dist. LEXIS 30791 page 26

¹²⁹ See generally DSM V (Diagnostic and Statistical Manual of Mental Disorders) by American Psychiatric Association.

¹³⁰ See Warning section "Clinical Worsening and Suicide Risk" in any current antidepressant label. www.fda.gov

"serotonin syndrome." It is "a potentially life threatening adverse drug reaction that results from therapeutic drug use...or inadvertent interactions between drugs...anxiety and akathisia may be misattributed to the patient's mental state...the onset of symptoms is usually rapid with clinical findings often occurring within minutes after a change in medication...the onset of symptoms...usually rapid, with clinical findings often occurring within minutes after a change in medication." ¹³²...

There is little chance that law enforcement or coroner's investigation will conclude a suicide was medicated induced, even though it was--without the PA. One has to conclude after all these years of struggle that that is why the Army is opposed to PAs. Toxicology tests, by themselves, cannot answer the questions answered by the PA. Medical examiners do not routinely and thoroughly test for antidepressants. Normal screens for drugs of abuse often fail to detect antidepressants, but after focused testing often detect the antidepressant though at reduced amounts. Even if alerted to do alkaline screening associated with antidepressants, results are frequently inconclusive. Even if therapeutic dosage amounts are detected as the result of several days' continuous dosage, that will not equate to causation in establishing the decedent's intent. The inverse of that, e.g. the absence of detection and/or the detection of an amount less than what is considered a therapeutic mount is often, and erroneously presumed that the antidepressant had no role in the suicide. Indeed the antidepressant side effects inducing suicidality can occur virtually immediately, before reaching concentration levels toxicology tests would measure reliably. 133

In the case of any symptom but particularly, for example, akathisia, the mental health professional conducting the PA would talk to family, co-workers, and other individuals in the victim's unit to obtain an accurate time line of the symptoms juxtaposed on medication and dosage. Taking the example of the SSRI user pacing the floor and becoming agitated the day after starting medication, the mental health professional conducting the PA would tie these factors together chronologically and, under this scenario, attempt to confirm other factors pointing to the medication. Law enforcement and medical examiner investigators would almost certainly not pick up this evidence given they don't need it and are not seeking it.

"Challenge" and "dechallenge" aspects of taking and stopping the medication also would apply in any PA and be weighed by the psychiatrist or psychologist conducting it.¹³⁴

¹³¹ N Engl J Med 2005;352:1112-20

¹³² Ibid

¹³³ See *Principles of Psychopharmacology for Mental Health Professionals*, Wiley Publishing, by Kelsey, Newport, and Nemeroff. Page 27: "Side effects can also occur quickly after a single dose of medication. For example, some antidepressants (e.g. selective serotonin reuptake inhibitors) can cause nausea, stomach upset, loose stools, and even diarrhea. All of these side effects can occur within minutes or hours of taking a single dose of the medication. These side effects are also the result of the direct effects of the medication in the synapse."

¹³⁴ Determining causation is greatly aided if at any time medication is started, stopped, and started again. This can be directed by a physician's instructions, or sometimes by the patient unilaterally. "Challenge" entails symptoms arising after dosage starts. "Dechallenge" occurs when after the initial symptoms appears, dosage stops, and then the symptoms stop as well. "Rechallenge" occurs when after the initial symptoms abate after dosage stops, and dosage is recommenced, the original symptoms again appear. Short of DBRCTs reaching statistical significance, this method is the next most effective method of validating causation, and in many way more desirable because it is cheaper, quicker, and accomplished by only the doctor and the patient. See also

Competence and objectivity, e.g. the absence of bias, are essential to the integrity of the PA. It is questionable whether the structural composition of the Army as currently constituted in the Department of the Army and MEDCOM is capable of such objectivity. The Army's singular focus on mental health and "13 continuous years of war" to explain the suicide crisis while disregarding antidepressants requires a change of Army leadership to impose a new perspective in solving this national tragedy.

Scientific reliability would be enhanced immediately by the Army's initiation of PAs to determine its suicide problem. There is no excuse for not doing so.

Violence Towards Others

Specialist Lopez gunned down fellow soldiers and, when confronted by military police ("MP"), put a .45 caliber to his head and pulled the trigger. Suicide and murder are as dissimilar as two acts can be, but merge in certain individuals in terms of antidepressant side effects. Ivan Lopez has to be a primary candidate for consideration in this grouping.

The FDA linked antidepressant induced suicidality with 3rd party violence from the beginning of the antidepressant controversy in 1991. In the initial hearing of its kind that year the FDA convened an expert's panel and asked them to answer the compound question whether antidepressants "cause the emergence and/or intensification of suicidality and/or other violent behaviors." That panel, meeting a dozen years before pharmaceutical claims to the contrary were finally dismissed, answered with a unanimous "no."

In 2003 when the suicidal side effects of antidepressants were publicly divulged and the FDA hearings about to commence, the New York Times contacted the original panelists and reported "seven members from...(that)...panel...in recent interviews said newly unearthed information about some antidepressants might make them reconsider their 1991 votes..." 136

Researchers have identified 1527 cases of 3rd party violence committed by patients taking antidepressants that have been disproportionally reported to the FDA's Adverse Event Reporting System ("AERS"). The primary drug class reported, by far, was antidepressants. Moore et al identified therein reports on homicide, homicidal ideation, physical assault, physical abuse, and violence related symptoms.¹³⁷

Adverse events experienced by patients taking antidepressants continue to be reported to the FDA in matters related to violence towards others. Other commonly reported adverse events experienced by antidepressant patients include hostility, aggression, agitation, and anger. ¹³⁸

http://www.who.int/medicines/areas/quality_safety/safety_efficacy/S.AfricaDraftGuidelines.pdf

[&]quot;Pharmacovigilance Guidelines" at

¹³⁵ PDAC September 20, 1991 pp 259-260

¹³⁶ New York Times August 7, 2003 "Debate Resumes on the Safety of Depression's Wonder Drugs" by Gardiner Harris.

¹³⁷ Moore TJ, Glenmullen J, Furberg CD (2010) "Prescription Drugs Associated with Reports of Violence Towards Others" PLoS ONE 5(12); e15337. Doi:101371/journal.pone.0015337.

¹³⁸ See FDA Adverse Event Reporting System ("FAERS"); Latest Quarterly Data Files; Jan-Mar 2013,

Courts, that is to say judges and/or juries, after hearing technical evidence in individual cases have weighed the matter and determined that antidepressants caused or contributed to violence toward others. What should be the relevance of these cases is that, unlike unilateral processes, they were full blown adversarial proceedings where truth has its best chance to prevail. Any Army report, however well intended, cannot compete with the objectivity of adversarial trials in arriving at the truth.

Specialist Ivan Lopez

Fifteen year Army veteran Specialist Ivan Lopez was the perpetrator of the April 2nd Fort Hood violence against his fellow soldiers and himself.

The press' collective frenzy over the "motive" of the shooter began immediately. After determining fairly quickly that Lopez had no apparent ties to terrorism as did the 2009 Fort Hood shooter, Major Nidal Hasan, the press went here and there to poke at various keying events that may have set Lopez off. To those having studied antidepressant induced suicide and violence, the press' frenzy over motive was proving, once again, the press either was ignorant on antidepressant side effects or staying away from issue intentionally.

Press coverage on Lopez by the New York Times reported there was a verbal altercation immediately before the shooting, that Lopez "had a clean record," that he "was active in the band" in his Puerto Rico high school, that he joined the National Guard in 1999 and in 2008 transferred to the regular Army, that he "was a very experienced soldier," that Lopez' wife "was surprised and saw no clues coming in to this" that two of his earlier supervisors from the Puerto Rico National Guard "said he had been an exemplary soldier" and that he was the most responsible, obedient, humble person, and one of the most skillful guys on the line." ¹⁴⁰

One presumes the press coverage was neither comprehensive nor current in terms of what Army investigators will ultimately discover on Lopez' activities in his final days. It is clear enough already, however, that Ivan Lopez was neither inherently insane nor a serial killer. The families of the victims Lopez killed deserve not only our sympathy but our best effort to find out why. Lopez should be considered a prime candidate as suffering the effects of psychotropic medications as the reason for his rampage. The Army should not be seeking excuses for either itself or Lopez—but the truth!

Concluding

One has to bet that the Army will continue to obfuscate antidepressants and attribute Fort Hood and Specialist Lopez to some combination on mental health, PTSD, and war related stress.

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects

http://www.PLoSmedicine.org/article/info%3Adoi%2F10.1371%Fjournal.pmed.0030372; "Antidepressants and Violence: Problems at the Interface of Medicine and Law" September 12, 2006. Article cited 9 cases of contested issues in court. In 4 cases the judge and/or jury determined that the antidepressant caused or contributed to 3rd party violence.

¹⁴⁰ New York Times, April 3, 2014, "Fort Hood Gunman Was Being Treated for Depression." By David Montgomery, Manny Fernandez, and Timothy Williams.

No one will ever know with certainty why Lopez did what he did. One could be completely wrong in presuming with the sketchy factual information available to date that Lopez killed others and himself primarily as the result of a psychotropic drug. This paper presumes no such thing, only that the U.S. Army has no chance of finding the truth by the manner in which it purports to seek the truth on Army suicides.

The Army's bad policies and liberal dispensing of drugs known to cause suicidal behavior could be at the heart of the Army's prolonged tragedy of suicides. Institutions large and small have been guilty of bad policy throughout history and covering it up out of fear of the consequences. In the larger context of the Army's suicide epidemic, however, there is no defense to ignoring the ramifications of suicidality inducing drugs.

What one does know is that some science is on the side of those suggesting Army suicides and violence is attributable to antidepressants---and that the Army has no science supporting what amounts to idle speculation on "mental health" and "13 years of continuous war." The Army's resort to the latter has nothing more than speculation, conjecture, and unscientific opinion to sustain it. Suicide is certainly a difficult dilemma, and scientifically complicated. But the Army's pattern must be broken; it must be stopped!

There are steps that can be taken to get to the bottom of the problem. The best, immediately, is to adopt a policy of convening a psychological autopsy for every future Army suicide. The perishable nature of evidence valuable to a PA quickly evaporates, but some value could accrue with maximum effort to reconstruct the past 5 years of Army completed suicides. Diverting funds from STARRS to fund the necessary psychiatrists and psychologists to conduct these abbreviated PAs are in order. STARRS as currently conceived is not giving the Army or the public the bang for the buck, and certainly is not putting an end to this tragedy anytime soon.

If psychological autopsies confirm that antidepressants are not a cause or a factor in the suicides, the results of the PAs will nevertheless point the Army and nation to the best causal explanations and rid the Army and nation of this plague.

The Army will never lead us to where we must go if it continues to ignore the elephants in the room—whatever they are. First Secretary McHugh, please get off the "Ambien" script and tell us what antidepressant Specialist Lopez was taking. That would be a good beginning.

go