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Presented to the United States House of Representatives

House Committee on Veterans' Affairs, Subcommittee on Health

May 18, 2016

The International Society for Ethical Psychology and Psychiatry (ISEPP) is pleased to submit this statement concerning legislation to establish increased informed consent for psychiatric drugs within the Department of Veterans Affairs (VA), as part of an overall effort to improve the care of our nation's veterans. We are pleased this effort has bipartisan support and we support the proposed bill.

ISEPP is a 501(c)(3) non-profit volunteer organization of mental health professionals, physicians, educators, ex-patients and survivors of the mental health system, and their families. We use the standards of scientific inquiry to address the ethics of psychology and psychiatry and to educate our members and the public about the true nature of "mental illness", the de-humanizing and coercive aspects of many forms of mental health treatment, and the alternative humane ways of helping people who struggle with very difficult life issues. Informed consent is at the heart of our mission because it ensures people are treated humanely and with respect.

We support this bill because it would require more robust procedures when psychiatric drugs are proposed as treatment for veterans, allowing them access to the full information about its risks and thus enabling truly informed consent. In addition to expressing our support for the bill, we would also like to raise a number of concerns regarding statements already submitted to the subcommittee by two organizations with heavy financial ties to the very industry that supplies these drugs: the American Psychiatric Association and the National Alliance on Mental Illness. ISEPP has no financial ties to the pharmaceutical industry or any other industry.

The American Psychiatric Association (APA) statement to the Subcommittee on Health, dated April 20, 2016:

The APA stated it, "...believes that any legislative initiative should not segregate mental health from other medical care, such as segregating psychotropic medications as posing certain risks. Psychotropic medications are in a class of pharmaceuticals along with other classes of medications that contain potential adverse effects, including cardiac, hematologic, oncologic, rheumatologic, steroids, as well as most commonly prescribed antibiotics."

Although some non-psychiatric drugs do have potential adverse effects, all psychiatric drugs cause adverse effects because their main action is to disrupt natural and normal brain functioning, and of all the drugs regulated by the FDA, psychiatric drugs are



clearly the most dangerous and problematic in terms of violence. Of the top 31 prescription drugs associated with violence, 26 are psychiatric drugs¹.

Psychiatric drugs are not similar to other classifications of drugs in that they do not target real biological pathology in order to correct or cure a defect. In that sense, psychiatry is qualitatively different than the other medical specialties that the APA lists in their statement. Psychiatric drugs simply interfere with brain functioning and change thoughts, feelings and behaviors by increasing or decreasing neurotransmitter availability. They act like chemical straight jackets and they do not correct chemical imbalances².

The APA admitted, "To date, the Food and Drug Administration has few indications on combination use with psychotropic drugs", and seemingly uses this to justify their stance that there should not be greater caution for ensuring informed consent. ISEPP argues the opposite: that this is exactly why increased informed consent is needed. Prospective patients must be made aware of this lack of data regarding the simultaneous prescription of multiple psychiatric drugs before they consent to taking them. ISEPP agrees with APA in that "...the FDA must provide comprehensive data that would allow for informed decisions on complex treatment", but that data does not exist.

Further, the APA statement uses questionable reasoning to argue against the need for greater safeguards by stating, "Frequently, veterans will utilize primary care office visits to seek care for mental disorders. In these incidents, antidepressants are more often prescribed by primary care providers than psychiatric physicians. Any additional steps for increased informed consent may unintentionally reduce a primary care provider's receptivity to prescribe psychotropic drugs." The psychiatric drugs commonly prescribed by primary care providers are antidepressants. Given that some of these carry the most stringent FDA black box warning, additional informed consent seems appropriate, not an inconvenience. It is incomprehensible why the APA would assume that patients visiting non-psychiatric doctors should have less information about one of the most dangerous classes of drugs on the market prior to consenting to their use.

Lastly, the APA's statement wrongly dismisses the need for the proposed informed consent bill by falsely claiming that giving more information to the patient about the risks and benefits of psychiatric drugs would create a stigma, which, according to the APA, would create a "barrier to seeking treatment." This is false because if informed consent is being given, the veteran is already seeking treatment, as they are already in the office. Moreover, the APA appears more worried that people might "decide not to take them" than honestly informing them about the significant and potentially dangerous effects of psychiatric drugs. Is the APA more interested in getting a patient to "take them" or in helping the person make a truly informed decision?

The National Alliance on Mental Illness (NAMI) statement to the Subcommittee on Health, dated April 20, 2016:

² Pies, R. (2011). Psychiatry's New Brain-Mind and the Legend of the "Chemical Imbalance". *Psychiatric Times*. Available at: http://www.psychiatrictimes.com/blogs/couch-crisis/psychiatry-new-brain-mind-and-legend-chemical-imbalance#sthash.vrEiNljb.dpuf.

¹ Moore TJ, Glenmullen J, Furberg CD (2010) Prescription Drugs Associated with Reports of Violence Towards Others. PLoS ONE 5(12): e15337. doi:10.1371/journal.pone.0015337.

NAMI stated, "The proposal unfairly singles out mental health conditions and the medications used to treat them as part of a new mandatory protocol that stigmatizes both these disorders and their treatment." This parrots the main complaint of the APA about singling out psychiatry from all other medical specialties. But NAMI's statement also mirrors the APA's in that it wrongly thinks proper informed consent "stigmatizes" both mental health problems and interventions. Psychiatric drugs have already been classified and acknowledged as having some of highest risks for potential harm. Ensuring that adequate informed consent is given to patients who are prescribed these drugs does not create a stigma, even if based on this increased knowledge the patient decides not to take the drug. It is about informed consent.

Again, NAMI echoes the APA in complaining that adequate informed consent for veterans will cause "limited access" to psychiatric treatment. The proposed bill would only affect a veteran once the veteran has already been seen, diagnosed and is in the process of choosing a treatment option. Thus, it would not limit access in any way, but rather would ensure proper discussion between a physician and a veteran if a particular psychiatric drug were to be prescribed.

NAMI continues to parallel the APA's concerns about the proposed assurance that a prescriber will disclose to a veteran that there are "unknown dangers of mixing drugs and dosages in sizes and combinations that have not been approved or tested by the FDA." ISEPP believes it is paramount that a veteran be told about this lack of evidence and data regarding psychiatric drug polypharmacy. There is a poverty of research related to taking multiple psychiatric drugs, and as such, special precautions must be taken to ensure the veteran understands there are certainly "unknown dangers" related to taking two or more such drugs at the same time. This discussion needs to happen between a doctor and patient, and veterans have reported such discussions are essentially nonexistent.

NAMI further expresses concern about whether the bill would apply to the use of psychiatric drugs for non-psychiatric conditions. ISEPP contends that since the issue is about the safety of the prescribed drug, the condition is irrelevant. The issue is about providing full information about the risks and benefits of the drug, regardless of the condition or diagnosis because any potential harm does not change based on the diagnosis.

Lastly, NAMI gives the false impression that non-drug treatment options having "no scientific basis for safety and efficacy" are prevalent and that physicians should not be "forced to disclose these treatment options". Physicians absolutely have a duty to propose a wide range of treatment options, other than psychiatric, and in fact, have an ethical obligation to use the least intrusive or potentially harmful method first, which certainly may include lifestyle changes prior to drug intervention. There is also a mountain of evidence for the efficacy of non-drug psychological, nutritional, social, and environmental interventions that do not have the potentially harmful chemical effects of psychiatric drugs. Unfortunately though, the great majority of people asking for help for a mental health concern are routinely prescribed psychiatric drugs. And ironically, drug treatment has the least amount of evidence for safety and efficacy.

ISEPP agrees with the proposed legislation in promoting enhanced communication to veterans, and mandatory, complete, informed consent procedure for the prescription of

psychiatric drugs. ISEPP supports veterans and military members in their struggles inherent in their profession. In testimony to this, ISEPP launched Operation Speak Up in 2012 to focus on this issue and offer humane and effective ways of helping them. One ISEPP member runs a non-medical, non-drug, non-clinical veteran/military retreat called Operation TOHIDU in the greater Washington DC area. See more about Operation TOHIDU at https://www.youtube.com/watch?v=m-8XJ56UnxQ.

ISEPP understands the work, time restraints and demands placed upon physicians. But time constraints cannot trump humane and honest informed consent. By passing the proposed legislation, it will protect and ensure informed consent has been obtained and will surely create additional dialog between the prescriber and the veteran about other options for improving their condition, outcome and life. Telling a veteran about potential dangers of taking psychiatric drugs known to have dangerous effects and a long-term worsening of the condition does not create stigma. It creates informed consent and a more humane approach to helping our fellow human beings, allowing the veteran to be watchful for potential negative effects of the drug. It also certainly may safe a life.

ISEPP fully supports the proposed legislation and looks forward to assisting the Subcommittee with any questions or work.

Thank you for the consideration and trust with this important matter. If you have any questions or if we can be of further assistance, please contact our Executive Director, Chuck Ruby, Ph.D., Lieutenant Colonel (retired) at <u>docruby@me.com/</u> 301-646-6022 or Toby Watson, Psy.D., Board Member and Past Executive Director at <u>drtobywatson@drtobywatson.com/</u> 920-918-7377.