

To: Members of the House of Representatives & Senate

We, the undersigned doctors, understanding the potentially serious risks versus possible benefits of Black Box medications, agree that consent should require Written rather than Verbal Consent.

What is a Black Box warning?

A black box warning is the strictest and most serious type of warning that the FDA (Federal Drug Administration) can give any medication and highlights potentially fatal, life-threatening, or disabling adverse effects of these medications.

A black box warning is a tool that provides crucial information to both parties and allows each to perform a benefit-risk analysis before prescribing/taking the medication.

Included amongst the most serious side effects of Black Box medications are:

- Suicidal ideation
- Death
- Homicide
- Hospitalization
- Hallucinations
- Anxiety
- Depression

When does the FDA require a medication to carry a Black Box warning?

The FDA requires a Black Box warning when a medication causes serious, undesirable side effects (such as fatal, life-threatening, or permanently disabling adverse reactions).

Why is this increased level of consent needed?

Veterans, who are trained to follow orders, and may already be fragile due to their service, often hesitate to ask questions of superiors or may not have enough information to ask relevant questions. It is the duty and responsibility of the physician to ensure the veteran understands whether the risks of the prescribed medication outweigh the benefits.

Once implemented, we believe that Written Informed Consent will greatly reduce the incidence of veteran suicide by providing an increased level of understanding regarding any possible side effects.

Finally, a well-informed veteran, who is a partner in their health care decisions, who understands the risks and benefits of their treatment, especially any invasive procedures or medications, is much more likely to adhere to their treatment protocol.

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