

## **LAW REVIEW<sup>1</sup> 24002**

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### **Advocating for Written Informed Consent for Military Members<sup>2</sup>**

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#### **9.0—Miscellaneous**

The Reserve Organization of America (ROA) conducted its 2023 annual convention in Baton Rouge, Louisiana in late September and early October. At the convention, several resolutions were considered, including the following resolution:

**Whereas**, it would be beneficial to patients and providers to require written informed consent for drugs that have an FDA black box warning;

It is in the best interest of military members and veterans to receive adequate care and information, which is why written informed consent should be the new standard. Currently, the Veteran's Health Administration (VHA) only requires oral

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<sup>1</sup> We invite the reader's attention to [www.roa.org/lawcenter](http://www.roa.org/lawcenter). You will find more than 2,000 "Law Review" articles about the Uniformed Services Employment and Reemployment Rights Act (USERRA), the Servicemembers Civil Relief Act (SCRA), the Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA), the Uniformed Services Former Spouses' Protection Act (USFSPA), and other laws that are especially pertinent to those who serve our country in uniform. You will also find a detailed subject index, to facilitate finding articles about specific topics. The Reserve Officers Association, now doing business as the Reserve Organization of America (ROA), initiated this column in 1997, and we add new articles each month. These articles are available for free to everyone, not just ROA members.

<sup>2</sup> Thank you to John Spagnola, President/CEO of Veterans Strategic Solutions, for providing information regarding written informed consent.

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informed consent for treatments and procedures provided to veteran and military members.<sup>4</sup> With the sole requirement of oral informed consent, it is nearly impossible to ensure that patients sufficiently understand their treatment options and the potential side effects to medications they are blindly consenting to, especially medications that have an FDA black box warning. Patients have the right to pertinent information about recommended treatment options so they can make informed decisions about their care. The adoption of a written informed consent requirement has the potential to not only help veterans and military members fully understand their treatment options, but also to reduce the number of veteran suicides, overdoses, and other preventable health issues.

Now, therefore, be it resolved, that the Reserve Officers Association, d.b.a. the Reserve Organization of America, urges Congress to compel the Secretary of Defense and Secretary of Veterans Affairs to ensure patients prescribed black box warning drugs provide written informed consent prior to any authorization or agreement to undergo such medical intervention.

The purpose of this article is to explain this resolution, which I did not draft, and to opine as to the advisability of ROA endorsing this resolution. After having researched the issue and having considered it in detail, I wholeheartedly endorse this proposed resolution.<sup>5</sup>

### **What does “Black Box Warning” mean?**

The FDA (Food and Drug Administration) requires a “black box warning” for certain medications that carry serious safety risks in order to

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<sup>4</sup> White-Paper-Strengthening-Informed-Consent-for-Prescription-Medications.pdf (veteranseducationproject.org)

<sup>5</sup> The resolution was adopted at the 2023 convention.

communicate potential side effects as well as instructions on how to safely use the medication.<sup>6</sup> This label is for both the medical provider and for the patient to read and understand so that an informed decision can be made before prescription and use of the drug. However, it has come to the attention of The Veteran's Education Project that veterans are being prescribed large amounts of FDA black box warning medications but are not receiving sufficient explanations of the risks that accompany such drugs.<sup>7</sup> Due to the lack of information, veterans who are already deemed to be at risk of suicide, are being prescribed medications that are known to cause depression and suicidal thoughts. It is important for both the medical provider and the patient to be aware of these risks so that the patient can be monitored and receive the utmost care. The black box warning is just the first step to properly educating patients of the drugs they are taking. The FDA is doing their part to identify and label certain high risk medications that have potentially serious side effects with a black box warning in order to educate users about the drug, as well as to mitigate any misuse. To complement the efforts of black box warnings and to further encourage the full understanding of medications and their side effects, written informed consent is vital.

### **Implementing Written Informed Consent Will Save Lives**

The process of written informed consent is simple and can be easily implemented. In addition to the patient and medical provider orally discussing the reasoning why it is necessary to prescribe a high risk medication, the patient and provider will also fill out and sign a form explaining everything in writing. This form not only includes the possible side effects of the medication, but also includes a plethora of other important information such as a description of the treatment, the

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<sup>6</sup> What Does a Black Box Warning on Meds Mean? – Cleveland Clinic

<sup>7</sup> White-Paper-Strengthening-Informed-Consent-for-Prescription-Medications.pdf ([veteranseducationproject.org](http://veteranseducationproject.org))

goals of the treatment, benefits of the treatment, and alternative treatment options.<sup>8</sup> This information is important because sometimes these drugs cause extreme side effects such as hallucinations, blurred vision, fatigue, depression, or even the inability to function normally. Due to such effects, patients ought to know and understand so that they can be prepared, understand what to expect, and seek additional help if necessary. Furthermore, if the potential side effects are determined to be too large of a risk for the patient, then an alternative solution can be sought out. The patient can then read and review this document containing everything they need to make an informed decision on whether they would like to consent to taking the medication and proceeding with the treatment despite the potential side effects they may encounter. In some cases, it is medically necessary for a high risk drug to be prescribed to a patient. Nevertheless, the patient has a right to be informed of all the potential risks and benefits of such medication, and informatively consent to such treatment.

### **Please join or support ROA**

This article is one of 2,100-plus “Law Review” articles available at [www.roa.org/lawcenter](http://www.roa.org/lawcenter). The Reserve Officers Association, now doing business as the Reserve Organization of America (ROA), initiated this column in 1997, and we add new articles each month. ROA is more than a century old—it was established on 10/1/1922 by a group of veterans of “The Great War,” as World War I was then known. One of those veterans was Captain Harry S. Truman. As President, in 1950, he signed our congressional charter. Under that charter, our mission is to advocate for the implementation of policies that provide for adequate national security. For more than a century, we have argued that the

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<sup>8</sup> Informed Form - Consent for Long-Term Opioid Therapy for Pain.pdf

Reserve Components, including the National Guard, are a cost-effective way to meet our nation's national defense needs. Through these articles, and by other means, including amicus curiae ("friend of the court") briefs that we file in the Supreme Court and other courts, we educate service members, military spouses, attorneys, judges, employers, Employer Support of the Guard and Reserve (ESGR) volunteers, Department of Labor (DOL) investigators, congressional and state legislative staffers, and others about the legal rights of service members and about how to exercise and enforce those rights. We provide information to service members, without regard to their membership status, or lack thereof, in our organization, but please understand that ROA members, through their dues and contributions, pay the cost of providing this service and all the other great services that ROA provides.

If you are now serving or have ever served in any of our country's eight uniformed services,<sup>9</sup> you are eligible for membership in ROA, and a one-year membership only costs \$20 or \$450 for a life membership.<sup>10</sup> Enlisted personnel as well as officers are eligible for full membership, and eligibility applies to persons who are serving or have served in the Active Component of the armed forces, as well as the National Guard and Reserve.

You can join ROA on-line at

<https://www.roa.org/page/memberoptions/> or call ROA at 800-809-9448.

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<sup>9</sup> Congress recently created the United States Space Force as the 8th uniformed service.

<sup>10</sup> If you are under the age of 35, you can become an associate member for free for five years or when you turn 35, whichever comes first.