Why the military can use emergency powers to treat service members with trial COVID-19 drugs

May 11 2020, by Jennifer Bard

Credit: CC0 Public Domain

Infectious disease has always been one of the military's greatest threats. By its own estimates, the U.S. Army lost almost as many soldiers from

the 1918 flu as died on the battlefields of the first World War.

Troops are at risk during an outbreak due to the tight quarters in which they live and work. It is therefore not surprising that all branches of the service – Army, Navy, Marines, Air Force and Coast Guard – have been hit hard by COVID-19. The military has also played an important role in responding to the virus, from evacuating State Department officials from Wuhan in January to its current role building and staffing civilian field hospitals and augmenting civilian research teams.

To mitigate any risk, the Department of Defense has enforced rigorous social distancing policies and a military-wide travel ban halting nonessential deployments.

New treatments

But in addition to measures aimed at keeping people away from sources of infection, the military is also treating active duty personnel who become infected. Because the COVID-19 virus is new, there are as yet no FDA approved treatments. As a result, military physicians are turning to either treatments approved for other conditions or seeking access to newly developed treatments, such as the antiviral Remdesivir, which to date has received FDA emergency use approval only for COVID-19 patients with severe conditions. That presents a significant legal challenge due to existing laws protecting military personnel by recognizing that their obligation to follow orders reduces their ability to provide informed consent.

As an expert in public health law and human subject research, I study the tension between protecting participants of biomedical research and responding quickly to emerging threats. But I have also had personal experience with the events that led to the passing of the law that allows the military to work with the FDA in order to get emergency

authorization to respond quickly to emerging threats.

Gulf War Syndrome

In 1998, I was working for now U.S. Senator, then Connecticut Attorney General, Richard Blumenthal when I met Russ Dingle and Thomas "Buzz" Rempfer, two remarkable airmen who filed a whistleblower complaint seeking protection from what they described as forced participation in an unlawful research experiment. Specifically, they asserted that the Department of Defense was mandating that all active duty personnel be vaccinated against anthrax using a product, AVA, not yet approved by the FDA for the purpose the Army was now using it.

The vaccine had been in use since the 1970s to protect wool workers and veterinarians at risk from touching naturally occurring anthrax spores, but had not been approved for protection against inhaling them, a method of spread reportedly developed by Iraqi scientists as a bioweapon. But many in the military were reluctant to be vaccinated because of their concern that it might be a cause of Gulf War Syndrome. To this day, there is no agreement about the specific symptoms, let alone cause, of Gulf War Syndrome.

A 2000 report by the well-respected Institute of Medicine found "no conclusive link to the vaccine." But the causal connection seemed plausible to many sufferers, especially given the continuing emergence of long-term harm suffered by veterans of the Vietnam War and their children from exposure to Agent Orange.

The whistleblower's primary claim was that the anthrax vaccination program was "research" and therefore the army was required to abide by two different protections. The first, called the Common Rule, is a law establishing that all research conducted by the federal government require the informed consent of participants. Their second claim was

that even if it was being used as a preventative measure, the Department of Defense was constrained by a 1998 law passed in direct response to concerns over possible links between unapproved drugs and Gulf War Syndrome. It prohibited "the administration of investigational new drugs, or drugs unapproved for their intended use, to service members without their informed consent" unless consent was waived by the president.

Blumenthal wrote to the secretary of defense warning him that administering an unapproved vaccine risked violating both laws and demanding that the research be stopped. That letter became part of a larger debate over whether the military's need for force protection exceeded the risks to any individual serviceperson.

Emergency use

In 2003, Colonel Rempfer and six other at first unnamed plaintiffs brought suit in federal court which resulted in a preliminary injunction halting the vaccine program. Responding to the lawsuit, the Department of Defense denied that they were conducting research and claimed the authority to waive consent because it was necessary to prevent infection with weaponized anthrax.

But in winning the battle, those seeking to stop the vaccine program lost the war. The Department of Defense appealed to Congress for a workaround. It resulted in the passing of the BioShield Act in 2004, creating the Emergency Use Authorization. This gave the FDA authority to recharacterize the status of a drug or vaccine from investigational to approved for emergency use. In December of 2005 it issued a "final order concluding that [the Anthrax Vaccine] was the best available medical countermeasure to the potential military emergency." Although Col. Rempfer filed a lawsuit to protest the FDA's decision, it was to no avail and shortly afterwards the Department of Defense resumed the vaccine program. Col. Dingle died of cancer in 2008, but Col. Rempfer

remained critical of the anthrax vaccine program and still actively advocates on behalf of past and future military personnel.

A compromise

Since the passage of the BioShield Act, Congress has continued to support the FDA's authority to make unapproved drugs available in response to new threats. In 2017, the Department of Defense sought power to unilaterally authorize use of unapproved drugs in battlefield situations. In the face of FDA objections to this level of autonomy, Congress created a compromise measure memorialized in a Memorandum of Understanding that allows the Department of Defense broad authority to declare the need for emergency use permission and request that the FDA "take actions to expedite the development of a medical product." But final authority to issue an emergency use order rests with the president.

It is because of the servicemen committed to the preservation of informed consent that troops today have early access to potential COVID-19 drugs and vaccines while still respecting their vulnerability as patients without the complete ability to give informed consent.

Provided by The Conversation