LETTER *to the* EDITOR

To the Editor:

In the Spring Vol 21, Ed 1, 2021 *Journal of Special Operations Medicine* (JSOM), we published the following article: "Making Use of Your Assets: Clinical Use of EOD Radiography in the Forward Deployed Setting." This article was a collaborative effort between deployed joint Servicemembers regarding austere medical care from 2018 through 2019 and was accepted for publication by *JSOM* in 2020. The Summer 2021 edition of *JSOM* included a removal notice of our article from the digital platform based on two claims: (1) prepublication approval by commander and public affairs officer (PAO) was not obtained and (2) only FDA-approved devices/products are eligible for use.

The authors did receive prepublication approval. Per AR 360-1, The Army Public Affairs Program, manuscript clearance is handled by the PAO at the local level and is escalated only if the material cannot be cleared at the local level.[1] *JSOM* author requirements state all submissions must be preapproved by one's commander and PAO prior to submission. At the time of manuscript development, all authors were assigned or tasked to units reporting to the Combined Joint Task Force (CJTF). Respective unit commanders, the Special Operations Joint Task Force (SOJTF), and the CJTF approved the manuscript for submission.

The second claim is the provision of care using non–FDA-approved devices. The US Food and Drug Administration (FDA) regulates the sale of medical devices and certain treatments; the FDA does not claim to exercise authority over physician practice.[2,3] According to the FDA,

> "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgement. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects."[4]

While the device used and described in our manuscript is not FDA approved, it was used on a very select group of patients in a resource-constrained setting with strong precautions in place. The information gained from its use impacted medical decision making and prevented critical disruption to the mission. Ultrasound, the only other imaging device available, did not provide the same information.

The two claims directed at us implied a lack of integrity and honesty. Off-label use, improvised devices, and use of non–US-developed medicines and treatments have all faced scrutiny. These differences of opinions have a place in academic medicine and help to guide future research and development of technologies and practices. This is especially important for the military in austere environments with limited capabilities. We applaud *JSOM* for continuing to support discussions regarding innovative uses of resources to further medical research and battlefield medicine.

Very respectfully,
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LtCol Regan Lyon, MD
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References

1. United States Government US Army. *Army Regulation 360-1. The Army Public Affairs Program*. Washington, DC: Department of the Army, 2020.
2. AAPM Task Group 121. *Off-Label Use of Medical Products in Radiation Therapy*. College Park, MD: American Association of Physicists in Medicine, 2010.
3. US Food and Drug Administration. *FDA's Role in Regulating Medical Devices*. Washington, DC: US Food and Drug Administration, 2018.
4. US Food and Drug Administration. *"Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices*. Washington, DC: US Food and Drug Administration, 1998.

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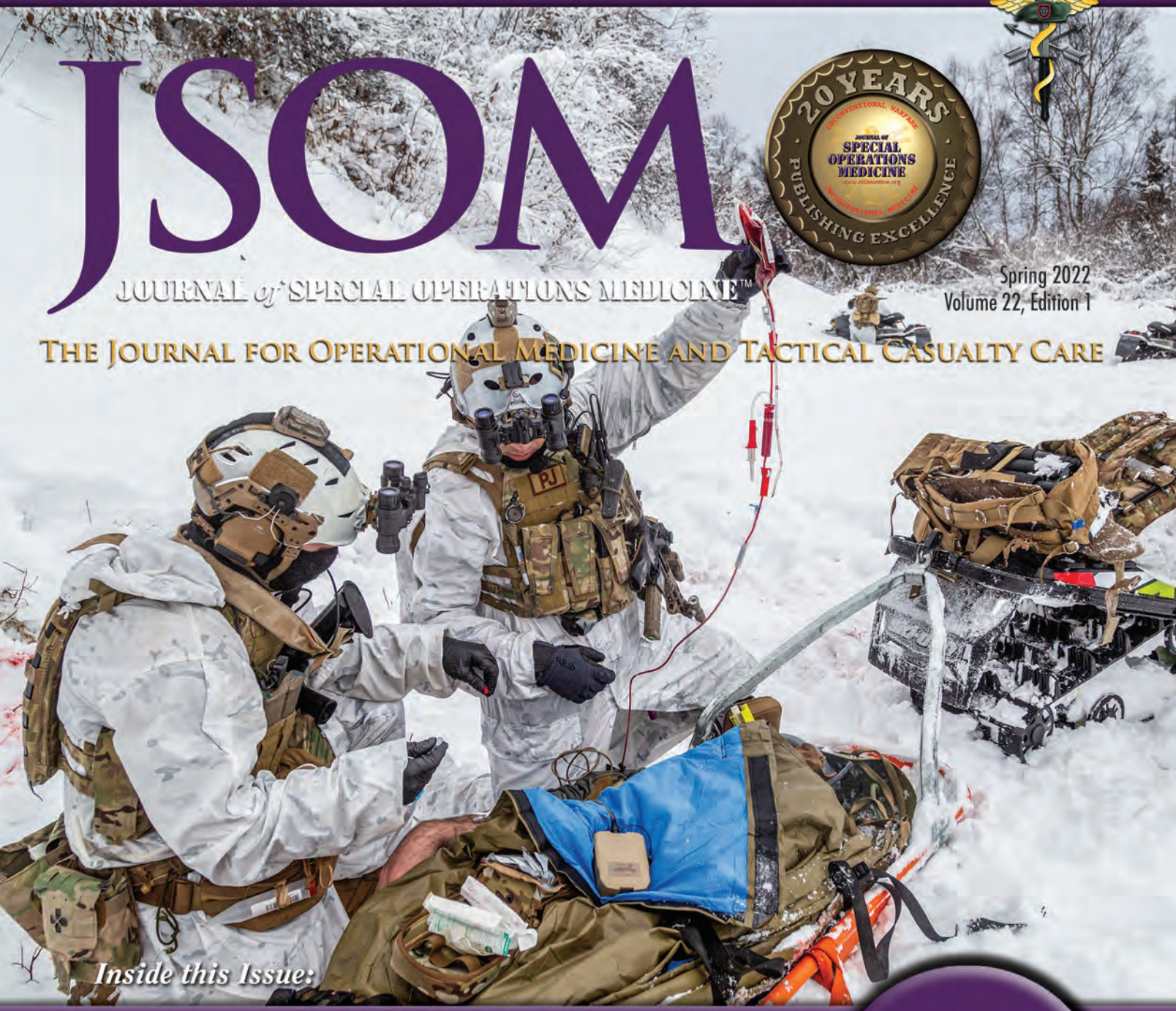

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