

New paper calls upon states to cease experimenting with lethal injection drugs and comply with FDA regulations

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The Johns Hopkins Clinic for Public Health Law and Policy at the Bloomberg School of Public Health has crafted an evidence-based paper that presents a new perspective on the legality of the lethal injection process in the United States. The shortage of the combination of the three drugs previously used in States that use lethal injection to carry out capital punishment, in an attempt to comply with the Eighth Amendment prohibition on cruel and unusual punishment, has led to unregulated and experimental protocols in the lethal injection process that violate existing federal laws. The paper argues that state Departments of Corrections are violating U.S. Food and Drug Administration (FDA) investigational new drug regulations by experimenting with lethal injection drugs when carrying out executions. The paper's completion comes on the heels of the botched lethal injection execution that occurred recently in Oklahoma.

Under federal law, state Departments of Corrections are required to submit an Investigational New Drug (IND) application when any [drug](#) is administered, dispensed or used outside of a medical practice on one or more human subjects. The Federal Food, Drug and Cosmetic Act and the FDA's IND regulations cite specific requirements for clinical investigations, which would include a state's experimentation with new lethal drug combinations during executions.

"The IND process – fortified by the FDA's unmatched expertise with

drug protocols would ensure that the Department's of Corrections protocols are effective in reducing the risk that [lethal injection](#) will subject a condemned prisoner to pain that would violate the Eighth Amendment," said Stephen Teret, JD, MPH, founding director of the Clinic for Public Health Law & Policy. "FDA law states that an IND application must be submitted when any new drug protocol or experiment is undertaken on a human outside of a medical practice or a doctor's office. The laws are in place, the process just isn't being implemented."

The paper concludes that as states continue to grapple with drug shortages and to experiment with new combinations and dosages of drugs used to carry out executions, they should adhere to the guidelines put in place by Congress over fifty years ago to safeguard the human subjects of clinical investigations, including prisoners on death row. The paper recommends that executions should be halted by the courts until an FDA approved protocol for lethal injection can be established and approved.

Provided by Johns Hopkins University Bloomberg School of Public Health

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