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News: Explainer

Death-row drug dilemma

Lack of anaesthetic used in lethal injection exposes ethics gaps in the supply chain.

Emma Marris

A shortage of a drug used in executions in the United States has sent US states scrambling to find supplies, or alternative drugs. Among the 35 states in which capital punishment is legal, some — including Arizona and California — had been sourcing a key execution drug, sodium thiopental, through a company in London — until UK government officials put a stop to its export. The only US company making the drug, which sought to move its manufacturing base to Italy, has now given up producing sodium thiopental because it cannot assure Italian officials that it won't be used for executions.

Execution by lethal injection is legal in 35 US states. *Mark Jenkinson/CORBIS*

The situation demonstrates that although pharmaceutical supply chains are global, the morals and mores of drug use are decidedly local. Will US states be forced to stop executing their death-row inmates by a drug embargo? And who decides which drugs are used to inject prisoners condemned to die? *Nature* explores an ethical dilemma.

How common is lethal injection?

Lethal injection is a common mode of execution in the United States. Of 1,238 executions since 1976 there, 1,064 have been by injection of lethal drugs. Outside the country, China is executing more prisoners given the death sentence by injection and fewer by firing squad. Officals there have called it "cleaner, safer and more convenient", according to a report by human-rights organization Amnesty International.

How was the US protocol devised?

A standard three-drug sequence is used in the United States to execute prisoners condemned to death. It was not developed by any scientific panel of pharmacologists or ever published in a peer-reviewed forum. Rather, it was invented by one man in 1977: then Oklahoma chief medical examiner Jay Chapman. Chapman was interested in devising a more humane alternative to the electric chair or firing squad. He chose three drugs, to be administered in sequence: sodium thiopental to render the condemned unconscious; pancuronium bromide, to paralyse the body and

lungs; and potassium chloride to stop the heart.

Experts have challenged the protocol as administered as cruel. One study suggested that some dying prisoners are aware and suffering as their lungs and heart stop[1].

Chapman's home-made recipe caught on, however. It is the standard for most of the US states that execute prisoners by lethal injection.

Why is there a shortage of sodium thiopental?

In recent years, sodium thiopental has been used less and less often for anaesthesia, as newer drugs have gained favour. For some time, all the sodium thiopental in the United States has come from a drug company called Hospira, based in Lake Forest, Illinois. In the summer of 2009, Hospira had to suspend production of the drug. The company that made the active ingredient — which Hospira would not name, but US Food and Drug Administration (FDA) records identify as Abbott Laboratories — stopped making it. Hospira began looking for a replacement source and was planning to move production of vials of the drug for all its markets to a plant in Liscate, near Milan, Italy.

Near the beginning of this year, the Italian government demanded that Hospira assure that none of the drug would be used for executions. Unable to control who buys their products and what they use them for, Hospira decided to stop making sodium thiopental on 21 January. "We cannot take the risk that we will be held liable by the Italian authorities if the product is diverted for use in capital punishment," the company said in a statement. "Exposing our employees or facilities to liability is not a risk we are prepared to take."

Hospira dropped the drug "with regret", according to spokesman Daniel Rosenberg, who says that it still has a legitimate medical use, although it currently accounts for less than a quarter of a percent of Hospira's sales. The decision will, however, end the company's qualms about the use of its product by prisons, which is something the company has long opposed. "We've been regularly reaching out to every state in the country to tell them that we don't approve of this use," says Rosenberg.

Has the shortage stopped any executions?

It delayed some. States had to work hard to find unexpired vials of the drug, and California and Arizona among others ended up importing some from a UK-based concern called Dream Pharma, based in west London, according to the London-based prisoner-rights group Reprieve. But on 30 November, the UK Department of Business, Innovation and Skills banned all export of sodium thiopental to the United States. "Our government is completely against capital punishment," says a spokesperson for the department. "The only trade we were doing on this drug was for capital punishment."

The UK government is now considering whether there is enough legitimate trade in the two other

drugs that are used in the US execution protocol to warrant keeping their export uncontrolled. (Pancuronium bromide, for instance, is used as a muscle relaxant.) Meanwhile, companies and government officials in Germany have come together against supplying the United States with any sodium thiopental for executions, according to the Associated Press.

Did the FDA 'help' states obtain sodium thiopental?

Not according to a spokesperson — but they didn't hinder the states either. They did not interfere with the importation of the drug from the United Kingdom, despite knowing where the drug was headed. A spokesperson says: "In 2009 and 2010, FDA permitted the importation of several shipments of sodium thiopental to state Departments of Correction. In doing so, FDA deferred to law enforcement in the use of substances for lethal injection, which is consistent with the agency's long-standing policy. The agency did not conduct any review of these products for safety, effectiveness or quality."

Now that Hospira has stopped making the drug and the United Kingdom has controlled export, will a lack of sodium thiopental end lethal injection in the United States?

Unlikely. States may be able to source the drug from countries less squeamish about its end use. Or, more likely, they will follow the lead of Oklahoma, which has recently switched to using pentobarbital in place of sodium thiopental. Pentobarbital is made by only one company in the United States, Lundbeck, based in Deerfield, Illinois, and owned by Copenhagen-based company H. Lundbeck.

A spokeswoman for Lundbeck, Sally Young, seemed horrified on Wednesday that her company's product had almost surely been used as part of the process to execute three prisoners in Oklahoma. She only learned of the use from reporters. "We do not in any way promote any off-label use of the product," she says. "The use of our product to end lives contradicts everything we are in business to do."

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With both its active ingredient supplier and wholesale manufacturer in the United States, Lundbeck may not face any disruptions of its supply chain on moral grounds, as Hospira did.

Young says Lundbeck has sent a letter to the state of Oklahoma formally objecting to the use of pentobarbital in executions, but "from a legal perspective, we can't control that".

If the FDA won't and the manufacturer can't stop a drug from being used in executions, who in the United States can?

A manufacturer can stop a drug being used for executions by ceasing to make it, although this will also affect any patients using the drug medicinally. Manufacturers sell to wholesalers, or sometimes direct to pharmacies. Then drugs are prescribed by a doctor and dispensed by a pharmacist, and it

is these two professionals who ultimately bear the onus of deciding whether the use of a drug is appropriate. The American Medical Association has **forbidden** its members from participating in executions, so any medical professionals who order drugs for executions do so at the risk of their professional reputations (see **'Will medics' qualms kill the death penalty?'**).

Oklahoma's Department of Corrections (DOC) spokesman Jerry Massie says that they obtained pentobarbital from "a private pharmacist" who is being kept anonymous for fear that he will be a target for attacks. The transaction is apparently in cash, and no receipt is filed. "He just obtains it and we pick it up from him," says Massie. "No prescription or anything."

Phil Woodward, executive director of the Oklahoma Pharmacists Association, says that according to the Oklahoma Pharmacy Practice Act, "a pharmacist would need a prescription from a physician" before dispensing the drugs. "So somewhere within the DOC, a physician would still have to submit an order for this product." As to whether the anonymous pharmacist acted ethically, Woodward says, "Our association has never taken a stand one way or the other on this matter." ■

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