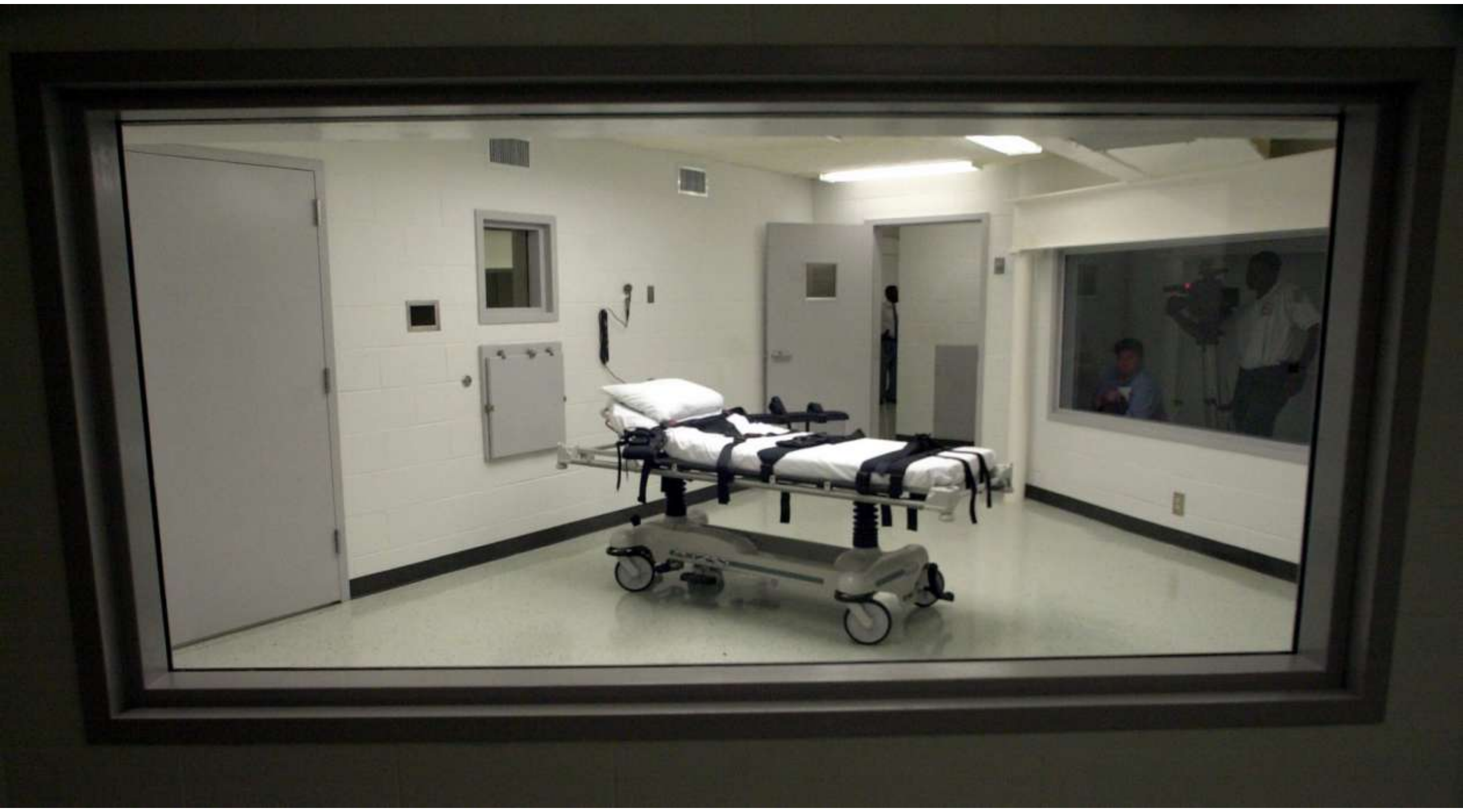
Health

Lethal injection drug access could put executions on hold

Pentobarbital, now most-commonly used execution drug, likely to face barriers in coming months

By Kimberly Leonard 6:00 am, April 4, 2012 Updated: 12:19 pm, May 19, 2014



Inmates on death row in the United States are executed by means of lethal injection. Dave Martin/AP

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A federal judge's decision to block imports of a drug used in executions will leave states to rely more on a substitute drug that could itself be getting scarce — developments that raise questions about both how these drugs are regulated and whether states will have the drugs they need to continue capital punishment by lethal injection.

Over the past three decades, lethal injection has become the primary method of execution in the United States because it is widely viewed as the most humane alternative. Thirty-five states and the federal government use this method and more than 1,100 inmates have been put to death by lethal injection.

State justice or corrections departments have conducted these executions by administering the anesthetic sodium thiopental in a lethal dosage on its own, or as part of a three-step "cocktail" in which sodium thiopental is followed by pancuronium bromide, a paralytic agent, then potassium chloride, which stops the heart and causes death.

But in late March, a federal judge blocked importation of sodium thiopental, ruling that the Food and Drug Administration (FDA) ignored the law by allowing it to be imported into the country without following regulatory protocol. The drugs were slated for executions, a purpose unapproved by the agency — and unlikely to ever be approved by the agency. Sodium thiopental is only available from overseas, because its U.S. manufacturer, Hospira Inc., stopped making it 2011, as a result of controversies over its use in executions.

Thomas Arthur has spent 29 years in prison. He was scheduled to be executed last week in Alabama, but the lethal injection was put on hold because of pentobarbital concerns. AP

Search for an alternative

The logical alternative to sodium thiopental is pentobarbital, an anesthetic that causes people to lose consciousness, sensation and memory. Since 2010, 12 state justice departments have used pentobarbital, a drug veterinarians also administer to euthanize animals, to execute 47 inmates, usually as part of a three-drug cocktail, according to the Death Penalty Information Center, a nonprofit organization that publishes annual reports on capital punishment.

Texas switches to 1-drug execution due to shortage
By The Associated Press July 10, 2012

With sodium thiopental now nearly impossible to access, pentobarbital is likely to become even more critical for those who want to carry out executions in the near future, Richard Dieter, executive director for the Death Penalty Information Center, told *iWatch News*. If the restrictions become effective, correctional departments may have to choose another drug or form of execution altogether, he said.

But pentobarbital could eventually become scarce. Most state justice departments say that for security reasons they cannot specify how much of the drug they have stored, but pentobarbital's manufacturers for human uses have in recent months acted on a number of fronts to prevent its use for executions.

Lundbeck Inc., a Danish pharmaceutical company that manufactured the

drug until late last year, sent letters last August to governors and correctional departments in 16 states — Alabama, Arizona, Florida, Georgia, Idaho, Louisiana, Mississippi, Montana, Nebraska, Ohio, Oklahoma, Oregon, South Carolina, Tennessee, Texas and Virginia — saying it did not want its drug used for executions.

When that request was ignored, the company switched from using several distributors last June to using a drop ship program, selling its product directly to health care facilities through a single distributor, Cardinal Health. In addition, every medical facility that received the drugs had to sign a document saying the product would not be used for executions or resold for that purpose.

"We stated very clearly that we're in the business of improving peoples lives and using it for capital punishment is against what we do," Matt Flesch, spokesman for Lundbeck, told *iWatch News*.

Finally last December Lundbeck sold its pentobarbital rights to Illinois-based Akorn Inc., which signed an agreement promising it would not sell the drug for the purpose of executions.

Stockpiled

For the moment, though, pentobarbital is still available. States bought supplies of the drug before distribution limitations were enacted, Flesch said, though some states may soon run out, or the drug could expire. Like most pharmaceuticals, pentobarbital has an expiration date of about 18 months.

Dale Baich, assistant federal public defender in the state of Arizona, said his state and other obtained pentobarbital some time ago. "In Arizona, the state was ordering it in 2010, along with sodium thiopental," he said. "Other states stockpiled it."

A spokesman for the Department of Criminal Justice in Texas, the state responsible for the highest number of executions in the country, would not specify how much pentobarbital the state had left, though he did confirm in an email to *iWatch News* that there was enough to carry out the seven executions it has scheduled for 2012. In Georgia, a spokeswoman also confirmed in writing that the state had "an adequate supply of all pharmaceuticals necessary to carry out lethal injections."

But the efforts to limit the supply for executions may be having some effect. Oklahoma only has enough pentobarbital to execute three more people, said Jerry Massie, public information officer at the state's Department of

Corrections. Two inmates were executed earlier this year, and the state had purchased enough pentobarbital for five executions. Two more executions have been scheduled for 2012, and the state has more than 60 inmates on death row.

Obstacles

The use of pentobarbital is facing other challenges, as well. In several cases, judges have put executions on hold until questions about the drug can be answered. Alabama was supposed to put Thomas Douglas Arthur to death by lethal injection last week, but shortly before the scheduled execution date, a federal appeals court put his execution on hold for the fifth time over the course of his 29 years in prison, because of concerns about pentobarbital.

His attorney, Suhana Han, argued it might not knock her client out all the way. This could make the subsequent injections extremely painful, she argued, falling under the definition of "cruel and unusual punishment," prohibited by the Eighth Amendment.

Megan McCracken, Eighth Amendment resource counsel at the University of California-Berkeley School of Law, is worried that states have simply switched to using pentobarbital in executions without much study or oversight. "There really hasn't been a thorough look at the use of this drug in a three-drug execution protocol," she said, "where the prisoner is paralyzed, and cardiac arrest is induced, shortly after administration of the pentobarbital."

Texas started using pentobarbital last year, and did not consult a physician in the process. The decision was made by officials within the correctional department, a department spokesman told *iWatch News*.

In Ohio and Washington state, the three-step execution cocktail has been scrapped altogether in favor of a single, lethal dosage of pentobarbital.

Mike Rushford, president and CEO at the Criminal Justice Legal Foundation, which supports the death penalty, is encouraging states to use this approach. The important thing is not whether states use pentobarbital or sodium thiopental, he said, but to simplify the process so the arguments against lethal injections fall away.

Regulatory limbo

Just who has the authority to decide whether pentobarbital can or should be used in executions is more than a little murky. Tightly monitoring the use of any drug is nearly impossible. The safety and efficacy of all drugs has to be approved by the FDA, but once pharmaceuticals are approved for any purpose,

it is up to physicians to determine to whom and for what reasons they will prescribe them, said Ed Elder, director at Lenor Zeeh Pharmaceutical Experiment Station at the University of Wisconsin-Madison.

The FDA-approved uses for pentobarbital include short-term treatment for insomnia and seizure control for patients with epilepsy. It is not FDA approved to alleviate Reye's syndrome, a disease of the brain and liver, though some physicians have prescribed it for that purpose.

It is also not FDA-approved for use in executions or for the use of anesthesia, but it's not clear the FDA believes that's its business. A spokeswoman declined to comment on the FDA's role in overseeing pentobarbital for the use of executions, but spoke generally of the agency's practices. "FDA has authority to take both administrative and judicial actions to protect the public from dangerous and illegal products, to punish persons and companies who violate the law, and to deter violations," she said.

Elder said drugs for the use of executions may fall outside their oversight definition, and in the past the FDA has publicly taken that stance. "The use of drugs for an indication that doesn't involve making people well is contrary to what the FDA is trying to do with approving drugs," he said.

In 2008, the Supreme Court upheld the constitutionality of the three-drug protocol that Kentucky used for lethal injections. The state was using the former drug, sodium thiopental, as its anesthetic. The high court hasn't said anything about pentobarbital, but several federal courts and the Florida Supreme Court have signed off on it.

Rushford from the Criminal Justice Legal Foundation sees the concerns raised about legal injections as merely the latest effort by groups whose mission is to thwart the death penalty. "These are claims by people who wouldn't want to execute any murderer under any circumstances by any means," he said.

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