OVERRIDE

The execution protocol used in most executing states in the U.S. consists of a cocktail of three drugs: the first, sodium thiopental, is supposed to anaesthetize the victim, the second, pancuronium bromide, paralyses him, and the third, potassium chloride, stops his heart.

In reality, the second drug serves a purely ‘cosmetic’ function in the lethal injection, designed to spare spectators the risk of seeing the prisoner in pain should the first drug not work effectively. The risk of this is a very real one (anaesthesiologists train for years to administer anaesthesia; prison wardens on average 2.5 days) and the consequences are grave. If the anaesthetic in a three-drug procedure fails, the prisoner will die slowly and in agony, unable to signal that something has gone wrong due to the paralysis. Even the Supreme Court has acknowledged that if the anesthetic does not work properly, there is an “unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride” Baze v. Rees, 553 U. S. 35, 53 (2008).

Execution Drug Shortages

In January of this year, Hospira, the sole US manufacturer of the first drug in the cocktail, sodium thiopental, officially pulled this product off the market. The company had been forced to cease production of the drug due to manufacturing issues in the summer of 2010 and six months later came to the conclusion that it was not worth their while to recommence production.

The market for sodium thiopental is small. The drug, which is used very widely in hospitals in the UK, India and Africa, is no longer used for medicinal purposes in the USA. And though the drug remains a staple in the lethal injection cocktail, the quantities used are very low (on average, 5g per execution, and rarely more than 40 executions across the USA per year). Being off-patent, the drug is also very cheap to buy (roughly 35 rupees a gram from the manufacturer).

Hospira made a simple calculation: profits from sales of sodium thiopental were low; cost of retooling the company plant to meet US regulations, and cost to the company’s reputation, however, would be extremely high. For a company claiming

1 http://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/LI/documents/kit/drugs.pdf
2 http://reprieve.org.uk/publiceducation/executioner_versus_anesthesiologist/
to be committed to *Advancing Wellness*, collaboration in capital punishment was a PR disaster.

So Hospira exited the market, leaving the shelves of the execution chambers bare as the drugs reached their expiration date. Executions were put on hold while prison wardens scrambled to source lethal injection drugs elsewhere.

First, they came to the **UK**. Then they tried **Germany**. Then **Italy**. Then **Denmark**. Then (most recently) **India**.

Every attempt was riddled with problems – problems which plagued the prisons and pharmaceutical manufacturers alike. It barely needs to be said that the US is an **intensely litigious** society, particularly when it comes to the death penalty. The issue is always furiously debated in legal and political circles and efforts to change the execution drugs or the protocol have spawned intense litigation, as well as provoking close federal scrutiny into the importation of these small but deadly quantities of drugs.

No importation of execution drugs has been made without multiple obstacles. The US Drug Enforcement Agency (DEA) seized the supplies of drugs imported from the UK from California, Georgia and Tennessee, they ordered the seizure and destruction of drugs imported from India to Nebraska and South Dakota, and sent letters of admonition to a number of other states requesting that they hand over their illegally imported drugs.

But this is not all. Lawyers acting on behalf of death row inmates in every executing State have fought tooth and nail against the imports. Pharmaceutical manufacturers – most of whom were unaware that their products have been sold for this purpose until it is too late – find themselves dragged into lengthy and costly litigation in the US which inevitably affects their global reputation. The company which sold the British drugs, for example, is still being pursued by the US courts, who, most recently have been trying to issue a subpoena to the CEO of the company for documents relating to the drug sales.

**Litigation on these issues is expected to last not months, but many years, and the manufacturers are the ones who suffer** – in addition to the prisoners on death row. It is an extremely unfortunate position for any healthcare provider to be in, as the manufacturers who have fallen victim to the execution drug trade in the past year and a half can attest. The damage, as will be seen below, is not only reputational, but fiscal too. Investors do not want to invest in drugs made for killing, and global manufacturers don’t want to partner with companies that collaborate in executions.

For the pharmaceutical industry more generally, trade in lethal injection drugs with the US will invariably have serious and wide-reaching implications. As has been seen already in Britain and in India, drugs which are exported to the US for use in executions are subject to the most intense and calculated scrutiny. Many of the legal arguments against lethal injections – particularly where the drugs have been imported – undermine the efficacy of the drugs, or the manufacturer of the drugs, that the prison is intending to use. Unfortunately, this often results litigation that will spill out of the court documents and sully the reputation of the industry as a whole.
The companies which have been drawn into the execution drug trade since the shortages began have explicitly disavowed the use of their medicines to kill and taken active steps to ensure they are not rendered complicit in this again in the future. The purpose of this document is to help everyone avoid having to shut the stable door after the horse has bolted: better that companies know what might happen and have the opportunity to make decisions beforehand.

**EXECUTION DRUGS FROM THE UK**

In October 2010, Reprieve discovered that a wholesale company in Britain was supplying sodium thiopental to prisons across the USA.

The company, Dream Pharma, run by Matt Alavi from the back of a driving school in west London, had exported significant quantities of drugs from the UK to the US for use in executions. The exports had taken place with neither the knowledge or consent of either the manufacturer (Sandoz in Austria) or marketing authorisation holder (Archimedes Pharma in the UK). By the time they learned of the exports (their names were revealed during litigation in the US), it was too late. Sandoz and Archimedes, both reputable, conscientious manufacturers committed to manufacturing medicines to improve lives, were scandalized to hear that their drugs had instead been used to end lives.

In order to prevent further exports of the kind, Reprieve requested that UK Business Secretary, Vince Cable, put an export control on exports of sodium thiopental to the USA. The Minister agreed to do so when he learnt that:

1) there is no legitimate trade in sodium thiopental between the UK and the US; and
2) sodium thiopental is no longer used for medical purposes in the US.

The UK government put an export control in place on 29th November, 2010, putting an abrupt end to Matt Alavi’s drug business. In the meantime, however, Mr. Alavi had managed to sell drugs to around 7 different execution chambers across the USA. He had hiked the cost up by 35 times the market rate for the drug, but even so, the profits he made could not outweigh the damage that was done to his and his business’ reputation as a result of his willing complicity in executions.

Mr. Alavi was pilloried by the press. He was condemned by pharmaceutical industry experts, manufacturers and doctors alike. No manufacturer wanted to do business with him following the revelations (which were covered in every big newspaper in the UK and the US) and his small backroom pharma company suffered significant losses.

Though Mr. Alavi was stopped in his tracks and much of the quantities of drugs he exported were subsequently seized by the DEA, several people were killed using the drugs before sanctions and preventative measures were put in place. Jeffrey Landrigan was the first in Arizona, then Brandon Rhode and Emanuel Hammond in Georgia.

Disturbingly, it seems that Dream Pharma’s sodium thiopental did not work effectively in the lethal injection when it was used. As a result, Rhode, Landrigan and Hammond would likely have died in agony. Dr Mark Heath, a renowned lethal
injection expert, filed a sworn declaration stating that the fact that Brandon Rhode's eyes remained open throughout his execution was highly unusual and strongly suggested that he was not properly anaesthetized and therefore conscious throughout the process. He also wrote that:

“...if the thiopental was inadequately effective Mr Rhode’s death would certainly have been agonizing; there is no dispute that the asphyxiation caused by pancuronium and the caustic burning sensation caused by potassium would be agonizing in the absence of adequate anaesthesia.”

Lawyers in Arizona (where supplies of Dream Pharma sodium thiopental are still in the prison’s possession) continue to fight this issue in the courts. It is extremely unlikely that the prison will ever be allowed to use the drugs in executions, and in the meantime they, the manufacturer and the middleman will all be tied up in litigation that is likely to drag on for years.

EXECUTION DRUGS FROM ITALY

Before Hospira decided to pull out of the execution drug market, they had considered transferring the manufacture of sodium thiopental from their plant in the US to a plant in Italy. Reprieve held a press conference on the issue with Livia Firth and members of the anti-death penalty group, Hands Off Cain in Rome in December 2010. They worked directly with the Italian government on strategies to prevent drugs manufactured in Italy from being used to kill prisoners in the USA. The Italian government line was firm: Hospira was to guarantee that the drugs wouldn’t be used in executions, or would not be permitted to manufacture in Italy at all.

Since Hospira knew that in all probability the drugs would be used in executions in the US, they decided to pull out of the market, stating:

“Hospira had intended to produce Pentothal at its Italian plant. In the last month, we've had ongoing dialogue with the Italian authorities concerning the use of Pentothal in capital punishment procedures in the United States – a use Hospira has never condoned. [...] 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. Exposing our employees or facilities to liability is not a risk we are prepared to take. Given the issues surrounding the product, including the government's requirements and challenges bringing the drug back to market, Hospira has decided to exit the market.”3

EXECUTION DRUGS FROM GERMANY

By this point, most manufacturers in Europe were aware of the issues surrounding the execution drug trade and extremely reluctant to be involved. The health and trade ministries in Austria and Germany had issued statements to their national

3 http://phx.corporate-ir.net/phoenix.zhtml?c=175550&p=irol-newsArticle&ID=1518610&highlight
pharmaceutical industries, warning them of the dangers and advising them not to sell sodium thiopental to the USA.

Despite Germany’s resolute opposition to the use of medicines in executions, in July of this year, US Commerce Secretary, Gary Locke, asked his German counterpart (Philip Rösler) if Germany would be prepared to sell sodium thiopental to the US. Rösler, who had been in contact with Reprieve about these issues previously, denied the request, telling the German media that he would also put in place a ban on exports of this drug to the US should the necessity arise.4

EXECUTION DRUGS FROM DENMARK

Failing to get hold of sodium thiopental, some States opted to change their lethal injection protocol to pentobarbital. Pentobarbital is a sedative licensed in the US by the Food and Drug Administration (FDA) for certain therapeutic uses, including preoperative sedation and the treatment of seizures.

Ohio, Oklahoma, Arizona and Texas were the first States to switch, and others soon followed suit.

The move was a disaster for the one FDA-approved manufacturer of the drug: Danish company, Lundbeck. They quickly became known as the US prisons’ execution drug supplier of choice, and every time there was an execution, their name was splashed across the newspapers in Denmark and the US. The company tried writing letters to prisons and governors in the US expressing their opposition to the use of their drugs in executions, but to no avail. The US authorities would not listen.

Over the next 6 months, Lundbeck saw key investors publically divest over this issue, their public image rating drop by 25 points in the leading business paper’s annual report, stock prices drop, online protests and boycotts against them, and constant negative media coverage (including an open letter signed by 100 doctors in leading medical journal, The Lancet).

Lundbeck took matters in hand and block the prisons from getting hold of their drugs directly. Since the drug was manufactured in the US, export controls wouldn’t work. However, Lundbeck was able to redesign their distribution system to ensure that only legitimate medical users of pentobarbital would be allowed to purchase it.

On July 1st 2011, Lundbeck announced the distribution overhaul, denying the US prison executioners access to their drugs once and for all.5 Their desire not to be complicit in capital punishment was satisfied, and they further received accolades from the press and public alike. Indeed, the very same doctors who petitioned against the company in The Lancet then bought shares in the company after the distribution change in a show of moral and fiscal solidarity and support.

4 http://www.spiegel.de/international/world/0,1518,767613,00.html
5 http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=605775
Lundbeck still faces the public relations nightmare of having the drugs that got through (before their new protocol) used in executions. Litigation will continue over this for years to come.

**EXECUTION DRUGS FROM EUROPE**

There has been extensive media coverage of this issue in Europe over the past 18 months, and it has been a hot topic of debate among politicians, medical professionals and the pharmaceutical industry alike. There is a consensus in Europe are agreed that medicines should be used to improve the life and health of patients, not to torture and kill prisoners. As such, and to prevent any further shipments of execution drugs slipping through the net and into the US prison system, the European Commission has drafted an amendment to a European regulation which will make it illegal to sell sodium thiopental and other potential execution drugs to the US without a license. This EU-wide control will have a major impact on the execution drug market in the USA. No longer able to get sodium thiopental from Europe or pentobarbital from Danish manufacturer, Lundbeck, the prisons will once again find their execution chambers dry and be looking for a new supply.

**EXECUTION DRUGS FROM INDIA**

And it looks highly likely that they’ll turn again to India.

India has already been the source of three shipments of execution drugs to US prisons. The first two went to South Dakota and Nebraska prisons in February 2011; the latest went to Nebraska prison (last month). There was a another attempted shipment in May, but the manufacturer in question realised what the purpose of the sale was in time and managed to cancel it before any drugs were shipped.

Each of the shipments has apparently been co-ordinated by an Indian businessman named Chris Harris. On the first occasion, Mr. Harris used drugs marketed by Kayem Pharmaceuticals; on the second, he tried to use Ganpati Exim’s drugs; on the third and most recent, he exported drugs manufactured by Naari. All three of these companies have distanced themselves from Mr Harris and say they do not want – and never wanted – anything to do with the execution drug trade.

*Kayem* was the first corporate victim. Following the revelation that Nebraska prison had received enough drugs to kill over 166 prisoners, the company found itself the subject of huge press interest (articles in The Hindu and the Times of India, as well as US papers like the Wall Street Journal) and put through serious legal and regulatory scrutiny. The premises were searched by the Indian FDA, lawyers wrote to the company directors, the site was photographed by journalists and investigators, and the material became the centre of litigation in the US which continues in South Dakota and Nebraska to this day.

Mr. Harris had been working at Kayem Pharmaceuticals at the time. Following (and as a result of) the execution drug affair, Navneet Verma, the Director of Kayem, broke off all ties with Mr. Harris. Mr. Verma issued a press statement declaring that “as an
Indian pharma dealer who cherish the ethos of Hinduism, [they] will refrain from selling the drug where the purpose is for lethal injection”. He further stated in an email to a lawyer working on behalf of a death row inmate in Nebraska expressing his gratitude that his company was no longer in the firing line, and that Mr. Harris would not be able to get the company into further trouble: “we are extremely thankful that we have been saved from the blackmail of these Drug Peddlers who were exercising coercion on us for the sake of Foreign Orders”.

Leaving Kayem, Mr. Harris apparently then set up shop with a US business partner (www.harrispharmallp.com). He tried to buy execution drugs from another Indian manufacturer, Ganpati Exim, but when the company directors realised the purpose of the sale, they also cut off ties with him, stating: “We at Ganpati Exim are committed to providing access to medicines for the purposes of improving the lives of patients around the world. We are deeply opposed to the use of medicines in killing prisoners and wish to have no part in facilitating capital punishment in the USA or elsewhere.”

Mr. Harris met with similar resistance from the US import broker, Caligor Rx, who also ceased dealing with Mr. Harris when they learnt of the controversy surrounding this drug, stating: “Our mission is to connect patients with the medicines that will improve their lives, and as such we will not engage in trade of products used for capital punishment.”

Most recently, Mr. Harris turned to Naari. According to the company, Mr. Harris claimed that he wanted to get supplies of sodium thiopental to take over to Zambia for registration there (sodium thiopental is still widely used as an anaesthetic in Africa, whereas it is used solely for executions in the US). Believing that Mr. Harris was sincere in his aims, and keen to provide this essential medicine to the developing world, Naari supplied Mr. Harris with 485 vials of sodium thiopental.

Little did Naari know that Mr. Harris would sell these drugs directly on to Nebraska prison and that the first Naari would hear of this would be via a press release issued by the prison. Naturally, Naari too has since broken all ties with Mr. Harris and has also written to the Chief Justice of Nebraska Supreme Court to inform him that they are “deeply opposed to the use of medicines in executions” and that “Mr. Harris misappropriated our medicines and diverted them from their intended purpose and use”.

Reprieve is working with Naari to help them prevent their drugs being used in executions. Things are going well, Naari are doing all they can, and there is hope that we may be successful. Nevertheless, there can be no doubt that Naari’s global reputation has been affected by this affair. As in the case of the Kayem drugs, the exported sodium thiopental will be the subject of much heated debate and litigation, will be tested, contested, and tested again. And it is not just Naari that suffers. The Indian pharmaceutical industry as a whole will be scrutinised by the US authorities. Any possible vulnerable area will be leapt upon. And all for $130 dollars a year.

6 http://bloximages.chicago2.vip.townnews.com/journalstar.com/content/tncms/assets/editorial/9/66/02f/96602f02-44af-56c6-917f-864abc39cea2-revisions/4dd2bc85dfeb5.pdf.pdf
The value of this trade is so small – and the cost of it so great – that no US manufacturer wants to participate in it. At 35 rupees a gram, 5 grams an execution, and rarely more than 40 executions a year, this really is a profitless business. What’s more, the cost to an individual manufacturer – and to the pharmaceutical industry as a whole – is unthinkably high. Litigation is fraught, embroiled and lengthy. Opposition to the trade is fierce. Protests from the medical community are strong. Ethical investors won’t tolerate it. Big pharma manufacturers eschew it. **There really is no capital to be gained in capital punishment.**

**FURTHER INFORMATION**


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**ABOUT REPRIEVE**

*Reprive*, a legal action charity, uses the law to enforce the human rights of prisoners, from death row to Guantánamo Bay. *Reprive* investigates, litigates and educates, working on the frontline, to provide legal support to prisoners unable to pay for it themselves. *Reprive* promotes the rule of law around the world, securing each person’s right to a fair trial and saving lives. Clive Stafford Smith is the founder of *Reprive* and has spent 27 years working on behalf of people facing the death penalty in the USA.

*Reprive* has represented, and continues to represent, a large number of prisoners who have been rendered and abused around the world, and is conducting ongoing investigations into the rendition and the secret detention of ‘ghost prisoners’ in the so-called ‘war on terror.’

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