

Submission to the European Commission on amending Council Regulation (EC) No. 1236/2005 to include drugs used in the 'automatic drug injection systems for the purpose of execution of human beings by the administration of a lethal chemical substance'.

5 January 2011

This submission has been endorsed by the following international NGOs¹:

- Amicus, UK
- Amnesty International
- Ensemble Contre la Peine de Mort (ECPM), France
- International Federation for Human Rights (FIDH)
- International Federation of Action by Christians for the Abolition of Torture (FIACAT)
- International Harm Reduction Association (IHRA), UK
- Murder Victims' Families for Human Rights (MVFHR), US
- National Association of Criminal Defense Lawyers (NACDL), US
- Omega Research Foundation (ORF), UK
- Penal Reform International (PRI), UK
- Reprieve, UK
- Texas Coalition to Abolish the Death Penalty (TCADP), US
- World Coalition Against the Death Penalty (WCADP)

Introduction:

On 26 October 2010, Jeffery Landrigan was executed by lethal injection for the 1989 murder of Chester Dean Dyer in Phoenix, Arizona, United States. The execution took place in spite of a US-wide shortage of sodium thiopental, the anaesthetic agent in the three-drug cocktail used in lethal injections in Arizona. The Arizona Attorney-General revealed that the sodium thiopental used to execute Landrigan was imported from the United Kingdom.²

In two US states (Ohio and Washington) executioners administer just one drug to cause death: a single, extra-large dose of sodium thiopental. In the rest of the US states that carry out executions, three drugs are used in the lethal injection protocol. Sodium thiopental is the anaesthetic agent that induces unconsciousness. Without it there would be serious risk of suffocation and excruciating pain resulting from the injection of the two subsequent drugs, pancuronium bromide (Pavulon - which cause muscle paralysis and respiratory arrest) and finally potassium chloride (which causes cardiac arrest). In one state (Oklahoma), a federal judge ruled on 19 November 2010 that pentobarbital, a drug used in euthanizing animals, could replace sodium thiopental in lethal injections, despite the risk that the use of pentobarbital may constitute cruel and unusual punishment because it is unknown whether the anesthesia will

¹ Signatories to this submission all work in various specialised ways toward the abolition of the death penalty.

² *Arizona execution drug 'supplied by UK firm'*, BBC News (27 October 2010) <<http://www.bbc.co.uk/news/world-us-canada-11630187>> (accessed 6 December 2010).

mask the hurtful effects of the last two drugs.³ On 16 December 2010, John David Duty was executed at the Oklahoma State Penitentiary with a mix of drugs that included pentobarbital.⁴

Only one pharmaceutical company in the world – Hospira, Inc. – has been authorised by the US Food and Drug Administration (FDA) to produce and distribute sodium thiopental in the United States. Hospira Inc., whose headquarters are in Lake Forest, Illinois, stopped producing the drug in late 2009 as a result of problems obtaining its active ingredient, which is supplied by another company.⁵ Hospira then decided to move production of sodium thiopental to its manufacturing plant in Liscate, Italy. Hospira is currently planning to resume production and exports of sodium thiopental from Italy to the US in the first trimester of 2011, and perhaps as early as January 2011.⁶

Hospira's production problems have led to a US-wide shortage of sodium thiopental. As a consequence, some states have delayed executions, and others have sought to obtain sodium thiopental from foreign sources that are not FDA-approved. Although one execution was carried out in Arizona, that state has since stayed other executions in light of questions raised by attorneys regarding the source of the sodium thiopental obtained by the Arizona Department of Corrections.⁷ Executions have also been delayed in California⁸, Tennessee⁹, and Kentucky¹⁰. Reports indicate that Missouri's supply of the drug expires in January 2011¹¹, and Texas has announced that its supply of sodium thiopental expires in March 2011¹².

Lethal injection is the most common method of execution in the US. All but two of the 46 people executed by the US in 2010 were executed using this method.¹³ Lethal injection is also provided for as a method of execution in China¹⁴, Guatemala¹⁵, Taiwan¹⁶, Thailand¹⁷, and Vietnam¹⁸.

³ Judge allows new lethal injection drug for Oklahoma executions, NewsOK (20 November 2010)

<http://newsok.com/judge-allows-new-lethal-injection-drug-for-oklahoma-executions/article/3516331?custom_click=rss> (accessed 9 December 2010).

⁴ US inmate John Duty executed with animal drug, BBC News (17 December 2010), <http://www.bbc.co.uk/news/world-us-canada-12014323> (accessed 22 December 2010).

⁵ Kevin Sack, *Shortage of Widely Used Anesthetics Is Delaying Executions in Some States*, New York Times (29 September 2010), <http://www.nytimes.com/2010/09/30/us/30drug.html?_r=1&pagewanted=all> (accessed 9 December 2010).

⁶ Reprieve have reported that *Hospira Spa*, a subsidiary of the US multinational, based in Liscate, just outside Milan, was commissioned to produce sodium thiopental and that, starting in January 2011, it would begin exporting the substance to the US, see *Reprieve Press Conference*, Rome, Italy, 2 December 2010

<http://www.reprieve.org.uk/2010_12_02_hospira_italy_press_conference> (accessed 9 December 2010).

⁷ Michael Kiefer, *Arizona Supreme Court puts off date for execution*, The Arizona Republic (1 December 2010), <<http://www.azcentral.com/community/pinal/articles/2010/12/01/20101201execution1201.html>> (accessed 9 December 2010).

⁸ Julie Small, *California Prisons release details of lethal injection drug acquisition*, Southern California Public Radio (8 December 2010), <<http://www.scpr.org/news/2010/12/08/california-prisons-release-details-of-lethal-injec/>> (accessed 9 December 2010).

⁹ *State v. West*, No. M1987-00130-SC-DPE-DD (Order Staying Executions, 29 November 2010), available at <<http://www.tsc.state.tn.us/OPINIONS/TSC/CapCases/WestStephenM/West%20-%20Stay.pdf>> (accessed 9 December 2010).

¹⁰ Jessie Halladay, *Anesthesia shortage may delay executions*, USA Today (28 August 2010), <http://www.usatoday.com/news/nation/2010-08-28-lethal-injection-shortage_N.htm> (accessed 9 December 2010).

¹¹ Andrew Welsh-Huggins, *Shortage of drug holds up some US executions*, Associated Press (27 September 2010).

¹² Mike Ward, *AG: Make public info about execution drugs*, statesman.com (19 November 2010),

<http://www.statesman.com/blogs/content/shared-gen/blogs/austin/politics/entries/2010/11/19/ag_make_public_info_about_exec.html> (accessed 9 December 2010).

¹³ *Executions in 2010*, Death Penalty Information Center, <<http://www.deathpenaltyinfo.org/execution-list-2010>>.

The legal requirement to control the trade in goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment:

In 2006 the European Union, a global leader in efforts to abolish the death penalty, introduced groundbreaking controls to prohibit and restrict the international trade in equipment that could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment, through Council Regulation (EC) [No. 1236/2005](#).

The prohibition on the export of goods used for capital punishment reflects the EU's political and legal commitment to the abolition of the death penalty. Article 2 of the Charter of Fundamental Rights of the European Union provides that no one shall be condemned to death or executed, and abolition is a prerequisite for accession to the EU. Protocols No. 6¹⁹ and 13²⁰ to the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) also provide for the abolition of the death penalty. With the entry into force of the Lisbon Treaty in December 2009, the Charter of Fundamental Rights has now become legally binding on all EU institutions, and the European Union is negotiating accession to the ECHR.

In *Soering v. UK* (1989) 11 EHRR 439, the European Court of Human Rights held that extradition to the US, with the prospect of being held on death row for 6-8 years, would give rise to a breach of article 3 of the ECHR (article 3 of the ECHR prohibits torture, and 'inhuman or degrading treatment or punishment'). Earlier this year, the Court expanded its decision in *Soering* in *Al Saadoon and Mufdhi v. UK*²¹. There, the Court found that the United Kingdom had violated its obligations under article 3 of the Convention merely by exposing the applicants to the threat of capital punishment. Although it did not base its decision on article 2 of the Convention (article 2 provides for the right to life), the Court made clear that article 2 may currently prohibit the death penalty in all circumstances. We believe that the export of a drug to the US, that will inevitably and indisputably be used to carry out executions by lethal injection, gives rise to a breach of articles 2 and 3 of the ECHR.

The EU Guidelines on the Death Penalty, adopted by the European Council in 1998 and reviewed in 2008, make clear that EU Member States are united in their view that the fight against the death penalty is one of the EU's highest priorities. One of the main objectives of the EU Guidelines on the Death Penalty is to: 'work towards universal abolition of the death penalty... [and]... where the death penalty still exists, to call for its use to be progressively restricted...' In order to achieve these objectives, the EU acts both in its bilateral relations with third countries and in multilateral fora.

¹⁴ *Death Sentences and Executions in 2009*, Amnesty International, AI Index ACT 50/001/2010 (March 2010), p. 6.

¹⁵ *Execution by Lethal Injection*, Amnesty International, <<http://www.amnestyusa.org/document.php?lang=e&id=engact500072007>>.

¹⁶ *Ibid.*

¹⁷ *Death Sentences and Executions in 2009*, Amnesty International, AI Index ACT 50/001/2010 (March 2010), p. 6.

¹⁸ The law changing the method of execution to lethal injection will come into force in July 2011, see *Vietnam to use lethal injections for death penalty*, Hindustan Times (18 June 2010), <<http://www.hindustantimes.com/Vietnam-to-use-lethal-injections-for-death-penalty/Article1-559522.aspx>>.

¹⁹ Adopted by the Council of Europe in 1982.

²⁰ Adopted by the Council of Europe in 2002.

²¹ Application No. 61498/08, judgement issued 2 March 2010, Strasbourg.

Council Regulation (EC) No. 1236/2005 reflects the EU's political and legal commitment to working towards universal abolition of the death penalty. The Regulation bans the export of equipment which 'have no practical use other than for the purpose of capital punishment or for the purpose of torture and other cruel, inhuman or degrading treatment or punishment, irrespective of the origin of such equipment'.²²

Annex II of the Regulation provides a distinct list of prohibited items, and includes, *inter alia*, 'goods designed for the execution of human beings', such as gallows, guillotines, electric chairs, gas chambers and the 'automatic drug injection systems for the purpose of execution of human beings by the administration of a lethal chemical substance'. Article 3 of the Regulation also prohibits the supply of technical assistance relating to the items in Annex II.

The Regulation also introduces EU-wide export controls on a limited range of equipment that 'could be used for the purpose of torture or other cruel, inhuman or degrading treatment or punishment'.²³ Article 6 of the Regulation obliges Member States to regulate the export of these controlled items, listed in Annex III of the Regulation, and to deny authorisation for exports of such items 'when there are reasonable grounds to believe that goods listed in Annex III might be used for torture' capital punishment or other ill-treatment.

The Regulation is directly binding on all 27 EU Member States, and has the status of national law in all these states. However, the effectiveness of the Regulation is dependent upon Member States and the European Commission adequately implementing, monitoring and enforcing it.

Over the past year, serious concerns regarding the Regulation's implementation have been raised by both civil society and the European Parliament, which resulted in a meeting of the Committee on Common Rules for Export Products on 29 June 2010. At this meeting, the European Commission and Member States recognised the need to improve the Regulation, notably by updating the annexes and proposing an amendment to the Regulation to include a 'torture end-use catch-all' clause. However, six months later there has still been no follow-up on the recommendations discussed at this meeting, either by the European Commission or by Member States.

The addition of a 'torture end-use catch-all' clause was originally suggested to the European Commission by the UK.²⁴ This would allow governments to prohibit the trade in *any* items not listed in the Regulation that clearly have no practical use other than for the purposes of capital punishment, torture or cruel, inhuman or degrading punishment; or where there are reasonable grounds to believe that such items would be used for those purposes. This would essentially enable Member States to control the export of *any* goods which were destined for use in such acts as capital punishment, without creating onerous controls over legitimate business.

Sodium thiopental and other drugs currently used in lethal injections: pancuronium bromide (Pavulon), potassium chloride, and the newly approved pentobarbital, are neither prohibited items (under Annex II of the Regulation) nor controlled items (under Annex III the Regulation). In

²² Council Regulation (EC) No 1236/2005, articles 3 and 4.

²³ *Ibid*, article 5.

²⁴ *Review of the Export Control Act 2007, Government's Response to the Public Consultation*, UK Department for Business, Enterprise and Regulatory Reform (December 2008), p. 6.

fact the only chemical substances included under Annex III are two substances for the purpose of riot control or self protection.

The export of sodium thiopental from any European country to the US for the purpose of lethal injections would undermine not just the spirit and purpose of the Regulation, but the EU's policy of fighting against the death penalty in countries where it still exists.

US export controls:

Significantly, the US has recently introduced comparable export controls on such equipment based upon Council Regulation (EC) No. 1236/2005. In July 2010, the US Commerce Department added 'equipment designed for the execution of human beings'²⁵ to its Commerce Control List. This means that any company seeking to export electric chairs, lethal injection equipment or other execution equipment to any foreign country must first obtain a US export licence. According to the Department, these new controls were implemented 'because equipment designed for the execution of human beings has a clear nexus to crime control and an obvious potential use in repressing human rights'.²⁶

UK restriction on the export of sodium thiopental:

On 29 November 2010, the UK Secretary of State for Business Innovation and Skills made a statement²⁷ to the High Court of Justice indicating that the UK Department for Business Innovation and Skills would issue an order under s. 6 of the Export Control Act 2002 (ECA) controlling the export of sodium thiopental to the US. According to the statement, the order was to be issued 'as soon as practicable'. Once the order enters into force, any person exporting sodium thiopental from the UK to the US will require an export license issued by the UK Export Control Organisation. While decisions to issue an export license are made on a case-by-case basis, we assume that export licenses for sodium thiopental would be refused by the Export Control Organisation where there is evidence or a risk of the drug being used in lethal injections. Breach of the order will be a criminal offence.

Such an order serves to reinforce the UK's moral opposition to the death penalty in all circumstances, without undermining legitimate business.

Only one company in the UK manufactures sodium thiopental. That firm, Archimedes Pharma UK, has insisted it has no control over how the substance is used, and denied knowingly providing the drug for use in the Arizona execution.²⁸ In fact, Archimedes has stated that sodium thiopental was being manufactured not by them but by a pharmaceutical company, Sandoz,

²⁵ Rule ECCN 0A981.

²⁶ *Revisions to the Commerce Control List To Update and Clarify Crime Control License Requirements: A Rule by the Industry and Security Bureau*, Federal Register (15 July 2010), <<http://www.federalregister.gov/articles/2010/07/15/2010-17338/revisions-to-the-commerce-control-list-to-update-and-clarify-crime-control-license-requirements#p-31>> (accessed 8 December 2010).

²⁷ Statement to be made in open court on 29 November 2010 on behalf of the UK Secretary of State for Business Innovation and Skills, <<http://www.brickcourt.co.uk/uploads/zagorski-court-statement-final.pdf>> (accessed 9 December 2010).

²⁸ David Cronin, *Britain: Not Executing, Just Enabling*, Inter Press Services (4 November 2010) <<http://ipsnews.net/news.asp?idnews=53456>> (accessed 6 December 2010).

based in Austria,²⁹ and that Archimedes was used as an intermediary in the export of sodium thiopental to Arizona, US.

The control on UK exports of sodium thiopental may result in temporary stays of execution in a number of US states. However, while we commend the UK government for issuing the order, an EU-wide control is both necessary and urgent. The UK's decision does not affect the impending export of sodium thiopental from Italy, nor does it prevent other European manufacturers from exporting this and other lethal injection drugs directly – or through an intermediary – to the United States. It is also worth observing that orders made under s. 6 of the ECA last for a maximum of 12 months.

We therefore welcome the UK Secretary of State's decision to instruct his officials to explore with the European Commission, the European Parliament and other Member States the possibility of implementing an export control on sodium thiopental on an EU-wide basis.

Other EU suppliers:

Reports indicate that Hospira has begun to produce all its sodium thiopental in its manufacturing plant in Liscate, Italy, and that it intends to begin exporting the sodium thiopental from Italy to the US as early as January 2011.³⁰

The Italian Green Party lodged a formal complaint with the Prosecutor of the City of Milan concerning the proposed export, stating that the 'export of the anaesthetic, sodium thiopental to the US for capital punishment is a grave violation of articles 26 and 27 of the Italian Constitution, and therefore should be stopped immediately.' On 22 December 2010, the Italian Chamber of Deputies (the lower house of parliament) approved a motion presented by the Italian Radical Party which called on the Italian government to immediately impose restrictions on the export of sodium thiopental. The motion, signed by members of all political groups, commits the Government 'to take every initiative towards guaranteeing that the production and foreign sale by pharmaceutical company Hospira (based in Liscate) of sodium thiopental and of other substances contained in lethal injection protocols in the US are only authorised for medical purposes. For the drug to be sold it must be stated that the use of the product is allowed only in hospitals and in the contract of sale must be clearly specified that Hospira cannot allow the distribution of the product for the practice of lethal injection.'³¹

On 13 December 2010, the Foreign Minister of Italy, Franco Frattini, met with members of the Hands Off Cain campaign, the Sant'Egidio Community and the parliamentary Radical Party, where he confirmed that he wanted the exportation of sodium thiopental to be controlled by all Members of the European Union in line with national and community norms that prohibit the practice of the death penalty. Minister Frattini then met with the Italian heads of Hospira on 20 December 2010, who were willing to collaborate with the Italian authorities. They accepted that the production and sale of sodium thiopental should be authorised exclusively for medical

²⁹ *R (Zagorski and Baze) v Secretary of State for Business, Innovation and Skills* [2010] EWHC 3110 (Admin).

³⁰ Reprieve Press Conference, Rome, Italy, 2 December 2010,

<http://www.reprieve.org.uk/2010_12_02_hospira_italy_press_conference> (accessed 9 December 2010).

³¹ *Italy: the chambers approves Zamparutti motion against pentotal exportation for lethal injection*, Hands Off Cain (22 December 2010), <<http://www.handsoffcain.info/news/index.php?iddocumento=13317776>> (accessed 4 January 2011).

purposes. The pharmaceutical company would commit to not selling the product to foreign jails and insert a clause in contracts that specifies that the distribution of the product is not allowed for the practice of lethal injection.³²

The drug is also reportedly manufactured in France by two companies: Hospira France, and RotexMedica (a subsidiary of the French company Panpharma, which also manufactures sodium thiopental in Germany). So far there have been no reports that French or German sourced sodium thiopental will be exported to the US. However, there is reliable evidence that sodium thiopental produced by Sandoz in Austria has been exported to the United States through the UK-based intermediary (Archimedes Pharma).³³ In addition, the Tennessee Department of Corrections has revealed that sodium thiopental manufactured by Sandoz will be used in upcoming executions.³⁴ Sandoz is owned by Novartis, a Swiss company.

Recommendations:

We urge the European Commission, in consultation with Member States and at the earliest possible opportunity, to extend the scope of Regulation (EC) No. 1236/2005 to include sodium thiopental in its Annex III, and to introduce a catch-all safeguard provisions as proposed by the UK government which would also address the export of the other lethal injection drugs: pancuronium bromide (Pavulon), potassium chloride and pentobarbital, thereby subjecting these drugs to the export control systems of their respective Member States. This would ensure that any future exports of sodium thiopental, pancuronium bromide (Pavulon), potassium chloride and pentobarbital will not be used for capital punishment, but only for legitimate medical purposes.

The ‘torture-death penalty end-use catch-all’ clause should be included in the Regulation to allow EU governments to prohibit trade of any drugs not listed in the Annexes of the Regulation that clearly have no practical use other than for the purposes of capital punishment; or where there are reasonable grounds to believe that such items would be used for the purposes of capital punishment. The recent example of Oklahoma approving pentobarbital as a replacement for sodium thiopental in lethal injections is indicative that there is an ever developing supply of pharmaceuticals that could be used in lethal injections. Since pancuronium bromide (Pavulon), potassium chloride and pentobarbital are very widely used in normal medical applications, the ‘torture-death penalty end-use catch-all’ clause would enable governments to prevent such drugs being used in capital punishment where there is a substantial risk of such an end use, without hindering legitimate business.

These proposed amendments to the Regulation would reinforce the EU’s fight against the death penalty and have an immediate impact on executions in the US, without placing overly burdensome controls on legitimate exports. For example, sodium thiopental is a limited product, and is produced by a limited group of manufacturers. In fact, sodium thiopental has

³² *Ibid.*

³³ It was subsequently clarified in Archimedes’ press release that they do not in fact manufacture sodium thiopental but have the marketing licence for the UK on behalf of Sandoz in Austria who manufacture the drug, see Witness Statement of Maya Foa in *R (Zagorski and Baze) v Secretary of State for Business, Innovation and Skills* [2010] EWHC 3110 (Admin).

³⁴ Letter from Paul R. Bottei (Assistant Federal Public Defender, Tennessee) to Clive Stafford-Smith (Reprieve), (2 December 2010).

been largely supplanted by other anaesthetics in the US, and hospitals do not stock much of it.³⁵ Therefore, although sodium thiopental may be legitimately used in other countries, any exports to the US would almost always be for use in executions.

Finally, we recommend that while the European Commission is reviewing Regulation (EC) No. 1236/2005, Member States where the drugs are manufactured replicate the UK government's decision to implement emergency export controls at the national level.

Conclusion:

While there has been a global trend towards the abolition of the death penalty over the past 50 years, 58 states in the world still retain it.³⁶ Implementing controls to prohibit the trade in equipment used for capital punishment sends a strong message to retentionist states. If those states wish to carry out executions, they should not receive assistance – either directly or indirectly – from Europe. A suspension of exports may lead to a moratorium on executions in the United States while US companies are not able to produce these drugs, and will likely lead to a review of lethal injection procedures in states that actively execute. Moratoriums on executions have been repeatedly recognised, even by retentionist states, as a first step towards full abolition, as is witnessed by the recent vote at the UN General Assembly on 21 December 2010, where 109 states called for a universal moratorium on the death penalty.³⁷

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³⁵ Andrew Welsh-Huggins, *Shortage of drug holds up some US executions*, Associated Press (27 September 2010).

³⁶ *Abolitionist and retentionist countries*, Amnesty International, <<http://www.amnesty.org/en/death-penalty/abolitionist-and-retentionist-countries>> (accessed 9 December 2010).

³⁷ UN General Assembly resolution 65/206 (21 December 2010).