Advocatenkantoor
Stapert

COMPLAINT TO THE NETHERLANDS NATIONAL CONTACT POINT UNDER THE SPECIFIC INSTANCE PROCEDURE OF THE OECD GUIDELINES FOR MULTINATIONAL ENTERPRISES

Mylan

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Contents

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1. Preface

1.1. The complainant, Bart Stapert, has longstanding experience as an attorney in the representation of defendants in complex criminal cases in the Netherlands and the United States. He is known as an expert in the defense of capital cases, recognized as such by the Ministry of Foreign Affairs of the Netherlands. In 1996, he was a witness to the execution of Ronald Lee Hoke in the Commonwealth of Virginia, United States. This execution took place by lethal injection.

1.2. Mylan is one of the world's largest generic and specialty pharmaceuticals manufacturers. It has a market capitalization of approximately $20.9 billion and claims sales in 140 countries and territories.[i, ii] According to the business news channel Forbes, Mylan has 20,000 employees and is the world's 601st biggest company by market value.[iii]

1.3. On 28 January Mylan announced that shareholders had by a 98% majority approved a deal which would see the company move its headquarters to the Netherlands by the end of Q1 2015.[iv] Under the terms of this deal Mylan would create a new public company organized in the Netherlands called "New Mylan", then immediately merge with a wholly owned subsidiary of New Mylan. The effect of this deal is to make Mylan a Dutch company, domiciled in the Netherlands, under the responsibility of Dutch and European Government authorities.

1.4. Mylan manufactures a medicine called rocuronium bromide. Rocuronium bromide has recently been adopted into the lethal injection execution protocols of a number of US States and was used in an execution in Oklahoma in January of this year.[v] In contrast to all other American and European manufacturers of FDA-approved medicines which have the potential for misuse in executions, Mylan has refused to take meaningful action to prevent the sale of its medicine to US prisons for use in lethal injections.

2. Background and Summary

2.1. Lethal injection remains the primary method of execution in all 32 of the US states which retain the death penalty.[vi] Approximately 1402 lethal injections have been carried out since 1976.[vii] These executions are conducted in the main using commercially manufactured medicines. These medicines were designed to improve and save the lives of patients, and manufacturers have long objected to their perverse misuse in executions designed to end the lives of prisoners.

2.2. In addition to making public statements in opposition to the use of medicines in executions,[viii] recent years have seen a large number of manufacturers take concrete action to try to end this misuse, including by establishing comprehensive distribution controls to prevent sales of their medicines to prisons for use in executions.[ix]

2.3. The last few years have also seen a series of changes in execution protocols across US states, in part in response to the effective action taken by manufacturers to prevent the use of their medicines in lethal injections. A number of states have hastily adopted experimental new protocols using untested combinations of medicines. The result has been

a series of high profile "botched", including the torturous executions of Dennis McGuire in Ohio, Clayton Lockett in Oklahoma and Joseph Wood in Arizona last year.[x]

2.4. Mylan manufactures a medicine called rocuronium bromide. Rocuronium bromide has recently been adopted into the lethal injection execution protocols of a number of US States and was used in an execution in Oklahoma in January of this year.[xi] The Oklahoma protocol (which includes rocuronium bromide) has now been taken up by the United States Supreme Court.[xii]

2.5. In contrast to all other American and European manufacturers of FDA-approved medicines which have the potential for misuse in executions, Mylan has refused to take any meaningful action to prevent the sale of its medicine to US prisons for use in lethal injections.

2.6. Mylan has failed to assess the impact of its inaction on this issue, to acknowledge its involvement, to develop a (public or internal) policy on the issue, or to engage in a meaningful way with its stakeholders or interested parties. This puts Mylan in breach of a number of requirements set out in Chapters II and IV of the OECD Guidelines for Multinational Enterprises (the Guidelines).[xiii] In particular:

2.6.1. Mylan is in breach of Chapter II, paragraph A2, and of Chapter IV, paragraph 1, by virtue of its failure to "respect human rights" as defined under Dutch, European and International law – specifically through its failure to take simple steps to prevent its medicines from being sold and used in executions which violate the right to life of prisoners in the USA.[xiv xv]

2.6.2. Mylan is in breach of Chapter II, paragraph A11, and of Chapter IV, paragraph 2, by failing to "avoid contributing to an adverse human rights impact" – specifically the execution of prisoners in experimental and potentially torturous executions by lethal injection.[xvi xvii]

2.6.3. Mylan is in breach of Chapter II, paragraph A12, and of Chapter IV, paragraph 3, as a result of its refusal to "seek ways to prevent or mitigate the human rights impacts" of its medicines being sold to prisons for use in executions. Unlike other manufacturers of potential execution drugs, Mylan has declined to introduce industry standard supply chain controls restricting the sale of its medicines to execution chambers.[xviii xix]

2.6.4. Mylan is in breach of Chapter II, paragraph A10, and of Chapter IV, paragraph 5, in respect of its failure to carry out effective due diligence processes (appropriate to its size as a $20.9bn multinational enterprise and in line with the actions of other similarly sized companies) to assess whether Mylan medicines might be purchased by prisons for use in the execution of prisoners by lethal injection; or indeed if Mylan medicines have already been used in such procedures.[xx xxi]

2.6.5. Mylan is in breach of Chapter II, paragraph A13, by virtue of its failure to encourage the direct and third party distributors of its medicines to "apply principles of responsible business conduct compatible with the Guidelines", and specifically to refrain from selling its medicines on to prisons for use in executions.[xxii]

2.6.6. Mylan is in breach of Chapter II, paragraph B2, as a result of its refusal to "engage in or support… private or multi-stakeholder initiatives and social dialogue on responsible supply chain management", demonstrated by its failure to substantively respond to outreach on this issue from numerous investors and civil society groups.[xxiii]

2.6.7. Mylan is in breach of Chapter IV paragraph 4 as a result of its refusal to "have a policy commitment to respect human rights", and specifically one which reflects that the company has considered the human rights of prisoners who may be executed using its medicines".[xxiv]

3. Dutch responsibility for preventing human rights abuses: the death penalty, torture, and CIDT

3.1. While US states' lethal injection executions of prisoners using experimental drug cocktails is not taking place within the Netherlands, the Dutch National Contact Point for the OECD Guidelines has both the authority and the responsibility to investigate a Dutch company's role in a process leading to such serious human rights abuses.

3.2. The UN Guiding Principles on Human Rights, which the OECD Guidelines seek to integrate into a coherent international instrument, make clear that states are "not prohibited" from efforts to "regulate the extraterritorial activities of businesses domiciled in their territory and/or jurisdiction… provided there is a recognized jurisdictional basis".[xxv] The Guiding Principles also note that "some human rights treaty bodies recommend that home States take steps to prevent abuse abroad by business enterprises within their jurisdiction."[xxvi]

3.3. The OECD Guidelines' accompanying guidance brochure notes that one of the Guidelines' principal functions is to "ensure (multinational enterprises') operations are in harmony with government policies".[xxvii] Mylan's links to US executions could not be further out of step with the policies of the Dutch Government, Dutch obligations under European and international treaties, or the Dutch Constitution.

3.4. Mylan's decision not to take action to protect its medicines from being purchased for use in lethal injection executions in the USA puts it at risk of complicity in a number of human rights abuses, including capital punishment (a violation of the right to life) and torture or other cruel, inhuman or degrading treatment or punishment (CIDT).

3.5. The death penalty is prohibited under Dutch and European law (Article 114 of the Dutch Constitution, Protocols 6 and 13 of the European Convention on Human Rights (ECHR) and the Charter of Fundamental Rights).[xxviii] The Netherlands abolished the death penalty in 1870, with the exception of capital punishment for crimes committed during war. Since 1983 the Dutch constitution explicitly prohibits the death penalty, both in times of peace and war.

3.6. Furthermore, the global abolition of capital punishment is a formal Dutch foreign policy objective promoted as follows on the website of the Dutch Government:

> *"The Netherlands works to combat the use of the death penalty and torture, acting as much as possible through the European Union (EU). The EU calls for the abolition of the death penalty worldwide, with a moratorium on executions as an interim goal. The Netherlands supports human rights organizations working towards these ends."*[xxix]

3.7. Recently, after the execution of a Dutch national in Indonesia, for whom complainant served as the attorney, Dutch Minister of Foreign Affairs Bert Koenders reiterated the Dutch position on the death penalty, holding that it is a "*cruel and inhuman punishment that represents an unacceptable denial of human dignity and integrity.*"[xxx]

3.8. The administration of the death penalty in the US has also been found to constitute a form of form of torture or CIDT (prohibited under Dutch, European and International law)[xxxi] in European jurisprudence. The European Court of Human Rights found that the death row phenomenon in the United States constituted cruel, inhuman or degrading treatment in *Soering v United Kingdom and Germany.* The Judicial Committee of the British Privy Council held similarly in *Pratt et al v Attorney-General for Jamaica et al.*

3.9. The recent spate of "botched" executions in the USA further highlights the cruel, inhuman and degrading nature of the punishment (Dennis McGuire in Ohio, Clayton Lockett in Oklahoma, and Joseph Wood in Arizona).[xxxii] Indeed, following Oklahoma's botched execution of Clayton Lockett, who died of a heart attack on the execution gurney after the failed insertion of an IV drip left him "writhing in agony"[xxxiii] for over 40 minutes, the UN's Office of the High Commissioner for Human Rights (OHCHR) noted:

> *"The suffering of Clayton Lockett during his execution in Oklahoma on Tuesday 29th April, may amount to cruel, inhuman and degrading treatment according to international human rights law."*[xxxiv]

3.10. The European Union's High Representative for Foreign Affairs went a step further, noting:

> *"The details regarding the conditions for the aborted execution and subsequent death by heart attack of Mr Lockett underline the concerns over the fundamental fairness of the death penalty, as it is increasingly perceived as a brutal form of punishment that disregards human values.* ***The European Union is opposed to the use of capital punishment in all cases and under any circumstances, based on the conviction that the death penalty is cruel, inhumane, and irreversible.***" [xxxv] (emphasis added)

3.11. European law has developed in such a way as to minimize European involvement in human rights abuses (including the death penalty, torture and CIDT) overseas. In late November 2010, the UK government put an export control in place on sodium thiopental to prevent exports of the medicine to the USA. The emergency measure came in response

to evidence that British drugs were being exported to the US for use in lethal injection executions.[xxxvi] The exports contradicted the UK government's anti-death penalty position, and the new legislation was brought in to honor the British commitment to abolition and avoid direct or indirect complicity in the death penalty in the USA.

3.12. One year later, in December 2011, the European Commission published a newly amended version of EC Regulation 1236/2005 (known colloquially as "the Torture Reg"). The Torture Regulation controls exports of instruments that could be used in "*torture, capital punishment, and other cruel, inhuman or degrading treatment or punishment in non-European Union countries.*" The December amendment added a series of execution drugs to the list of goods that require export controls from Europe (Annex II of EC Regulation 1236/2005).[xxxvii]

3.13. Mylan's direct or indirect sale of medicines to death rows may circumvent this regulation by virtue of the fact that the drugs in question are not physically manufactured in Europe, but such sales are nonetheless counter to the spirit and intention of European law in this area, which is designed to prevent complicity in capital punishment, torture and CIDT in third countries and promote the global abolition of the death penalty.

3.14. The dramatic disharmony between the Dutch Government's opposition to capital punishment and the potential use of a Dutch company's medicines in executions in the USA warrants serious examination and remediation. The Netherlands' National Contact Point for the OECD Guidelines should urgently investigate Mylan's failure to prevent its potential involvement in US executions.

4. Mylan and the use of rocuronium bromide in US executions

4.1. A number of the states still carrying out executions use a three drug cocktail which aims to render the prisoner unconscious with an initial sedative, prevent them from moving with a paralytic, and stop their heart with a lethal dose of potassium chloride. States which currently use a three drug cocktail of this nature include Alabama, Colorado, Connecticut, Delaware, Florida Indiana, Mississippi, Montana, Nebraska, Oklahoma, South Carolina, Utah, Virginia, Washington, and Wyoming.

4.2. The original purpose of the paralytic in a three drug execution protocol is purely cosmetic: it is designed to mask the suffering of the prisoner by paralyzing their voluntary muscles so that they cannot speak out if the sedative administered doesn't work effectively. The use of a paralytic drug in executions has been highly controversial. In 2008 the US Supreme Court ruled that if the initial sedative fails to work in such procedures (as it has in a number of recent executions) the administration of a paralytic poses a "constitutionally unacceptable risk of suffocation".[xxxviii]

4.3. Mylan manufactures rocuronium bromide, a paralytic which is frequently used when a patient is under anesthesia to ease the insertion of a tube into the windpipe in order to assist the breathing. Mylan is one of a small number of companies[xxxix] to hold a license from the United States Food and Drug Administration (FDA)[xl] to distribute rocuronium bromide in the United States.

4.4. In recent months, a number of states have announced that they intend to use rocuronium bromide as the second drug in their lethal injection protocols. The paralytic agent is listed in the execution protocols of Virginia and Alabama and was used in an execution in Oklahoma just last month (that of Charles Warner, who cried out "my body is on fire" during the execution process).[xli] Rocuronium bromide is also set to be used in a number of other executions scheduled for 2015.[xlii]

4.5. There are seven pharmaceutical manufacturers licensed by the FDA to sell rocuronium bromide in the United States.[xliii] Six of these manufacturers have taken steps to prevent the sale of their products for use in executions.[xliv] Mylan is the only company which has taken no effective action to protect its medicine from being sold to prisons for use lethal injections; as such, it risks becoming a go-to supplier of execution drugs to states across the USA.

4.6. Mylan has thus far refused to address this issue in any meaningful way with stakeholders, civil society or the press. Its sole public statement on the issue reads as follows:

> *"Mylan is committed to setting new standards in healthcare and providing access to affordable medicines for the world's 7 billion people. We are dedicated to upholding the highest standards of quality and integrity in everything we do. We only distribute our products through legally compliant channels, intended for prescription by healthcare providers consistent with approved labeling or applicable standards of care."*[xlv]

4.7. Mylan's statement does not address the human rights implications of the sale of its medicines to prisons for use in lethal injection executions in the US. Whilst judicial executions in the US are not illegal, this does not mean it is appropriate for a multinational pharmaceutical company dedicated to healthcare to willingly allow its medicines to be sold to prisons for use in what may be torturous executions, particularly when there are simple steps the company can take to prevent this. This is all the more true when one is speaking of a company headquartered in a European State which categorically opposes the death penalty.

4.8. Mylan's statement that it distributes its products through "leally compliant channels" and assertion that its products are "intended for prescription by healthcare providers consistent with approved labeling or applicable standards of care" reflects a serious abdication of corporate responsibility. Distribution through "legally compliant channels" will not prevent the products from being purchased by prisons for use in executions; prisons have long been diverting medicines from legitimate medical channels, apparently without the need of a valid prescription.[xlvi]

4.9. Mylan's statement disregards the industry standard of best practice and respect for human rights that has been set by Mylan's competitors, all of whom have taken active steps to try to preserve their medicines from being misused in capital punishment procedures. One company, Fresenius Kabi, has created a public web page which states that:

"In order to best prevent the drug from being used for purposes other than its FDA approved indications, Fresenius Kabi does not accept orders for Propofol from any department of correction in the U.S. In addition, the company has voluntarily implemented tight distribution controls. The aim is to protect the supply of Propofol for patients who rely on this medically necessary drug and to secure the availability of the drug in all clinically approved settings. Affected U.S. healthcare providers have been informed of the measures taken on August 28, 2012".[xlvii]

4.10. With no such position statement or statement of intent to remedy the situation, Mylan is an outlier in the pharmaceutical landscape.

5. Industry standard supply chain controls

5.1. Companies that do not wish to allow their medicines to be misused in executions in the US have a number of options. Over the last few years, affected manufacturers have designed supply chain controls and restricted distribution systems that have proved extremely effective at preserving medicines from misuse in lethal injections.

5.2. Danish manufacturer, Lundbeck, was the first company to implement a new distribution model to prevent the sale of its medicine, pentobarbital, to US prisons for use in executions in July of 2011.[xlviii] The control system was extremely effective; after it went into force, no further supplies of Lundbeck pentobarbital were sold to US prisons for use in executions and Lundbeck successfully separated itself and its medicines from the execution drug business.

5.3. Since then, over a dozen other companies have followed Lundbeck's lead, implementing simple and effective distribution control systems to ensure their medicines are sold for legitimate medical use on patients, not to prisons for use in the executions of prisoners.

5.4. Different distribution systems may be designed depending on the properties of the product whose distribution is being controlled and its intended patient population. By restricting the range of distributors entitled to sell its medicines and entering into contracts with these distributors, the manufacturer is able to control the distribution of its medicine and prevent its sale for use in lethal injection executions. One manufacturer describes its distribution model thus:

"Fresenius Kabi does not accept orders from correctional institutions. The company has limited its distribution network from 34 to 14 authorized distributors/wholesalers. This is the minimum number of distributors needed to assure next-day delivery anywhere in the United States. Each distributor/wholesaler has signed a contractual commitment that they will not sell or distribute to correctional facilities. Fresenius Kabi is imposing a contractual obligation to assure that wholesalers will distribute Propofol to authorized health care providers only. Fresenius Kabi is in exchange with experts to ensure the effectiveness of the distribution controls on a rolling basis".[xlix]

5.5. Should the company be so inclined, Mylan could simply and effectively follow the example of its competitors in imposing distribution controls on rocuronium bromide to prevent the sale of the medicine for use in executions in the US.

6. Breaches of the OECD Guidelines

6.1. Mylan's failure to restrict the sale of its products to US prisons risks enabling the executions of prisoners using rocuronium bromide, in violation of their right to life and, potentially, their right not to be subjected to cruel, inhuman and degrading treatment.

6.2. As set out in Section 2 above, this puts Mylan is breach of a number of the Guidelines' General Policies (Chapter II) and Human Rights requirements (Chapter IV). Specifically, these breaches result from Mylan's failure to a) "*Respect human rights*" (as required by Chapter II, paragraph A2, and Chapter IV, paragraph 1); b) "*Avoid causing or contributing to adverse human rights impacts*" (as required by Chapter II, paragraph A11, and Chapter IV, paragraph 2); c) "*Prevent or mitigate adverse human rights impacts*" that are directly linked to the company via a business relationship (as required by Chapter II, paragraph A12 and Chapter IV, paragraph 3); d) "*Carry out human rights due diligence*" (to the extent that it is required by Chapter II, paragraph A10 Chapter IV, paragraph 5); e) "*Encourage...suppliers and sub-contractors, to apply principles of responsible business conduct compatible with the* Guidelines*"* (as required by Chapter II, paragraph A12); f) "*Engage in or support...private or multi-stakeholder initiatives and social dialogue on responsible supply chain management*" (as encouraged by Chapter II, paragraph B2); g) "*Make a policy commitment to respect the human rights of prisoners whom states seek to execute using its drugs*" (Chapter IV Paragraph 4).

a) Failure to respect human rights

Under the OECD Guidelines, enterprises are required to *"respect the internationally recognised human rights of those affected by their activities"* and "*address adverse human rights impacts with which they are involved."*[l]
Mylan's failure to take steps to prevent the use of its medicines in executions risks rendering the company complicit in violations of the basic human rights of condemned prisoners – in particular the right to life and the right to be free from cruel, inhuman and degrading treatment or punishment.[li]

b) Failure to avoid causing or contributing to adverse human rights impacts

Under the OECD Guidelines, enterprises are expected to *"avoid* ***causing or contributing*** *to adverse impacts on matters covered by the Guidelines through their own activities"*[lii] and "*address such impacts when they occur"* (emphasis added).[liii]
As a global pharmaceutical company with sales in 140 territories, the sale of rocuronium bromide to US prisons should certainly be viewed as "[w]ithin the context of [Mylan's] own activities". End-to-end control of the medicines supply chain has for decades been within the capacity (and regulatory responsibility) of global pharmaceutical companies. As discussed above, best practice standards for distribution have been developed and are successfully upheld by the majority of Mylan's competitors.

The adverse impact of selling potential execution drugs to prisons is clear. Mylan's unrestricted sales of rocuronium bromide could result in prisons purchasing this medicine for use in lethal injection executions; that these executions might then be "botched", adds to the risk of grave impacts on human rights.

c) Failure to prevent or mitigate adverse human rights impacts

The OECD Guidelines are clear that enterprises should "*seek to prevent or mitigate an adverse impact*" even "*where they have not contributed to that impact,*" when the impact is nevertheless "*directly linked to their business operations, products or services by a business relationship*".[liv] [lv]

Mylan's failure to put distribution controls in place on rocuronium bromide creates a real risk that Mylan's medicines may be sold to prisons and used in potentially torturous lethal injection executions.

Mylan has refused to "seek to prevent" or even to "mitigate" minimally this potential adverse impact which is "directly linked to [its] business operations [and] products". The public statement released by the company (see above at 4.6) indicates unwillingness to modify its behaviour or business practice in any way.

d) Failure to carry out appropriate human rights due diligence

The OECD Guidelines advise that enterprises should "*carry out risk-based due diligence, for example by incorporating it into their enterprise risk management systems, to identify, prevent and mitigate actual and potential adverse impacts*"; the "*nature and extent*" of the due diligence will depend on "*[the company's] size, the nature and context of operations and the severity of the risks of adverse human rights impacts.*"[lvi] [lvii]

Mylan's global supply chain encompasses sales in 140 territories, and it is by recent measures the world's 601st largest and 934th most profitable company.[lviii] With this in mind, Mylan cannot claim that it does not have the appropriate scale or resources to undertake effective due diligence processes in order to assess its adverse human rights impact.
Neither can Mylan claim that the "severity of risks of adverse human rights impacts" are not high enough to warrant such due diligence. As long as Mylan remains one of very few FDA-approved manufacturers that allow their medicines to be sold to US prisons for use in executions, the likelihood its products will be used in such procedures is serious and sustained. Experimental executions of this nature could imply a number of human rights abuses prohibited under Dutch, European and international law (see above), and as such "the severity of the risks" of such abuses should be seen as extremely high.

e) Failure to encourage suppliers and sub-contractors, to apply principles of responsible business conduct compatible with the *Guidelines*

Paragraph A13 of Chapter II of the OECD Guidelines states that enterprises should "*encourage, where practicable, business partners, including suppliers and sub-contractors, to apply principles of responsible business conduct compatible with the Guidelines.*"[lix]

As discussed (see Section 5 above), an industry best practice has developed in this area. The large majority of companies facing a risk that their medicines might be misused in executions have established contracts with distributors and business partners to try to ensure that their products are prevented from being sold to prisons for this purpose.

Mylan has refused to enter into negotiations of this kind with distributors or partners; its lack of engagement is at odds with industry best practice, and falls short of the commitment to responsible business that is expected under the OECD Guidelines.

f) Failure to engage in or support private or multi-stakeholder initiatives and social dialogue on responsible supply chain management

According to Paragraph B2 of Chapter II of the OECD Guidelines, enterprises should *"engage in or support, where appropriate, private or multi-stakeholder initiatives and social dialogue on responsible supply chain management* [...]".[lx]
Many of Mylan's largest institutional investors have attempted to enter into constructive dialogue with the company around the risk its medicines may be sold to prisons for use in executions, offering support in mitigating this risk. A number of these engagements have been broadly publicised, including an investor-led initiative spearheaded by the French investor BNP-Paribas Investment Partners, which at time of filing is still awaiting a detailed response from Mylan setting out what due diligence it has carried out relating to this issue. Unfortunately, Mylan has to date refused to engage in a meaningful way on this issue with any of the concerned stakeholders.
Investors have publically criticised Mylan's failure to respond to their efforts to initiate constructive dialogue on this issue, and some have gone so far as to divest from the company as a result. In October 2014 the German Venture Capital firm DJE Kapital pulled a £70 million investment from the company in October 2014, noting that "if clients find out we have shares in companies that supply that drug, we have problems with our clients."[lxi]

In contrast to other pharmaceutical companies, Mylan has also refused to engage meaningfully with civil society organizations seeking to support the company in developing systems to protect its medicines from misuse.[lxii]

g) Failure to make a policy commitment to respect the human rights of prisoners whom states seek to execute using its drugs

Finally, the OECD Guidelines recommend that enterprises should *"have a policy commitment to respect human rights"*.[lxiii]

By refusing to directly acknowledge that its medicines might be used in the execution of prisoners, Mylan is effectively ignoring the risk that its products might be directly associated with adverse human rights impacts. The company has no public policy in place on this issue, and its only de facto private policy appears to be restating its compliance with the minimum requirements of US domestic law. This is in clear breach of the spirit and specifics of Chapter IV Paragraph 4's requirement: that companies address human rights concerns in a proactive and systematic way.

Mylan's failure to develop such a policy leaves it increasingly isolated in an industry where multiple manufacturers have made their views on this issue clear. Companies which have clear public policies stating that their products should not be used in executions include Abbott Laboratories, Akorn, Fresenius Kabi, Ganapati, Hikma, Hospira, Kayem, Lundbeck, Naari, Par Pharmaceutical, Sagent, Shrenik, Tamarang, and Teva. In May 2014, for instance, Par Pharmaceutical published its policy on this subject, which states that:

> *"Brevital is a medically important anesthetic that physicians and hospital pharmacies have relied upon for more than 50 years. The state of Indiana's proposed use of Brevital is inconsistent with its medical indications as outlined in its U.S. Food and Drug Administration reviewed and approved product labelling. Brevital® is intended to be used as an anesthetic in life-sustaining procedures. As a pharmaceutical company, Par's mission is to help improve the quality of life. The state of Indiana's proposed use is contrary to our mission. Par is working with its distribution partners to establish distribution controls on Brevital® to preclude wholesalers from accepting orders from departments of correction".*[lxiv]

Furthermore, other affected pharmaceutical companies have chosen to implement strong internal policies which they have taken the decision not to publicise. Mylan is notable in that it is the only affected manufacturer who at this stage has failed to implement either a public or private policy on this issue – choosing instead to evade the subject and ignore the impact its inaction may have on the human rights of prisoners."

7. Recommended actions

The complainant submits that Mylan should:

7.1. Follow the vast majority of its competitors and acknowledge the risk that without distribution controls in place its medicines may be purchased by US prisons and used to execute prisoners;

7.2. Actively and seriously investigate what distribution controls it may impose to prevent the sale of its medicines to prisons for use in executions while maintaining access for legitimate medical users (where appropriate consulting third party experts and peer companies which have already done so successfully);

7.3. Take swift action to implement comprehensive distribution controls to prevent Mylan medicines from being purchased for use in lethal injection executions;[lxv]

7.4. Take active steps to try to prevent the use of any Mylan medicines which may already have been being sold to prisons in executions;

7.5. Publish a policy statement confirming Mylan's commitment to human rights, in particular in relation to the human rights abuses associated with the use of medicines in lethal injection executions.

8. References

[i] Nasdaq, Mylan N.V. Stock Quote & Summary Data, March 2015, available at: http://www.nasdaq.com/symbol/myl.
[ii] Mylan website, http://www.mylan.com/company/about-us.
[iii] Forbes, Mylan overview, May 2014, available at: http://www.forbes.com/companies/mylan/.
[iv] PRNewswire, "Mylan Shareholders Overwhelmingly Approve Agreement Implementing Acquisition of Abbott's Non-U.S. Developed Markets Specialty and Branded Generics Business", January 29, 2015, available at: http://www.prnewswire.com/news-releases/mylan-shareholders-overwhelmingly-approve-agreement-implementing-acquisition-of-abbotts-non-us-developed-markets-specialty-and-branded-generics-business-300027892.html.
[v] See: Alabama protocol (at: http://www.al.com/news/index.ssf/2014/09/alabama_changes_execution_drug.html); Virginia protocol (at: http://washington.cbslocal.com/2012/07/27/virginia-adds-new-lethal-injection-drug-rocuronium-bromide/); Oklahoma execution of Charles Warner: available at: http://www.supremecourt.gov/opinions/14pdf/14a761_d18f.pdf.
[vi] Death Penalty Information Center, Overview, available at: http://www.deathpenaltyinfo.org/lethal-injection-moratorium-executions-ends-after-supreme-court-decision.
[vii] Death Penalty Information Center, Executions by year since 1976, updated February 11, 2015, available at: http://www.deathpenaltyinfo.org/executions-year.
[viii] For example, Danish manufacturer Lundbeck writes: *"[Lundbeck] is opposed to the use of its products for the purpose of capital punishment. Use of our products to end lives contradicts everything we're in business to do – provide therapies that help improve people's lives."*, Lundbeck, "Lundbeck's position regarding misuse of Nembutal® CII Sodium Solution (pentobarbital sodium injection, USP) in the execution of prisoners", available at: http://www.lundbeck.com/upload/us/files/pdf/Products/NembutalStmtwithDistSystem_US_website.pdf.
[ix] Reprieve, "Manufacturer Action on Execution Drugs", available at: http://www.reprieve.org.uk/case-study/manufacturer-action-on-execution-drugs/.
[x] Huffington Post, "Executed Killer Dennis McGuire Gasped And Snorted For 15 Minutes Under New Lethal Drug Combo", March 18, 2014, available at: http://www.huffingtonpost.com/2014/01/16/dennis-mcguire-execution_n_4610582.html; The Guardian, "Clayton Lockett writhed and groaned. After 43 minutes, he was declared dead", April 30, 2014, available at: http://www.theguardian.com/world/2014/apr/30/clayton-lockett-oklahoma-execution-witness; New York Times, "Arizona Takes Nearly 2 Hours to Execute Inmate", July 23, 2014, available at: http://www.nytimes.com/2014/07/24/us/arizona-takes-nearly-2-hours-to-execute-inmate.html?_r=0.
[xi] See Alabama protocol at: http://www.al.com/news/index.ssf/2014/09/alabama_changes_execution_drug.html; Virginia protocol at: http://washington.cbslocal.com/2012/07/27/virginia-adds-new-lethal-injection-drug-rocuronium-bromide/); Oklahoma execution of Charles Warner: http://www.supremecourt.gov/opinions/14pdf/14a761_d18f.pdf.
[xii] Glossip v. Gross, No. 14-7955, available at: http://www.law.com/sites/jamesching/2015/01/30/supreme-court-grants-certiorari-in-glossip-death-penalty-appeal-ninth-circuit-ponders-jones-death-penalty-overthrow/?slreturn=20150123050913.
[xiii] OECD, Guidelines for Multinational Enterprises, 2011 Edition, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xiv] See Chapter IV Paragraph 1, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xv] See Chapter II Paragraph A2, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xvi] See Chapter IV Paragraph 2, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xvii] See Chapter II Paragraph A11, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf
[xviii] See Chapter IV Paragraph 3, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xix] See Chapter II Paragraph A12, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xx] See Chapter IV Paragraph 5, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[xxi] See Chapter II Paragraph A10, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xxii] See Chapter II Paragraph A13, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xxiii] See Chapter II Paragraph B2, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xxiv] See Chapter IV Paragraph 4, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.
[xxv] UN Guiding Principles on Business and Human Rights, p. 3-4, available at: http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf.
[xxvi] UN Guiding Principles on Business and Human Rights, p. 3-4, available at: http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf.
[xxvii] OECD, Guidelines for Multinational Enterprises, Responsible Business Conduct Matters, available at : http://mneguidelines.oecd.org/MNEguidelines_RBCmatters.pdf.
[xxviii] Government of the Netherlands, The Consitution of the Kingdom of the Netherlands, available at : http://www.government.nl/documents-and-publications/regulations/2012/10/18/the-constitution-of-the-kingdom-of-the-netherlands-2008.html; Council of Europe, Protocol No. 6 to the Convention for the Protection of Human Rights and Fundamental Freedoms concerning the abolition of the death penalty as amended by Protocol No. 11, Strasbourg, 28.IV.1983, available at : http://conventions.coe.int/Treaty/en/Treaties/Html/114.htm.
[xxix] Government of the Netherlands, Combating the most serious human rights violations, dealth penalty and torture, available at : http://www.government.nl/issues/human-rights/combating-the-most-serious-human-rights-violations.
[xxx] Idem.
[xxxi] Article 11 of the Dutch Constitution, Article 5 of the Universal Declaration of Human Rights, Article 7 of the International Covenant on Civil and Political Rights (ICCPR), Article 3 of the European Convention on Human Rights, Article 5 of the American Convention on Human Rights (1978), Article 5 of the African Charter on Human and People's Rights and the UN Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment).
[xxxii] Huffington Post, "Executed Killer Dennis McGuire Gasped And Snorted For 15 Minutes Under New Lethal Drug Combo", March 18, 2014, available at: http://www.huffingtonpost.com/2014/01/16/dennis-mcguire-execution_n_4610582.html; The Guardian, "Clayton Lockett writhed and groaned. After 43 minutes, he was declared dead", April 30, 2014, available at: http://www.theguardian.com/world/2014/apr/30/clayton-lockett-oklahoma-execution-witness; New York Times, "Arizona Takes Nearly 2 Hours to Execute Inmate", July 23, 2014, available at: http://www.nytimes.com/2014/07/24/us/arizona-takes-nearly-2-hours-to-execute-inmate.html?_r=0.
[xxxiii] The Independent, Death row inmate Clayton Lockett died after writhing in agony for 40 minutes in botched execution that lawyer described as 'torture', April 30, 2014, available at: http://www.independent.co.uk/news/world/americas/death-row-inmate-clayton-lockett-died-after-writhing-in-agony-for-forty-minutes-in-botched-execution-that-lawyer-described-as-torture-9304438.html.
[xxxiv] United Nations, Office of the High Commissioner for Human Rights, Press briefing notes on South Sudan, Ethiopia, United States, Palestine and Thailand / South East Asia, May 2, 2014, available at: http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?LangID=E&NewsID=14556.
[xxxv] European Union, Statement by EU High Representative on the execution of Clayton Lockett in the US State of Oklahoma, May 9, 2014, available at: http://eeas.europa.eu/statements/docs/2014/140509_01_en.pdf.
[xxxvi] The Guardian, "London firm supplied drugs for US executions", January 6, 2011, available at: http://www.theguardian.com/world/2011/jan/06/london-firm-supplied-drugs-us-executions.
[xxxvii] European Union, Council Regulation (EC) No 1236/2005 of 27 June 2005 concerning trade in certain goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment, available at:http://eur-lex.europa.eu/legal-content/EN/ALL/;ELX_SESSIONID=5Fn3JqWZPSQp9Bcm8grvQdg7JSZv1RnBc93552NTMNj0KlWZfRHv!-1508197558?uri=CELEX:32005R1236.
[xxxviii] Supreme Court of the United States, Baze et al. v. Rees,, January 7, 2008, available at: http://www.supremecourt.gov/opinions/07pdf/07-5439.pdf.
[xxxix] US Food and Drug Administration, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=ROCURONIUM%20BROMIDE.
[xl] US Food and Drug Administration, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=ROCURONIUM%20BROMIDE.

[xli] The Independent, "Charles Warner execution: Oklahoma inmate's last words are 'my body is on fire' as state carries out first death penalty in nine months", January 16, 2015, available at: http://www.independent.co.uk/news/world/americas/charles-warner-execution-my-body-is-on-fire-9981842.html.

[xlii] Death Penalty Information Center, Schedule executions, available at: http://www.deathpenaltyinfo.org/upcoming-executions.

[xliii] US Food and Drug Administration, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=ROCURONIUM%20BROMIDE.

[xliv] Hospira, Fresenius Kabi, Teva, Sandoz, Tamarang, Sagent Strides.

[xlv] NBC News, "Drug Maker Mylan Takes $70 Million Hit in Battle over Lethal Injection", October 21, 2014, available at: http://www.nbcnews.com/storyline/lethal-injection/drug-maker-mylan-takes-70-million-hit-battle-over-lethal-n230051.

[xlvi] For example, Delaware Code, Title 11, Section 4209 – Punishment, procedure for determining punishment, review of punishment and method of punishment for first-degree murder, LawServer Online, Inc; Texas: http://edition.cnn.com/2013/11/15/justice/states-lethal-injection-drugs/.

[xlvii] Fresenius Kabi, Importance of distribution controls, available at: http://propofol-info.com/Voluntary-Distribution-Controls.htm.

[xlviii] Lundbeck, "Lundbeck overhauls pentobarbital distribution program to restrict misuse", July 1, 2011, available at: http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=605775.

[xlix] http://propofol-info.com/Voluntary-Distribution-Controls.htm.

[l] See Chapter IV Paragraph 3, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[li] Council of Europe, 2002. Protocol No. 13 to the Convention for the Protection of Human Rights and Fundamental Freedoms, concerning the abolition of the death penalty in all circumstances [PDF] 3 May, available at: <http://www.statewatch.org/news/2003/jul/prot13.pdf>.

[lii] See Chapter II Paragraph A11, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[liii] See Chapter IV Paragraph 2, OECD Guidelines for Multinational Enterprises http://www.oecd.org/daf/inv/mne/48004323.pdf.

[liv] See Chapter II Paragraph A2, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[lv] See Chapter IV Paragraph 3, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[lvi] See Chapter II Paragraph A10, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[lvii] See Chapter IV Paragraph 5, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[lviii] Forbes, Overview on Mylan, May 2014, available at: http://www.forbes.com/companies/mylan/.

[lix] See Chapter II Paragraph A13, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[lx] See Chapter II Paragraph B2, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[lxi] NBC News, "Drug Maker Mylan Takes $70 Million Hit in Battle over Lethal Injection", October 21, 2014, available at: http://www.nbcnews.com/storyline/lethal-injection/drug-maker-mylan-takes-70-million-hit-battle-over-lethal-n230051.

[lxii] See letter from Maya Foa to Heather Bresch dated 29th October 2013; copy held on file at *Reprieve*.

[lxiii] See Chapter IV Paragraph 4, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

[lxiv] Contract Pharma, "Par Pharmaceutical Statement on Brevital Sodium", May 27, 2014, available at: http://www.contractpharma.com/contents/view_news-releases/2014-05-27/par-pharmaceutical-statement-on-brevital-sodium/.

[lxv] See Chapter IV Paragraph 3, OECD Guidelines for Multinational Enterprises, available at: http://www.oecd.org/daf/inv/mne/48004323.pdf.

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