

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549



DIVISION OF CORPORATION FINANCE

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March 4, 2015

No Act PE 1/14/15

Kimberley S. Drexler Cravath, Swaine & Moore LLP kdrexler@cravath.com

Mylan Inc. Re: Incoming letter dated January 14, 2015

Act: Section: Rule: Public Availabilit

Dear Ms. Drexler:

This is in response to your letter dated January 14, 2015 concerning the shareholder proposal submitted to Mylan by the New York State Common Retirement Fund. We also have received a letter on the proponent's behalf dated February 6, 2015. Copies of all of the correspondence on which this response is based will be made available on our website at http://www.sec.gov/divisions/corpfin/cf-noaction/14a-8.shtml. For your reference, a brief discussion of the Division's informal procedures regarding shareholder proposals is also available at the same website address.

Sincerely,

Matt S. McNair Special Counsel

Enclosure

Cornish F. Hitchcock cc: Hitchcock Law Firm PLLC conh@hitchlaw.com

March 4, 2015

#### Response of the Office of Chief Counsel Division of Corporation Finance

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Re: Mylan Inc. Incoming letter dated January 14, 2015

The proposal requests that the company issue a report describing the company's policy position regarding whether the company or its subsidiaries will provide products for purposes of aiding executions, and including an analysis of potential reputational risks associated with such policy position.

We are unable to concur in your view that Mylan may exclude the proposal under rule 14a-8(i)(3). We are unable to conclude that you have demonstrated objectively that the portions of the supporting statement you reference are materially false or misleading. Accordingly, we do not believe that Mylan may omit the proposal from its proxy materials in reliance on rule 14a-8(i)(3).

Sincerely,

Sonia Bednarowski Attorney-Adviser

#### DIVISION OF CORPORATION FINANCE INFORMAL PROCEDURES REGARDING SHAREHOLDER PROPOSALS

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The Division of Corporation Finance believes that its responsibility with respect to matters arising under Rule 14a-8 [17 CFR 240.14a-8], as with other matter under the proxy rules, is to aid those who must comply with the rule by offering informal advice and suggestions and to determine, initially, whether or not it may be appropriate in a particular matter to recommend enforcement action to the Commission. In connection with a shareholder proposal under Rule 14a-8, the Division's staff considers the information furnished to it by the Company in support of its intention to exclude the proposals from the Company's proxy materials, as well as any information furnished by the proponent or the proponent's representative.

Although Rule 14a-8(k) does not require any communications from shareholders to the Commission's staff, the staff will always consider information concerning alleged violations of the statutes administered by the Commission, including argument as to whether or not activities proposed to be taken would be violative of the statute or rule involved. The receipt by the staff of such information, however, should not be construed as changing the staff's informal procedures and proxy review into a formal or adversary procedure.

It is important to note that the staff's and Commission's no-action responses to Rule 14a-8(j) submissions reflect only informal views. The determinations reached in these no-action letters do not and cannot adjudicate the merits of a company's position with respect to the proposal. Only a court such as a U.S. District Court can decide whether a company is obligated to include shareholders proposals in its proxy materials. Accordingly a discretionary determination not to recommend or take Commission enforcement action, does not preclude a proponent, or any shareholder of a company, from pursuing any rights he or she may have against the company in court, should the management omit the proposal from the company's proxy material.

#### HITCHCOCK LAW FIRM PLLC 5614 Connecticut Avenue, N.W. • No. 304 Washington, D.C. 20015-2604 (202) 489-4813 • Fax: (202) 315-3552

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February 6, 2015

Office of the Chief Counsel Division of Corporation Finance Securities & Exchange Commission 100 F Street, N.E. Washington, D.C. 20549

#### By Electronic mail: shareholderproposals@sec.gov

Re: Shareholder Proposal to Mylan Inc.

Dear Counsel:

The Comptroller of the State of New York, Thomas P. DiNapoli, submitted a shareholder proposal (the "Proposal") on behalf of the New York State Common Retirement Fund (the "Fund"), a beneficial owner of common stock of Mylan Inc. ("Mylan" or the "Company"), for inclusion in the Company's 2015 shareholder meeting proxy statement. By letter dated January 14, 2015, Mylan advised the Division of its intent to exclude the Proposal from the Company's 2015 proxy materials ("Mylan's No Action Letter" ("NAL")). For the reasons stated below, we submit that Mylan has not sustained its burden of establishing that the Proposal may be omitted, and we respectfully ask the Division to deny the requested no-action relief.

The Fund's Proposal.

The Proposal asks the Company to "issue a report at reasonable expense and excluding confidential information, describing the Company's policy position regarding whether the Company or its subsidiaries will provide products for purposes of aiding executions, and including an analysis of potential reputational risks associated with such policy position."<sup>1</sup>

The supporting statement recites the following facts: There has been a controversy in recent years over the use of lethal injections to execute prisoners, which was highlighted most recently by the prolonged execution of an Oklahoma inmate in 2014. Mylan's subsidiary, Mylan Institutional, manufactures a drug known as "rocuronium bromide," which at least two states have adopted for use as a substitute in lethal injections for the nationally scarce pancuronium bromide. At least three of Mylan's industry peers (which the Proposal identifies by name) have

<sup>&</sup>lt;sup>1</sup> Several months before filing the Proposal Comptroller DiNapoli wrote a letter to Mylan expressing the concerns in the Proposal and asking if the Company had a policy regarding the use of drugs manufactured by Mylan subsidiaries in lethal injection executions (Exhibit A). Mylan never responded.

taken steps to prevent their products from being utilized for lethal injections, whereas "Mylan has not taken similar preventative actions."

Following restrictions by the European Union ("E.U.") on the export of anaesthetics used in lethal injections, U.S. states have looked to domestic corporations, including Mylan, for alternative drugs. By being identified in the death penalty controversy, Mylan is said to have "been exposed to reputational risk," "jeopardized its role and reputation as a provider of health oriented products," and may face "increased financial and legal risk . . . resulting from the actual use of its products in executions."

In seeking no-action relief, Mylan asserts that several words or phrases render the Proposal impermissibly vague or misleading, thus violating Rule 14a-9 and permitting exclusion under Rule 14a-8(i)(3). We respond as follows.

#### Discussion.

Mylan's objections focus on statements regarding (1) the role and use of rocuronium bromide in lethal injections; (2) Mylan's role with respect to "lethal injection drugs," and (3) possible financial impacts on Mylan related to rocuronium bromide. Mylan NAL, p. 2. There is an irony here, namely that Mylan's discussion of key factual points is itself incomplete and unavailing. To put those charges in context – and to lay out some important facts that Mylan chooses to ignore – we offer the following brief description of rocuronium bromide and its role in lethal injections, followed by a factual summary about the current status of executions by lethal injection.

Rocuronium bromide is a muscle relaxant approved by the Food and Drug Administration ("FDA") for use during surgery. As is discussed in more detail below, while not an FDA-approved use, muscle relaxants are typically used as one of several drugs administered during an execution by lethal injection. The "cocktail" of drugs used for lethal injections consists of a sedative, a muscle relaxant to act as a paralytic, and a toxin (such as potassium chloride) to stop the heart. The latter two drugs are administered at a higher dosage than would be used in normal medical situations.<sup>2</sup> If the sedative does not work properly, the execution could be prolonged, as has occurred in executions in Arizona, Ohio and Oklahoma.<sup>3</sup> In such instances, the prisoner could remain conscious despite administration of the sedative and could

<sup>&</sup>lt;sup>2</sup> See also Associated Press, Alabama changes execution drug combination and seeks to set execution dates for 9 death row inmates (Sept. 12, 2014), available at http://www.al.com/news/index.ssf/2014/09/alabama\_changes\_execution\_drug.html (Exhibit B). Potassium chloride has a medical use in preventing or treating low blood levels of potassium (hypokalemia). See <u>http://www.drugs.com/potassium\_chloride.html</u>.

<sup>&</sup>lt;sup>3</sup> See also Lyman, Alabama adopts new death penalty protocol, MONTGOMERY ADVERTISER (Sept. 12, 2014), available at http://www.montgomeryadvertiser.com/story/news/politics/southunionstreet/2014/09/12/ alabama-has-new-death-penalty-protocol-says-ag-office/15526777/ (Exhibit C).

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experience significant pain prior to a protracted and agonizing death.

There has been a public controversy in recent years about the use of lethal injections; such controversy has influenced a campaign to prevent pharmaceutical companies from selling drugs with the potential for being used in executions.<sup>4</sup> For example, in 2011 a U.K. company known as Dream Pharma was found to be selling drugs to Arizona for use in its lethal injections. Thereafter, the U.K. business secretary restricted exports on the products. Later that same year, the E.U. imposed a ban on exports of drugs that could be used in lethal injections, which limited the ability of U.S. states to obtain drugs used in lethal injection executions and slowed the rate of executions in those states. The export restrictions thus spurred a search for alternative drugs by those U.S. states that allow the death penalty.

Responding to the shortage of various drugs previously used in lethal injections, Virginia and Alabama have adopted new protocols of drugs to be used in lethal injections, and both states specify that rocuronium bromide is a drug that may be used in executions.<sup>5</sup> Though Mylan correctly notes that no one has yet been executed via lethal injection in those states since 2011, Mylan ignores the fact that in December 2014, Alabama's Supreme Court set execution dates for two prisoners, one in February 2015 and one in March 2015.<sup>6</sup> Moreover, it appears that rocuronium bromide was in fact used in Oklahoma last month in the execution of Charles Warner.<sup>7</sup> Three other Oklahoma prisoners face execution in a similar fashion, although those executions have been stayed pending the U.S. Supreme Court's determination of whether Oklahoma's method of execution violates the Eighth Amendment prohibition on "cruel and

<sup>5</sup> Virginia apparently was the first state to adopt explicitly rocuronium bromide as the muscle relaxant in executions. CBS Local, *Virginia Adds new Lethal Injection Drug: Rocuronium Bromide* (July 27, 2012), *available at* http://washington.cbslocal.com/2012/07/27/virginia-adds-new-lethal-injection-drug-rocuronium-bromide/ (Exhibit F). Montana is another state that has published a protocol for lethal injections that contemplates the possible use of rocuronium bromide as part of the drug "cocktail." Montana Department of Corrections, Montana State Prison Execution Technical Manual (Jan. 16, 2013) at 51, *available at* http://www.deathpenaltyinfo.org/documents/ MontanaExecutionProtocol.pdf (Exhibit G).

<sup>6</sup> Associated Press, Supreme Court sets execution dates for 2 inmates, WIAT.Com (Dec. 30, 2014), available at http://wiat.com/2014/12/30/supreme-court-sets-execution-dates-for-2-inmates/ (Exhibit H). One suspects that dates may be stayed pending the U.S. Supreme Court's resolution of the Glossip case, discussed in the text at n.8.

<sup>7</sup> Mr. Warner sought a stay of execution, which was denied. In a dissent from that ruling for herself and three other Justices, Justice Sotomayor noted that Oklahoma was using rocuronium bromide in executions. *Warner v. Gross*, No. 14A761 (Jan. 15, 2015), *available at* http://www.supremecourt.gov/opinions/14/pdf/14a761 d18f.pdf.

<sup>&</sup>lt;sup>4</sup> The pertinent facts in this section are well summarized in Ward, *Mylan faces investor pressures over use of drugs in US executions*, FINANCIAL TIMES (Oct. 19, 2014), *available at* http://www.ft.com/intl/cms/s/0/da2859b8-5762-11e4-8493-00144feab7de.html#axz3Pxf1vGNM (Exhibit D) and Ford, *Can Europe End the Death Penalty in America?*, THE ATLANTIC (Feb. 18, 2014), *available at* http://www.theatlantic.com/international/archive/2014/02//can-europe-end-the-death-penalty-in-america/283790/ (Exhibit E).

unusual punishment."<sup>8</sup> Thus, the potential use of rocuronium bromide in five upcoming executions is hardly "theoretical" as the Company tries to assert.

Mylan argues that lethal injection is not a use that has been approved by the FDA for rocuronium bromide, that Mylan has "never promoted or distributed [rocuronium bromide]" as a lethal injection drug, that Mylan "markets rocuronium bromide only in accordance with its FDA-approved indications," and is "committed to distributing its products only through legally compliant channels for prescription by healthcare providers consistent with the approved labeling or standard of care" (Mylan NAL, pp. 3-4) (footnotes omitted). The FDA is required by law to determine whether drugs can be approved as "safe and effective" for uses that the FDA specifies. If the FDA learns that a drug approved for one use is being used for a non-approved use, it may take regulatory action. However, if the unapproved use involves a lethal injection, the FDA's policy is not to take regulatory action; the FDA's refusal to act was unanimously upheld by the Supreme Court 30 years ago in a case brought by several death row inmates challenging the agency's failure to regulate such unapproved uses. *Heckler v. Chaney*, 470 U.S. 821 (1985).<sup>9</sup> Therefore, Mylan's claim that the Fund has materially mischaracterized the drug and its intended purposes is baseless.

Even if Mylan is not itself distributing rocuronium bromide directly to prisons, it is possible that states may be purchasing rocuronium bromide in secondary or tertiary resale markets or retail markets. Mylan has not put in place any controls to prevent such sales by its distributors – a step that other manufacturers have taken to prevent their products from being purchased in downstream markets and used in lethal injections. For example, the Dutch company Lundbeck, which operates in the U.S. and whose drug pentobarbital had once been used for executions, disallowed prisons from obtaining pentobarbital from sources other than the manufacturer directly by discontinuing its use of multiple distributors and end-users who were entitled to sell this product. <sup>10</sup> Lundbeck now uses only one distributor, whose contract with Lundbeck authorizes it to sell pentobarbital to an approved list of end-users only, excluding prisons, secondary/tertiary distributors, or retail pharmacies, who might in turn provide the drug to prisons. In short, Lundbeck retains legal control until the product reaches the end-user.

Other manufacturers, including Hospira, Par Pharmaceutical Companies, Hikma

<sup>8</sup> Warner v. Gross, 2015 WL 137627 n.2 (10<sup>th</sup> Cir. Jan. 12, 2015), cert. granted sub nom. Glossip v. Gross, No. 14-7955 (Jan. 23, 2015).

<sup>9</sup> The FDA's refusal to act was based on a policy statement that the agency felt "obligated" to investigate the unapproved use of an approved drug if such use became "widespread" or "endanger[ed] the public health." 470 U.S. at 826.

<sup>10</sup> Lundbeck's practices and those of APP Pharmaceuticals, another manufacturer that is controlling its distribution chain to prevent the sale of its products to prisons, are described in *How manufacturers can prevent the sale of their drugs for use in executions*, posted by reprieve.org,uk, an anti-death penalty group, *available at* http://www. reprieve.org.uk/case-study/how- manufacturers-can-prevent-the-sale-of-their-drugs-for-use-in-executions/ (Ex. I).

Pharmaceuticals and Fresenius Kabi Pharmaceuticals have taken similar steps to control and disallow state prison officials from using their products as part of a lethal injection cocktail.<sup>11</sup> If anything, Mylan's failure to adopt such a policy makes Mylan an outlier. The Proposal is clear; it requests that Mylan report its policy on whether the Company, or its subsidiaries, will provide products for purposes of aiding executions, including an analysis of potential reputation risks associated therewith.

Mylan's Objections.

Before addressing Mylan's specific objections, we make two general observations.

First, Mylan never explains why the challenged statements, discussed below, are false or misleading as to "material" facts, which is a requirement in Rule 14-9. Not only are the statements in question not false or misleading, it is difficult to believe that a shareholder would vote for, rather than against, the Proposal because of the specific wordings to which Mylan objects. Second, Mylan's real objection appears to be that the Fund's recitation of the facts makes Mylan look bad, a strategy that conflicts with the guidance in section 4 of the Division's STAFF LEGAL BULLETIN 14B (2004), which states that a proposal may not be excluded simply because a company "objects to factual assertions because those assertions may be interpreted by shareholders in a manner that is unfavorable to the company, its directors, or its officers." This approach is only logical. After all, a shareholder is unlikely to sponsor a proposal unless he or she believes that a company's policies are deficient in some manner.

Turning to the specific points, Mylan first objects to the statement that rocuronium bromide "has been adopted by at least two states as being a substitute in lethal injections for the nationally scarce pancuronium bromide." Mylan NAL, p. 3. According to Mylan, this factually accurate sentence can somehow be read to suggest that rocuronium bromide is the *only* drug used in lethal objections and that the sentence mischaracterizes the drug. Indeed, as noted above, it is Mylan that is mischaracterizing the facts here when it discusses the possible use of its product as "theoretical" and proffers that there is no single-drug form of lethal injection. At no point does Mylan explain how the quoted sentence is inaccurate, nor does Mylan explain why a shareholder would find it "material" to learn that rocuronium bromide is used "only" to paralyze an inmate before the inmate's heart is stopped.

Mylan's second specific objection centers on the sentence stating that Mylan "has become a focus of public and media attention as one of the likely sources for lethal injection drugs." Mylan NAL, pp. 3-4.<sup>12</sup> This argument rests on Mylan's view that it operates in a legally

<sup>&</sup>lt;sup>11</sup> Exhibit J collects the public statements of these companies, as compiled by reprieve.org.uk.

<sup>&</sup>lt;sup>12</sup> Contrary to Mylan's suggestion (Mylan NAL, p. 4,  $\P$  2), the Proposal does not state that Mylan is "the" likely source for this product, only that Mylan is "one of the likely sources." The Proposal's statement is thus entirely accurate and, if anything, is buttressed by Mylan's citation of only five other companies now offering this product (Mylan NAL, p.4 n.5).

compliant manner and wants to sell its products only for medically-approved purposes. Mylan's defense does not address the Fund's point that Mylan has taken no steps whatsoever, much less steps comparable to those its peers have taken, to restrict the ability of Mylan's distributors to sell its product to prison systems, where a product may be used for non-FDA-approved purposes.

Moreover, even if Mylan is not selling its products directly to prison systems, public attention and investor attention have focused not on distribution agents, but on their principals – the drug manufacturers such as Mylan who can take responsibility for those agents and control the means of distribution of a product such as rocuronium bromide.

Mylan objects to statements about the possible financial and legal risk "resulting from the actual use of its products in executions" because the use of rocuronium bromide in an actual execution has never happened.

Along the same line, Mylan finds misleading the statement that after the 2011 E.U. export restrictions took effect, "states have been forced to look to domestic corporations, including Mylan for alternative drugs." Mylan NAL, pp. 4-5. This is misleading, Mylan argues, because there are non-U.S. and non-E.U. markets to which state prisons may turn. Even though Mylan has the burden of establishing that a statement is materially false or misleading, we are never told what those markets may be. Indeed, Mylan notes that there are five other sources of rocuronium injection products at this time, yet all of them do business in the United States.<sup>13</sup> In fact, two of them (Hospira and Fresenius Kabi) have adopted limitations on distribution of their products that could be used in lethal injections. The pool of "likely sources" is thus fairly small.

Finally, Mylan disputes the Fund's citation of an NBC News story headlined *Drug Maker Mylan Takes \$70 Million Hit in Battle Over Lethal Injection.*<sup>14</sup> According to Mylan the NBC story simply stands for the proposition that although a European investment fund sold \$70 million worth of Mylan stock, there has been no suggestion that Mylan's "sales, revenues or other financial metric related to the Company have been impacted." Mylan NAL, p.5.

If anything, the NBC article – if not the title alone – should underscore the point that there may be a financial impact if a drug manufacturer is identified as *not* taking action to control distribution of drugs that may find their way into an execution chamber. The NBC story quoted a managing director of the fund that sold its entire Mylan stake as saying "We don't want to

<sup>&</sup>lt;sup>13</sup> Note 5 of Mylan's letter refers to a document published by the American Society of Health-System Pharmacists that is available at http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=434Mylan appears to be relying on a list of manufacturers near the top of the document entitled "Reason for the Shortage," which refers to Mylan, as well as Hospira, Teva, Fresenius Kabi, Sargent and The Medicines Company.

<sup>&</sup>lt;sup>14</sup> The NBC story is available at http://www.nbcnews.com/storyline/lethal-injection/drug-maker-mylan-takes-70-million-hit-battle-over-lethal-n230051 (Exhibit K).

support this. If clients find out that we have shares in companies that supply that drug, we have problems with our clients" (Exhibit K at 2). Investors do care.

Of course, the Proposal does not say that Mylan has *already* suffered the potentially negative consequences beyond citation of the \$70 million. Instead the Proposal refers to how Mylan's identification with this issue "has exposed Mylan to "reputational risk" and "has jeopardized its role and reputation as a provider of health oriented products." These are forward-looking statements of what might happen, along with the "possibility of increased financial and legal risk . . . resulting from the actual use of its products in executions."

The family of the Ohio man who took 26 minutes to die from a prolonged execution has sued the drug manufacturer whose product was used in the execution.<sup>15</sup> Thus, there may be a liability risk for Mylan should rocuronium bromide be used in an execution that leads to a prolonged death, not to mention the risk of reputational damage. Moreover, the Supreme Court will decide whether a lethal injection that may use rocuronium bromide is cruel and unusual punishment. And now that rocuronium bromide has been used – and is scheduled to be used – in lethal injections, one may wonder how much longer Mylan can deny the risk of a negative impact on the Company. Mylan may also face reputational harm if the Company should be identified as the source of a product used in a future execution. The Fund is surely on solid ground in asking Mylan to examine the Company's current policy and practices.

#### Conclusion.

Mylan has failed to carry its burden of showing that the Proposal is materially false or misleading in violation of Rule 14a-9 and thus excludable under 14a-8(i)(3). Accordingly, we respectfully ask you to advise that the Division cannot concur with the Company's objections.

Thank you for your consideration of these points. Please feel free to contact me if any additional information would be helpful.

Very truly yours,

Counily John Shuth

Cornish F. Hitchcock

cc: Kimberly S. Drexler, Esq. Brad Wideman, Esq.

<sup>&</sup>lt;sup>15</sup> Associated Press, *Family Sues in Protracted Ohio Execution*, THE NEW YORK TIMES (Jan. 25, 2014), *available at* http://www.nytimes.com/2014/01/26/us/family sues-in-protracted-ohio-execution.html (Exhibit L).

## EXHIBIT A

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THOMAS P. DiNAPOLI STATE COMPTROLLER



110 STATE STREET ALBANY, NEW YORK 12236

#### STATE OF NEW YORK OFFICE OF THE STATE COMPTROLLER

July 21, 2014

Heather Bresch, CEO Mylan, Inc. Robert J. Coury Global Center 1000 Mylan Boulevard Canonsburg, PA 15317

Dear Ms. Bresch:

As New York State Comptroller, I am the Trustee of the New York State Common Retirement Fund and am responsible for overseeing its investments on behalf of the more than one million members, retirees and beneficiaries of the New York State and Local Retirement System. The Fund's portfolio includes 1,082,056 shares of Mylan, Inc. stock. It is my understanding that Mylan Institutional Inc. is a wholly owned subsidiary of Mylan that supplies unit dose pharmaceutical and specialty packaging for institutional and retail pharmacies in hospitals, nursing homes, and other health care institutions in the United States.

As you are likely aware, a recent execution in Oklahoma garnered considerable public attention due to its prolonged duration and the convict's apparently unexpected physical reaction after the drugs were administered. The execution has revived the death penalty debate generally, and has specifically highlighted a growing controversy surrounding the drugs used in lethal injection executions.

Mylan's webpage identifies Mylan Institutional as a manufacturer of rocuronium bromide, a drug that has been identified by at least one state as being a possible substitute in lethal injections for the nationally scarce pancuronium bromide. As public debate concerning the death penalty continues, and as the controversy surrounding drugs used in lethal injection executions increases, I am concerned about the possibility of reputational harm to Mylan as Mylan Institutional's parent company. Intense public outcry opposing the death penalty led the European Union to enact regulations in 2011 restricting the export of anaesthetics used in lethal injection executions. As a result, states are now forced to look domestically for alternative drugs, and if Mylan Institutional is publicly perceived as a source for the drugs, it is possible that Mylan will find itself embroiled in the death penalty controversy due to its ownership of Mylan Institutional. As a fiduciary with respect to the Fund's investments, I would like to know whether Mylan, as Mylan Institutional's parent company, has a policy regarding the use of drugs manufactured by its subsidiaries in lethal injection executions. I appreciate your time and attention to this important matter, and look forward to hearing from you within the next few weeks.

Yours truly,

Thomas P. DiNapoli

New York State Comptroller

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Fresenius Kabi USA, LLC

1501 E. Woodfield Road Suite 300 East Schaumburg, Illinois 60173 T 847-969-2700 T 888-391-6300 www.fresenius-kabl.us

August 28, 2012

Dear Healthcare Provider:

I am writing to provide you with important information about steps Fresenius Kabi USA, LLC, and our specialty pharmaceuticals division, APP, have taken regarding the anesthetic drug Propofol (Propofol Injectable Emulsion 1%, USP) due to its possible use in executions in the United States (U.S.). We understand that one or more departments of correction in the U.S. are considering amendment of their lethal injection protocols to include Propofol.

Clearly such use is contrary to the FDA approved indications for Propofol and inconsistent with Fresenius Kabi's mission of '*Caring for life'*. Fresenius Kabi objects to the use of its products in any manner that is not in full accordance with the approved indications. At the same time, Fresenius Kabi's obligation is to protect the supply of Propofol to patients who critically rely on this medically necessary drug and to secure the availability of Propofol in all clinically approved settings. Due to its clinical and safety profile, Propofol is one of the world's most widely used anesthetics and contributes to saving the lives of millions of patients every year.

In the U.S. alone, Propofol is administered some 50 million times annually in approximately 15,000 hospitals, clinics and other health care facilities. Our intent is to ensure that this important drug continues to be immediately available to those patients and health care facilities where its use is medically necessary. As one of the most frequently used drugs for the induction of general anesthesia, Propofol needs to be quickly accessible at all times.

Because Propofol is formulated as a lipid emulsion, it requires specialized manufacturing equipment to produce it, and all forms of Fresenius Kabi Propofol are manufactured in Europe where our Company has state of the art facilities for such production. This is important because a European Union (EU) regulation prevents products that may reasonably be expected to be used in executions from being exported from the EU. Should Propofol begin to be used in executions in the U.S. and should the EU Commission place Propofol on its list of export restricted substances under the anti-torture regulation, it could severely restrict U.S. access to the drug.

To best prevent Propofol from being used for purposes other than its approved indications, Fresenius Kabi does not accept orders for Propofol from any departments of correction in the U.S., nor will we do so, and we have voluntarily instituted tighter distribution controls on all forms of our APP branded Propofol (including Diprivan®). In the future, only selected wholesalers and distributors (see a list of Fresenius Kabi approved wholesalers and distributors with this letter) will be able to purchase Fresenius Kabi's Propofol under the condition that they agree to resell it only to acute care hospitals, clinics and health care facilities where its use is medically necessary within those facilities. Any changes to the Fresenius Kabi approved wholesalers and distributors of Propofol will be provided on our web site <u>www.APPpharma.com</u>.

We have also required these selected wholesalers and distributors to reject delivery to any correctional facilities and to exclude delivery to retail pharmacies or other distributors to reduce the possibility that our Propofol reaches correctional facilities.

We appreciate your understanding of our position on this matter. If you have any questions regarding availability of Propofol please contact your distributor or Fresenius Kabi customer service at 888-386-1300.

Sincerely,

Scott Meachanf Executive Vice President Chief Commercial Officer Fresenius Kabi USA, LLC

#### Fresenius Kabi USA, LLC (formerly, APP Pharmaceuticals, LLC)

#### **Authorized Propofol Distributors**

Effective as of August 27, 2012, Fresenius Kabi USA, LLC ("Fresenius Kabi") has appointed the following as Authorized Propofol Distributors:

AmerisourceBergen Drug Corporation Besse Medical, a division of ASD Specialty Healthcare, Inc. Cardinal Health Cesar Castillo, Inc. Priority Healthcare Distribution, Inc. d/b/a Curascript SD Specialty Distribution H.C. Pharmacy Central, Inc. H. D. Smith Wholesale Drug Co. and Smith Medical Partners, LLC Henry Schein, Inc. Kaiser Foundation Hospitals McKesson Corporation Morris and Dickson Co., L.L.C. Oncology Supply, a division of ASD Specialty Healthcare, Inc. PharMEDium Services, LLC PSS World Medical, Inc.

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### CRAVATH, SWAINE & MOORE LLP

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OF COUNSEL MICHAEL L. SCHLER

#### <u>Mylan Inc.</u> <u>Shareholder Proposal of the New York State Common Retirement Fund</u> Securities Exchange Act of 1934—Rule 14a-8

January 14, 2015

Ladies and Gentlemen:

JULIE A. NORTH

ANDREW W. NEEDHAM

ROBERT I. TOWNSEND, III

WILLIAM J. WHELAN, III

SCOTT A. BARSHAY PHILIP J. BOECKMAN

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STEPHEN L. BURNS

KEITH R. HUMMEL

DAVID J. KAPPOS

DANIEL SLIFKIN

On behalf of our client, Mylan Inc. ("Mylan" or the "Company"), we write to inform you of Mylan's intention to exclude from its proxy statement and form of proxy for its next Annual Meeting of Shareholders (collectively, the "Proxy Materials") a shareholder proposal and related supporting statement (the "Proposal") received from the New York State Common Retirement Fund (the "Proponent").

We hereby respectfully request that the Staff of the Division of Corporation Finance (the "Staff") concur in our view that Mylan may, for the reasons set forth below, properly exclude the Proposal from the Proxy Materials. Mylan has advised us as to the factual matters set forth below.

In accordance with Rule 14a-8(j), we have filed this letter with the Securities and Exchange Commission (the "Commission") no later than eighty calendar days before the Company intends to file its definitive Proxy Materials with the Commission. Also in accordance with Rule 14a-8(j), a copy of this letter and its attachments is being sent concurrently to the Proponent. Pursuant to Rule 14a-8(j) and Staff Legal Bulletin No. 14D (November 7, 2008) ("SLB 14D"), we have submitted this letter, together with the Proposal, to the Staff via e-mail at shareholderproposals@sec.gov in lieu of mailing paper copies.

Rule 14a-8(k) and SLB 14D provide that shareholder proponents are required to send companies a copy of any correspondence that the proponents elect to submit to the Commission or the Staff. Accordingly, we are taking this opportunity to inform the Proponent that if the Proponent elects to submit additional correspondence to the Commission or the Staff with respect to the Proposal, a copy of that correspondence should be furnished concurrently to the undersigned on behalf of Mylan pursuant to Rule 14a-8(k) and SLB 14D.

#### 1. The Proposal

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The Proponent requests that the following matter be considered by stockholders at Mylan's next Annual Meeting of Shareholders:

Therefore be it Resolved: Shareholders request that the Company issue a report at reasonable expense and excluding confidential information, describing the Company's policy position regarding whether the Company or its subsidiaries will provide products for purposes of aiding executions, and including an analysis of potential reputational risks associated with such policy position.

A copy of the Proposal, the Proponent's cover letter, dated November 7, 2014, submitting the Proposal and other correspondence relating to the Proposal are attached hereto as <u>Exhibit A</u>.

#### 2. Grounds for Omission

Mylan believes that it may properly omit the Proposal from the proxy materials under Rules 14a-8(i)(3) and 14a-9 because the Proposal contains false and misleading statements. Rule 14a-9 prohibits a company from making a proxy solicitation that contains "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact." In addition, Rule 14a-8(i)(3) provides, in part, that a proposal may be excluded from proxy materials if the proposal is materially false or contains misleading statements. The Staff has taken the position that a shareholder proposal may be excluded from proxy materials under Rule 14a-8(i)(3) if "the company demonstrates objectively that a factual statement is materially false or misleading." Staff Legal Bulletin No. 14B (Sept. 15, 2004) ("SLB 14B").

The Staff has repeatedly allowed the exclusion of shareholder proposals under Rules 14a-8(i)(3) and 14a-9 if the supporting statement contains false or misleading statements. *See, e.g., Entergy Corp.* (Feb. 14, 2007) (allowing for exclusion where the proposal and supporting statement contained false and misleading statements) and *Woodward Governor Co.* (Nov. 26, 2003) (allowing for exclusion where the supporting statement contained false and misleading statements).

The Proposal contains false and misleading statements regarding (i) the role and use of rocuronium bromide in lethal injections, (ii) Mylan's role with respect to "lethal injection drugs," and (iii) financial impacts on Mylan related to rocuronium bromide, and the Proposal therefore should be excluded pursuant to Rules 14a-8(i)(3) and 14a-9.

## i. The Proposal contains false and misleading statements regarding the role and use of rocuronium bromide in lethal injections.

The Proposal contains false and misleading statements regarding the role and use of rocuronium bromide in lethal injections. Specifically, the Proposal claims that rocuronium bromide "has been adopted by at least two states as being a substitute in lethal injections for the nationally scarce pancuronium bromide." The Proponent's statement, however, is false and misleading because rocuronium bromide is only one of a sequence of multiple drugs that may be used in executions and not, as the Proponent suggests, the only drug used. More specifically, the two states the Proponent likely refers to in its supporting statement-Virginia and Alabama-have issued guidelines for threedrug combinations available for use in lethal injections that include, among other drugs, rocuronium bromide<sup>1</sup> but according to deathpenalty.org, no state that uses a one-drug protocol administers rocuronium bromide.<sup>2</sup> The Proponent, however, would have shareholders believe that rocuronium bromide, on its own, is the new leading drug for lethal injections. More importantly, the Proponent would have shareholders believe that the drug has actually been used in executions. Rocuronium bromide, however, has never been used in an execution in the United States.<sup>3</sup> In addition, the Proposal suggests that the primary or common use of rocuronium bromide is as part of lethal injections. This, however, is only a theoretical use and, to Mylan's knowledge, the drug has never actually been used for that purpose either in the U.S. or anywhere else in the world and such a use is not one of the indications for rocuronium bromide approved by the U.S. Food and Drug Administration ("FDA"). By claiming that rocuronium bromide "has been adopted by at least two states as being a substitute in lethal injections for the nationally scarce pancuronium bromide," the Proponent has materially mischaracterized the drug, and Mylan's shareholders may be induced to vote in favor of the Proposal based on this false and misleading statements of material fact included in the Proposal. Accordingly, under Rules 14a-8(i)(3) and 14a-9, Mylan should be allowed to exclude the Proposal from its 2014 Proxy Materials.

# ii. The Proposal contains false and misleading statements regarding Mylan's role with respect to "lethal injection drugs".

The Proposal contains false and misleading statements regarding Mylan's role with respect to "lethal injection drugs". Specifically, the Proponent's description of Mylan as a likely source for lethal injection drugs is a materially misleading characterization. The Proponent's statement clearly is misleading because, as discussed above, rocuronium bromide itself is not a lethal injection drug, Mylan has never promoted or distributed it as such, and the alleged connection between Mylan's production and sale of rocuronium bromide for valid and approved medical purposes, on

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<sup>&</sup>lt;sup>1</sup> See http://www.al.com/news/index.ssf/2014/09/alabama\_changes\_execution\_drug.html (with respect to Alabama) and http://www.dailyprogress.com/newsvirginian/news/special\_reports/virginia-keeping-drug-used-in-botched-executions/article 2a1f82a8-146e-11e4-a2d1-001a4bcf6878.html (with respect to Virginia).

<sup>&</sup>lt;sup>2</sup> See http://www.deathpenaltyinfo.org/state-lethal-injection ("Eight states have used a single-drug method for executions—a lethal dose of an anesthetic (Arizona, Georgia, Idaho, Missouri, Ohio, South Dakota, Texas, and Washington). Six other states have announced plans to use a one-drug protocol, but have not carried out such an execution (Arkansas, California, Kentucky, Louisiana, North Carolina, and Tennessee).").

<sup>&</sup>lt;sup>3</sup> As discussed, the drug has only been approved for use in Alabama as of 2014 (but Alabama last performed a lethal injection in 2013) and Virginia as of 2012 (but Virginia last performed a lethal injection in 2011).

the one hand, and whatever other use a sovereign state may or may not make of the drug, on the other hand, is attenuated and speculative at best. Simply put, Mylan markets rocuronium bromide only in accordance with its FDA-approved indications<sup>4</sup> and is committed to distributing its products only through legally compliant channels for prescription by healthcare providers consistent with the approved labeling or standard of care. There is no approved labeling or standard of care in the United States that would include use in lethal injection. The Proponent, however, would have shareholders believe that Mylan is in the business of creating and supplying drugs for lethal injections. That is not only objectively false, but its very suggestion is materially misleading and offensive to a fair and accurate portrayal of Mylan.

Furthermore, the Proponent acknowledges that other companies may produce rocuronium bromide in saying that "states have been forced to look to domestic corporations, including Mylan, for alternative drugs," but still claims—without any further proof—that Mylan is "one of the likely sources for lethal injection drugs." Despite the fact that at least seven other companies produce rocuronium bromide and at least five other companies have the drug available for sale, <sup>5</sup> the Proponent offers no explanation as to why Mylan would be the "likely" source of lethal injection drugs. The Proponent does not offer any proof, and indeed there is none available, that any state has purchased rocuronium bromide (or any other drug) from Mylan for use in a possible lethal injection formula. As a result, by stating that Mylan is "one of the likely sources for lethal injection drugs," the Proponent may induce shareholders to vote in favor of the Proposal based on false and misleading statements of material fact included in the Proposal. Accordingly, under Rules 14a-8(i)(3) and 14a-9, Mylan should be allowed to exclude the Proposal from its 2014 Proxy Materials.

# iii. The Proposal contains false and misleading statements regarding financial impacts on Mylan resulting from its production of rocuronium bromide.

The Proposal contains false and misleading statements regarding financial impacts on Mylan resulting from its production of rocuronium bromide. First, the Proponent states that "[t]here is also the possibility of increased financial and legal risk to the Company resulting from the *actual* use of its products in executions" (emphasis added). Not only does the Proponent not identify any such risks beyond mere speculation and generalities but, as discussed above, rocuronium bromide—much less rocuronium bromide produced by the Company—has never been used in an execution. The Proponent also does not identify any drug that the Company produces that has been used in an execution. Further, the supporting statement says that since the European Union enacted regulations "in 2011 restricting the export of anesthetics used in lethal injection executions...states have been forced to look to domestic corporations, including Mylan,

<sup>&</sup>lt;sup>4</sup> As detailed in the prescribing information, "Rocuronium bromide injection is indicated for inpatients and outpatients as an adjunct to general anesthesia to facilitate both rapid sequence and routine tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation." See <u>http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f58803b0-f173-4997-b2f8-0f415b94dacf</u>.

<sup>&</sup>lt;sup>5</sup> See http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=434 (listing five other companies that have rocuronium bromide available, and including information about two more with shortages they are working to resolve).

for alternative drugs." Not only does the Proposal mislead shareholders by ignoring the fact that states could look to other markets besides Europe and the United States for these drugs and thus is misleading in suggesting that states must depend on domestic corporations like Mylan, but it again provides no proof that any states have in fact looked to Mylan-produced rocuronium bromide for these purposes.

Finally, the Proposal provides a hyperlink to an article from NBC News that includes the text of the article's headline, "Drug Maker Mylan Takes \$70 Million Hit in Battle Over Lethal Injection". The text in the hyperlink, much like the article's headline, falsely suggests that Mylan has endured a \$70 million loss because it has not taken preventative measures with respect to having its products utilized for lethal injections. The article, however, only states that a foreign investor sold its shares in Mylan. It does not in any way suggest that Mylan's sales, revenues or any other financial metric related to the Company have been impacted. As a result of these statements, shareholders may be induced to vote in favor of the Proposal based on false and misleading statements of material fact included in the Proposal. Accordingly, under Rules 14a-8(i)(3) and 14a-9, Mylan should be allowed to exclude the Proposal from its 2014 Proxy Materials.

#### 3. Conclusion

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Based on the foregoing, we hereby respectfully request that the Staff concur in our view that the Proposal may be properly excluded from Mylan's Proxy Materials. If the Staff has any questions with respect to the foregoing, or if for any reason the Staff does not agree that Mylan may omit the Proposal from its Proxy Materials, please contact me at (212) 474-1434. I would appreciate your sending your response via e-mail to me at KDrexler@cravath.com as well as to Mylan, attention of Brad Wideman, Vice President, Associate General Counsel and Assistant Secretary at bradley.wideman@mylan.com.

Very truly yours,

<u>/s/ Kimberley S. Drexler</u> Kimberley S. Drexler

Office of Chief Counsel Division of Corporation Finance Securities and Exchange Commission 100 F Street, NE Washington, DC 20549

VIA EMAIL: shareholderproposals@sec.gov

Encls.

Copies w/encl. to:

( ( ) )

Patrick Doherty Director of Corporate Governance State of New York Office of the State Comptroller Division of Corporate Governance 59 Maiden Lane—30th Floor New York, NY 10038

Bradley Wideman

Vice President, Associate General Counsel and Assistant Secretary Mylan Inc. 1000 Mylan Boulevard Canonsburg, PA 15317

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#### EXHIBIT A

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DIVISION OF CORPORATE GOVERNANCE 59 Maiden Lane-30th Floor New York, NY 10038 Tel: (212) 383-1428 Fax: (212) 383-1331

#### THOMAS P. DINAPOLI STATE COMPTROLLER

#### STATE OF NEW YORK OFFICE OF THE STATE COMPTROLLER

November 7, 2014

Joseph F. Haggerty Executive Vice President, Chief Legal Officer and Corporate Secretary Mylan Inc. 1000 Mylan Boulevard Canonsburg, Pennsylvania 15317

Dear Mr. Haggerty:

The Comptroller of the State of New York, Thomas P. DiNapoli, is the trustee of the New York State Common Retirement Fund (the "Fund") and the administrative head of the New York State and Local Retirement System. The Comptroller has authorized me to inform of his intention to offer the enclosed shareholder proposal for consideration of stockholders at the next annual meeting.

I submit the enclosed proposal to you in accordance with rule 14a-8 of the Securities Exchange Act of 1934 and ask that it be included in your proxy statement.

A letter from J.P. Morgan Chase, the Fund's custodial bank verifying the Fund's ownership of Mylan Inc. shares, continually for over one year, is enclosed. The Fund intends to continue to hold at least \$2,000 worth of these securities through the date of the annual meeting.

We would be happy to discuss this initiative with you. Should the Mylan Inc. board decide to endorse its provisions as company policy, the Comptroller will ask that the proposal be withdrawn from consideration at the annual meeting. Please feel free to contact me at (212) 383-1428 and or email at <u>pdoherty@osc.state.ny.us</u> should you have any further questions on this matter.

Very truly your

Patriek Doherty Director of Corporate Governance

#### POLICY ON DEATH PENALTY DRUGS

. . . .

Whereas, public controversy and human rights concerns regarding the use of the death penalty have escalated in recent years, in particular after a 2014 execution in Oklahoma received considerable public attention due to its prolonged duration and the convict's apparently unexpected physical reaction after lethal injection drugs were administered;

Mylan's subsidiary Mylan Institutional manufactures rocuronium bromide, a drug that has been adopted by at least two states as being a substitute in lethal injections for the nationally scarce pancuronium bromide;

Public reports state that many of Mylan's peers in the pharmaceutical industry, including Hospira, APP Pharmaceutical, and Par Pharmaceutical, have taken steps to prevent their products from being utilized for lethal injections, but according to media reports, including NBC News [http://www.nbcnews.com/storyline/lethal-injection/drug-maker-mylan-takes-70-million-hit-battle-over-lethal-n230051] Mylan has not taken similar preventive actions;

International human rights groups have publicly called on pharmaceutical companies to take steps to prevent rocuronium bromide from being used in executions, and the Company has become a focus of public and media attention as one of the likely sources for lethal injection drugs;

Intense public outcry opposing the death penalty led the European Union to enact regulations in 2011 restricting the export of anesthetics used in lethal injection executions. As a result, states have been forced to look to domestic corporations, including Mylan, for alternative drugs. As Mylan has become identified in the death penalty controversy, it has been exposed to reputational risk, and has jeopardized its role and reputation as a provider of health oriented products. There is also the possibility of increased financial and legal risk to the Company resulting from the actual use of its products in executions;

Therefore be it Resolved that: Shareholders request that the Company issue a report at reasonable expense and excluding confidential information, describing the Company's policy position regarding whether the Company or its subsidiaries will provide products for purposes of aiding executions, and including an analysis of potential reputational risks associated with such policy position.

J.P.Morgan

Daniel F. Murphy

Vice President CIB Client Service Americas

November 7, 2014

Mr. Joseph F. Haggerty Executive Vice President, Chief Legal Officer and Corporate Secretary Mylan Inc. 1000 Mylan Boulevard Canonsburg, PA 15317

Dear Mr. Haggerty:

This letter is in response to a request by The Honorable Thomas P. DiNapoli, New York State Comptroller, regarding confirmation from JP Morgan Chase that the New York State Common Retirement Fund has been a beneficial owner of Mylan Inc. continuously for at least one year as of and including November 7, 2014.

Please note that J.P. Morgan Chase, as custodian for the New York State Common Retirement Fund, held a total of 1,372,755 shares of common stock as of November 7, 2014 and continues to hold shares in the company. The value of the ownership stake continuously held by the New York State Common Retirement Fund had a market value of at least \$2,000.00 for at least twelve months prior to, and including, said date.

If there are any questions, please contact me or Miriam Awad at (212) 623-8481.

Regards,

Daniel F. Murphy

cc:

Patrick Doherty – NSYCRF Eric Shostal - NYSCRF

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