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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

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November 15, 2016

**VIA ELECTRONIC TRANSMISSION**

The Honorable Mary Jo White  
Chair  
Securities and Exchange Commission  
Washington, DC 20549

Dear Chair White:

On October 7, 2016, Mylan N.V. issued a press release announcing that it “agreed to the terms of a \$465 million settlement with the U.S Department of Justice and other government agencies [...]” Mylan proceeded to discuss the terms of the settlement, noting that “[t]he terms of the settlement do not provide for any wrongdoing on the part of Mylan Inc. [...]” and “[t]he settlement terms provide for resolution of all potential rebate liability claims by federal and state governments as to whether the product should have been classified as an innovator drug for CMS purposes and subject to a higher rebate formula.” Despite these strong words from Mylan, the Justice Department originally refused to comment saying “[t]he Justice Department does not confirm or deny the existence of an investigation.”<sup>1</sup> Later, the Justice Department said that “[t]here is no executed settlement agreement.”<sup>2</sup> Mylan’s press release buried this fact on the last sentence of the third paragraph when it said it “will continue to work with the government to finalize the settlement” after noting alleged agreed-upon terms of the settlement.<sup>3</sup>

On balance, Mylan’s press release appears to go well beyond the Justice Department’s position, calling into question the accuracy of the press release. First, it asserts that a settlement has been agreed to and even goes so far as to mention some of the terms of the settlement agreement which the Justice Department appears unwilling to confirm. Second, Mylan’s press release says that it provides for the resolution of “all potential rebate liability claims by federal and state governments.” However, it is doubtful that the Justice Department can bind non-

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<sup>1</sup> Ben Popken, “Mylan Agrees to Settle with DOJ for \$465 Million Over EpiPens,” NBC News (October 7, 2016). Available at <http://www.nbcnews.com/business/consumer/mylan-settles-doj-465-million-over-epipens-n662196>

<sup>2</sup> John Wilkerson, “DOJ: There is no executed settlement with Mylan on EpiPen rebates,” Inside Washington Publishers (October 14, 2016).

<sup>3</sup> Press Release, Mylan Agrees to Settlement on Medicaid Rebate Classification on EpiPen Auto-Injector, (October 7, 2016) available at <http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector>.

signatory state governments to a settlement. A state may choose to proceed with legal action against Mylan irrespective of the Justice Department's potential settlement with Mylan.<sup>4</sup>

Mylan's assertion that the settlement terms provide for "resolution of all potential rebate liability claims" whether by federal or state governments was also repeated in its 8-K report which was filed the same day as the press release.<sup>5</sup> The 8-K report also mentions a Securities and Exchange Commission investigation "seeking communications with the CMS and documents concerning Mylan products sold and related to the Medicaid Drug Rebate Program, and any related complaints."<sup>6</sup> This seems to contradict Mylan's claim that all potential liability claims have been resolved. Mylan made no mention of the fact that they are under an SEC investigation in their press release.

Given the dissonance between the press release, the 8-K filing, and the fact that no settlement agreement has been executed, Mylan should explain why it released such a strongly worded press release knowing that a finalized settlement did not yet exist and given the apparent SEC investigation. Further, it has now been over five weeks since Mylan's press release and apparently a settlement has still not been executed.

Under the Securities and Exchange Act of 1934, the SEC may bring an action against companies and individuals who use any "manipulative or deceptive device[s]" in connection with the purchase or sale of any security.<sup>7</sup> The purpose of this statute was to "achieve a high standard of business ethics in the securities industry,"<sup>8</sup> by preventing publicly traded companies from issuing false, manipulative or misleading statements in order to inflate their stock price, and mislead investors. Courts have also held that a company and its officers and directors can be held liable for misleading press releases under the Act. In the case of *Ames Dep't. Stores, Inc.*, the 2<sup>nd</sup> Circuit Court of Appeals elaborated further on the need to prevent false, manipulative, or misleading press releases by stating that "the securities market [is] highly sensitive to press releases," and holding that defendants may be held liable for "misstatements and omissions in press releases, news articles, and quarterly and annual public filings."<sup>9</sup> The 9<sup>th</sup> Circuit also determined in *SEC v. Platforms Wireless Int'l Corp* that a materially misleading press release opens the issuing party to liability.<sup>10</sup> And in *Basic Inc. v. Levinson* the Supreme Court noted the same.<sup>11</sup>

After Mylan's press release its stock prices increased 13%.<sup>12</sup> Given the 8-K filing and the SEC's request for documents relating to the Medicaid Drug Rebate Program, Mylan's assertion in its press release that the settlement "provide[s] for resolution of all potential rebate

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<sup>4</sup> John Wilkerson, "Mintz Levin: Mylan Settlement wouldn't guarantee resolution of all rebate suits," Inside Washington Publishers (October 20, 2016).

<sup>5</sup> Mylan N.V., Current Report (form 8-k) (Oct. 7, 2016).

<sup>6</sup> *Id.*

<sup>7</sup> Securities and Exchange Act of 1934, 15 U.S.C. § 78j (b); 17 C.F.R § 240.10b-5.

<sup>8</sup> *SEC v. Capital Gains Research Bureau*, 375 U.S. 180, 186 (1963).

<sup>9</sup> *In re Ames Dep't Stores*, 991 F.2d 953, 962-63 (2d Cir. 1996).

<sup>10</sup> *SEC v. Platforms Wireless Int'l Corp.*, 617 F.3d 1072, 1094-96 (9th Cir. 2010)

<sup>11</sup> *See Basic Inc. v. Levinson*, 485 U.S. 224 (1988).

<sup>12</sup> Zachary Tracer, *Mylan's Stock Jumps After \$465 Million EpiPen Settlement*, Bloomberg News (October 10, 2016), <http://www.bloomberg.com/news/articles/2016-10-10/mylan-jumps-in-early-trading-on-465-million-epipen-settlement>.

liability claims by federal and state governments [...]” is suspect. If Mylan’s purpose of the press release was to increase stock prices at the risk of misleading investors, it is exactly this set of facts and circumstances that the SEC should monitor. Companies cannot be allowed to manipulate the markets and investors via press releases. Accordingly, since the SEC is already investigating Mylan, I request that you inform the Committee as to whether the SEC is looking into Mylan’s press release to determine if it was materially misleading.

Please respond no later than November 29, 2016. If you have questions, please contact Josh Flynn-Brown of my Judiciary Committee staff at (202) 224-5225.

Sincerely,



Charles E. Grassley  
Chairman  
Committee on the Judiciary