

# United States Senate

COMMITTEE ON  
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

May 18, 2017

Mark Trudeau  
President and CEO  
Mallinckrodt Pharmaceuticals  
675 McDonnell Blvd.  
St. Louis, MO 63042

Dear Mr. Trudeau:

I am writing to request information relating to the price increase Mallinckrodt Pharmaceuticals instituted in 2014 for the drug Ofirmev, an injectable form of acetaminophen physicians use to treat pain in hospital settings. In early 2014, Mallinckrodt paid around \$1.4 billion for Cadence Pharmaceuticals, with the included acquisition of Ofirmev, which generated \$110.5 million in 2013 revenue, serving as “the crown jewel of the deal.”<sup>1</sup> At the time of the acquisition, Ofirmev had treated an estimated 6 million to 7 million patients for pain since its introduction in January 2011,<sup>2</sup> and according to Mallinckrodt, it is “the first and only IV formulation of acetaminophen to be approved and currently marketed in the United States.”<sup>3</sup>

Three months after the acquisition, according to the *Wall Street Journal*, Mallinckrodt more than doubled the list price for a 24-pack of Ofirmev vials to \$1,019.52,<sup>4</sup> and hospitals throughout the United States immediately felt the impact. The BJC HealthCare hospital system in Missouri, for example, estimated an additional \$2.16 million cost related to the price increase and removed Ofirmev from its adult formulary.<sup>5</sup> Similarly, according to *Bloomberg*, “large hospital systems like Johns Hopkins Medicine and New York University Langone Medical Center say their expenses surged \$1 million a year or more.”<sup>6</sup> Ofirmev-related expenses for

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<sup>1</sup> *Pharmaceutical Companies Buy Rivals' Drugs, Then Jack Up the Prices*, Wall Street Journal (Apr. 26, 2015).

<sup>2</sup> *Mallinckrodt Acquires San Diego Pharma Firm Cadence for \$1.3 Billion*, Los Angeles Times (Feb. 11, 2014).

<sup>3</sup> Mallinckrodt Pharmaceuticals, *Clinical Pharmacokinetic and Health Economic Data on OFIRMEV® (Acetaminophen) Injection Presented at 15th Annual Pain Medicine Meeting of ASRA* (Nov. 18, 2016).

<sup>4</sup> *Pharmaceutical Companies Buy Rivals' Drugs, Then Jack Up the Prices*, Wall Street Journal (Apr. 26, 2015).

<sup>5</sup> E-mail from BJC HealthCare to Minority Staff, Senate Homeland Security and Governmental Affairs Committee (May 4, 2017).

<sup>6</sup> *This Drugmaker Suffered the Consequences of Price Increases*, Bloomberg (Oct. 11, 2015) (online at <https://www.bloomberg.com/news/articles/2015-10-12/how-one-drugmaker-learned-the-consequences-of-price-increases>).

three hospitals in the Salt Lake City health system also jumped from \$20,000 or \$25,000 a month to \$55,000 a month.<sup>7</sup> And according to an analysis of market information from QuintilesIMS, the number of Ofirmev units sold dipped appreciably from the second quarter to the third quarter of 2014 and continues to linger below Q2 2014 levels.<sup>8</sup> In fact, in a Q2 2015 earnings call, you stated that Mallinckrodt had seen “about a 26% decline in volume from peak before we took the price increase.”<sup>9</sup>

These impacts are potentially troubling given that Mallinckrodt touts Ofirmev as an alternative to opioid painkillers—a substitution the company claims is supported in numerous medical publications.<sup>10</sup> Any obstacle to prescribing non-opioid alternatives, even those used solely in a hospital setting, is cause for concern. As one recent study noted, “opioids are one of the medications most frequently associated with in-hospital adverse drug events and incidents involving opioid ODs can lead to significant patient injury.”<sup>11</sup> And following the Ofirmev price increase, hospitals did, apparently, “fight back by seeking other options, cutting into Mallinckrodt’s projected sales growth.”<sup>12</sup> According to *Bloomberg*, this episode “underscores the risk for drugmakers that increase prices on medicine that doctors and health-care providers are already accustomed to using. As expenses mount, customers will look for alternatives, no matter how popular or useful the product.”<sup>13</sup>

At the same time, however, materials Mallinckrodt has provided to Committee staff indicate that Ofirmev use, combined with decreased opioid treatment, ultimately *lowers* hospital expenses by reducing opioid-related complications and hospital stays.<sup>14</sup> Mallinckrodt representatives have also stated that Ofirmev sales have recovered since 2014 and actually exceed Q2 2014 levels.<sup>15</sup> Moreover, it is also unclear whether hospitals have responded to

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<sup>7</sup> *Pharmaceutical Companies Buy Rivals’ Drugs, Then Jack Up the Prices*, Wall Street Journal (Apr. 26, 2015).

<sup>8</sup> QuintilesIMS, *Combined Audit from April 2011 to March 2017, Ofirmev 01/2011 C9D Units* (generated May 8, 2017).

<sup>9</sup> Mallinckrodt Plc, *Q2 2015 Earnings Call* (May 5, 2015).

<sup>10</sup> *This Drugmaker Suffered the Consequences of Price Increases*, Bloomberg (Oct. 11, 2015).

<sup>11</sup> Christy E. Cauley, MD, MPH, et al., *Predictors of In-hospital Postoperative Opioid Overdose After Major Elective Operations*, *Annals of Surgery* (April 2017).

<sup>12</sup> *This Drugmaker Suffered the Consequences of Price Increases*, Bloomberg (Oct. 11, 2015).

<sup>13</sup> *Id.*

<sup>14</sup> Briefing by Mark Tyndall, Vice President, Government Affairs, Policy & Advocacy, Mallinckrodt Pharmaceuticals, to Senate Homeland Security and Governmental Affairs Committee Staff (May 12, 2017).

<sup>15</sup> *Id.*

Ofirmev price changes by increasing their reliance on opioid treatments. The BJC HealthCare hospital system, for example, has replaced Ofirmev with other acetaminophen products instead of turning to opioid alternatives.<sup>16</sup>

As you may know, I recently launched an investigation into the manufacturers of the top five opioid products by 2015 worldwide sales, seeking information on sales, marketing, and educational strategies these companies have employed to promote opioid use.<sup>17</sup> While that inquiry focuses on the strategic decisions forming the root cause of the opioid epidemic, I also recognize the critical need to explore the economic considerations that may favor opioids as a treatment for pain. To clarify the impact of Ofirmev price increases on hospital decisionmaking, please provide responses to the document and information requests below:

- 1) Any medical journal articles or other research in the possession of Mallinckrodt concerning Ofirmev as an effective alternative to opioids for the treatment of pain;
- 2) The number of hospitals that have participated in any Mallinckrodt demonstration programs for Ofirmev and the number of hospitals that have continued and discontinued Ofirmev use after participating in these programs;
- 3) Documents sufficient to show quarterly Ofirmev unit sales to Missouri hospitals, and resulting revenue, from the date of the Mallinckrodt acquisition of Cadence Pharmaceuticals to the present; and
- 4) Documents sufficient to show quarterly Ofirmev unit sales to Missouri hospitals, and resulting revenue, from January 2011 to the date of the Mallinckrodt acquisition of Cadence Pharmaceuticals, to the extent such records are in the possession of Mallinckrodt.

Please provide your responses as soon as possible, but in no event later than June 8, 2017. If you have any questions related to this request, please contact Brandon Reavis of the Committee staff at [Brandon\\_Reavis@hsgac.senate.gov](mailto:Brandon_Reavis@hsgac.senate.gov) or (202) 224-2627. Please send any official correspondence relating to this request to [Amanda\\_Trosen@hsgac.senate.gov](mailto:Amanda_Trosen@hsgac.senate.gov).

Sincerely,



Claire McCaskill  
Ranking Member

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<sup>16</sup> Briefing by BJC HealthCare to Senate Homeland Security and Governmental Affairs Committee Minority Staff (May 9, 2017).

<sup>17</sup> See, e.g., Letter from Sen. Claire McCaskill to Heather Bresch, Chief Executive Officer, Mylan (March 28, 2017).

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cc: Ron Johnson  
Chairman