

**Pfizer Inc.**  
235 East 42<sup>nd</sup> Street  
New York, NY 10017



November 19, 2018

Office of the Vermont Attorney General

Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(c)

Dear Office of the Vermont Attorney General,

Pfizer Inc. (“Pfizer”) is issuing this notice pursuant to 18 V.S.A. § 4637(c), which requires prescription drug manufacturers to provide the Office of the Attorney General (the “Office”) with certain information following the release of a drug in the commercial market whose Wholesale Acquisition Cost (“WAC”) exceeds the threshold set for a specialty drug under the Medicare Part D Program.

Pfizer released Talzenna<sup>®</sup> (talazoparib) into the commercial market on October 17, 2018. Pfizer anticipates Talzenna’s<sup>®</sup> WAC to exceed the threshold set for a specialty drug under the Medicare Part D Program.

<b>Statutory Requirement</b>	<b>Reporting Information</b>
A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.	Pfizer does not believe this information is publicly available and has not released this information in the public domain. Accordingly, Pfizer is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).
The estimated volume of patients that may be prescribed the drug.	Pfizer does not believe this information is publicly available and has not released this information in the public domain. Accordingly, Pfizer is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).
Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration (FDA) prior to final approval?	Talzenna <sup>®</sup> did not receive breakthrough designation by the federal FDA. <sup>i</sup>
Did the drug receive a priority review by the federal FDA prior to final approval?	Talzenna <sup>®</sup> received priority review by the federal FDA. <sup>ii</sup>

Statutory Requirement	Reporting Information
The date and price of acquisition if the drug was not developed by the manufacturer.	<p>Medivation acquired the worldwide rights to Talzenna® (talazoparib) from BioMarin on October 6, 2015.<sup>iii</sup> Pfizer acquired Medivation on September 28, 2016.<sup>iv</sup></p> <p>Pfizer does not believe the acquisition price of Talzenna® (talazoparib) is publicly available and has not released this information in the public domain. Accordingly, Pfizer is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).</p>

In the event Vermont S. 92 and the laws it implements, including 18 V.S.A. § 4637, are found invalid, Pfizer reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Pfizer does not waive any legal claims or legal rights related to potential constitutional defects with Vermont S. 92.

Sincerely,



Matt Shaulis  
Regional President, North America  
Pfizer Oncology

For any questions concerning this notification please contact: [StateLawReporting@Pfizer.com](mailto:StateLawReporting@Pfizer.com)

<sup>i</sup> U.S. Food and Drug Administration, Breakthrough Therapy Approvals. Available at: <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicalapprovalreports/ndaandblaapprovalreports/ucm373418.htm>. Last accessed September 21, 2018.

<sup>ii</sup> FDA approves talazoparib for gBRCAm HER2-negative locally advanced or metastatic breast cancer. Available at: <https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm623540.htm>. Last accessed October 22, 2018.

<sup>iii</sup> Medivation, Inc., Current Report on Form 8-K filed with the United States Securities and Exchange Commission on October 7, 2015. Available at: <https://www.sec.gov/Archives/edgar/data/1011835/000119312515338849/d99291d8k.htm>. Last accessed October 25, 2018.

<sup>iv</sup> Pfizer Inc., Annual Report on Form 10-K filed with the United States Securities and Exchange Commission on February 23, 2017. Available at: <https://www.sec.gov/Archives/edgar/data/78003/000007800317000014/0000078003-17-000014-index.htm>. Last accessed October 25, 2018.