Pfizer Inc.
235 East 42nd Street
New York, NY 10017

September 27, 2019

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 Vyndamax™ (tafamidis) into the commercial market on August 27, 2019. Pfizer anticipates Vyndamax's ™ WAC to exceed the threshold set for a specialty drug under the Medicare Part D Program.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market." Further, Pfizer is not aware of any guidance issued by the Office or any Vermont regulation that defines "release of the drug in the commercial market" for the purpose of 18 V.S.A. § 4637.

As a result, Pfizer considers a drug to be "release[d] . . . in the commercial market" when Pfizer publishes a trade letter to wholesale customers announcing the introduction of the new drug and begins accepting orders for the drug.

Statutory Requirement	**Reporting Information**
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.	ATTR-CM is significantly under or misdiagnosed, and as a result, it is difficult to characterize prevalence. Based on our internal estimates and existing literature, we believe U.S. prevalence is approximately 100,000 with a diagnosis range of approximately 3%.
Was the drug granted breakthrough therapy designation by the federal Food and Drug Administration prior to final approval?	Vyndamax™ did not receive breakthrough designation by the federal FDA.

Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?	Vyndamax™ did not receive priority review by the federal FDA.
The date and price of acquisition if the drug was not developed by the manufacturer.	On October 6, 2010, we completed our acquisition of FoldRx Pharmaceuticals, Inc. (FoldRx), a privately held drug discovery and clinical development company, whose portfolio included clinical and preclinical programs for investigational compounds to treat diseases caused by protein misfolding. The total consideration for the acquisition was approximately $400 million, which consisted of an upfront payment to FoldRx's shareholders of about $200 million and contingent consideration with an estimated acquisition-date fair value of about $200 million. The contingent consideration consists of up to $455 million in additional payments that are contingent upon the attainment of future regulatory and commercial milestones.[i]

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.

For any questions concerning this notification please contact: StateLawReporting@Pfizer.com

[i] Pfizer Inc., Annual Report on Form10-K filed with the United States Securities and Exchange Commission on February 26, 2010. Available at: https://www.sec.gov/Archives/edgar/data/78003/000119312511048877/dex13.htm Last accessed September 23, 2019.