

H. F. No. 3538

2.1 (b) The report shall include all of the following for each qualifying drug:

2.2 (1) the total costs for the production of the drug, including all of the following:

2.3 (i) the total research and development costs paid by the manufacturer, and separately  
2.4 the total research and development costs paid by any predecessor in the development of the  
2.5 drug;

2.6 (ii) the total costs of clinical trials and other regulatory costs paid by the manufacturer,  
2.7 and separately the total costs of clinical trials and other regulatory costs paid by any  
2.8 predecessor in the development of the drug;

2.9 (iii) the total costs for materials, manufacturing, and administration attributable to the  
2.10 drug;

2.11 (iv) the total costs paid by any entity other than the manufacturer or predecessor for  
2.12 research and development, including any amount from federal, state, or other governmental  
2.13 programs or any form of subsidies, grants, or other support;

2.14 (v) any other costs to acquire the drug, including all or any costs for the purchase of  
2.15 patents, licensing, or acquisition of any corporate entity owning any rights to the drug while  
2.16 in development; and

2.17 (vi) the total marketing and advertising costs for the promotion of the drug directly to  
2.18 consumers, including but not limited to costs associated with direct-to-consumer coupons  
2.19 and the amount redeemed, total marketing and advertising costs for promotion of the drug  
2.20 directly or indirectly to prescribers, and any other advertising for the drug;

2.21 (2) a cumulative annual history of average wholesale price (AWP) and WAC increases  
2.22 for the drug, expressed as percentages, including the month each increase in each category,  
2.23 AWP and WAC, took effect;

2.24 (3) the total profit attributable to the drug as represented in total dollars and as a  
2.25 percentage of the total company profits that were derived from the sale of the drug; and

2.26 (4) the total amount of financial assistance the manufacturer has provided through patient  
2.27 prescription assistance programs, if available.

2.28 (c) All of the information in paragraph (b) shall be itemized and documented by the  
2.29 manufacturer and audited by a fully independent third-party auditor prior to filing.

2.30 (d) No later than May 1, 2019, and each May 1 thereafter, manufacturers shall file the  
2.31 information required by this subdivision annually with the commissioner on a form prescribed  
2.32 by the commissioner.

3.1        Subd. 4. **Report to legislature.** No later than August 1, 2019, and each August 1  
3.2        thereafter, the commissioner shall issue a report annually to the legislature summarizing  
3.3        the information submitted under this section. The commissioner shall also make the report  
3.4        available to the public on the agency Web site.

3.5        Subd. 5. **Advisory committee.** The commissioner shall convene an advisory committee  
3.6        to develop the form required by this section. The committee shall include, but is not limited  
3.7        to, representatives of the pharmaceutical industry, health carriers, pharmacy benefit managers,  
3.8        state agencies, consumer advocates, pharmacists, and physicians.

3.9        **EFFECTIVE DATE.** This section is effective the day following final enactment.