

HOUSE BILL No. 5691

March 6, 2018, Introduced by Reps. Garrett, Hoadley, Elder, Chang, Faris, Geiss, Cochran, Peterson, Neeley, Pagan, Brinks, Gay-Dagnogo, Byrd, Ellison, Hertel, Sabo, Scott, Robinson, Yancey, Cambensy, Camilleri, Chirkun, Lasinski, Durhal, Moss, Clemente, LaGrand, Liberati, Dianda, Hammoud, Rabhi, Howrylak, Singh, Guerra, Phelps, Jones and Kosowski and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled
"Public health code,"
(MCL 333.1101 to 333.25211) by adding sections 17748e, 17748f, and
17748g.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 SEC. 17748E. (1) SUBJECT TO SUBSECTION (2), BEGINNING OCTOBER
2 1, 2018, A MANUFACTURER OF A PRESCRIPTION DRUG THAT HAS A WHOLESALE
3 ACQUISITION COST THAT IS MORE THAN \$40.00 FOR A COURSE OF TREATMENT
4 AND THAT IS MADE AVAILABLE IN THIS STATE SHALL NOTIFY A QUALIFIED
5 PURCHASER THAT IS REGISTERED UNDER SUBSECTION (5) IF THE
6 MANUFACTURER IS INCREASING THE WHOLESALE ACQUISITION COST OF THE
7 PRESCRIPTION DRUG BY 12% OR MORE DURING ANY 24-MONTH PERIOD.

1 (2) THE MANUFACTURER SHALL PROVIDE THE NOTICE REQUIRED UNDER
2 SUBSECTION (1) AT LEAST 60 DAYS BEFORE THE PLANNED EFFECTIVE DATE
3 OF THE INCREASE IN THE WHOLESALE ACQUISITION COST. THE NOTICE MUST
4 INCLUDE ALL OF THE FOLLOWING:

5 (A) THE EFFECTIVE DATE OF THE INCREASE IN THE WHOLESALE
6 ACQUISITION COST.

7 (B) THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG AS
8 OF THE DATE OF THE NOTICE AND THE DOLLAR AMOUNT OF THE INCREASE IN
9 THE WHOLESALE ACQUISITION COST AS OF THE EFFECTIVE DATE OF THE
10 INCREASE.

11 (C) WHETHER A CHANGE OR IMPROVEMENT TO THE PRESCRIPTION DRUG
12 NECESSITATES THE INCREASE IN THE WHOLESALE ACQUISITION COST AND A
13 DESCRIPTION OF ANY CHANGE OR IMPROVEMENT.

14 (3) BEGINNING OCTOBER 1, 2018 AND EACH QUARTER THEREAFTER, A
15 MANUFACTURER THAT INCREASES THE WHOLESALE ACQUISITION COST OF A
16 PRESCRIPTION DRUG DESCRIBED IN SUBSECTION (1) SHALL REPORT ALL OF
17 THE FOLLOWING INFORMATION TO THE COMMISSION IN A FORM AND MANNER
18 REQUIRED BY THE COMMISSION:

19 (A) THE AMOUNT OF THE INCREASE IN THE WHOLESALE ACQUISITION
20 COST OF THE PRESCRIPTION DRUG.

21 (B) A DESCRIPTION OF THE SPECIFIC FINANCIAL AND NONFINANCIAL
22 FACTORS CONSIDERED BY THE MANUFACTURER IN INCREASING THE WHOLESALE
23 ACQUISITION COST OF THE PRESCRIPTION DRUG AND AN EXPLANATION OF HOW
24 THE FACTORS JUSTIFIED THE INCREASE IN THE WHOLESALE ACQUISITION
25 COST OF THE PRESCRIPTION DRUG.

26 (C) IF THE PRESCRIPTION DRUG WAS MANUFACTURED BY THE
27 MANUFACTURER WITHIN THE 5 YEARS PRECEDING THE DATE OF THE INCREASE

1 IN THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG, A
2 SCHEDULE OF THE INCREASES IN THE WHOLESALE ACQUISITION COST OF THE
3 PRESCRIPTION DRUG FOR THE PREVIOUS 5 YEARS.

4 (D) IF THE PRESCRIPTION DRUG WAS ACQUIRED BY THE MANUFACTURER
5 WITHIN THE 5 YEARS PRECEDING THE DATE OF THE INCREASE IN THE
6 WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG, ALL OF THE
7 FOLLOWING INFORMATION:

8 (i) THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG AT
9 THE TIME IT WAS ACQUIRED BY THE MANUFACTURER AND IN THE YEAR BEFORE
10 IT WAS ACQUIRED BY THE MANUFACTURER.

11 (ii) THE NAME OF THE COMPANY FROM WHICH THE PRESCRIPTION DRUG
12 WAS ACQUIRED BY THE MANUFACTURER, THE DATE IT WAS ACQUIRED, AND THE
13 PURCHASE PRICE.

14 (iii) THE YEAR THE PRESCRIPTION DRUG WAS INTRODUCED TO THE
15 MARKET AND THE WHOLESALE ACQUISITION COST OF THE DRUG AT THE TIME
16 OF INTRODUCTION.

17 (E) IF THE PRESCRIPTION DRUG IS UNDER PATENT, THE PATENT'S
18 EXPIRATION DATE.

19 (F) WHETHER THE PRESCRIPTION DRUG IS A MULTIPLE SOURCE DRUG,
20 AN INNOVATOR MULTIPLE SOURCE DRUG, A NONINNOVATOR MULTIPLE SOURCE
21 DRUG, OR A SINGLE SOURCE DRUG, AS THOSE TERMS ARE DEFINED IN 42 USC
22 1396R-8.

23 (G) WHETHER THERE HAS BEEN A CHANGE OR IMPROVEMENT TO THE
24 PRESCRIPTION DRUG. IF THERE HAS BEEN A CHANGE OR IMPROVEMENT TO THE
25 PRESCRIPTION DRUG, THE MANUFACTURER SHALL PROVIDE DOCUMENTATION OF
26 THE INCREASE WITH THE REPORT REQUIRED UNDER THIS SUBSECTION.

27 (H) THE VOLUME OF SALES OF THE PRESCRIPTION DRUG IN THE UNITED

1 STATES FOR THE YEAR PRECEDING THE DATE OF THE INCREASE OF THE
2 WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG.

3 (4) THE COMMISSION SHALL POST ON A PUBLICLY AVAILABLE WEBSITE
4 THE INFORMATION RECEIVED BY IT UNDER SUBSECTION (3) WITHIN 60 DAYS
5 AFTER RECEIVING THE INFORMATION. THE COMMISSION SHALL POST THE
6 INFORMATION IN A MANNER THAT DISCLOSES THE INFORMATION FOR EACH
7 PRESCRIPTION DRUG. HOWEVER, IF THE COMMISSION DETERMINES THAT ANY
8 INFORMATION RECEIVED BY IT UNDER SUBSECTION (3) FROM A MANUFACTURER
9 IS CONFIDENTIAL OR PROPRIETARY AND THE INFORMATION WOULD CAUSE
10 COMPETITIVE HARM TO THE MANUFACTURER IF DISCLOSED, THE COMMISSION
11 SHALL REFRAIN FROM POSTING THAT INFORMATION ON THE PUBLICLY
12 AVAILABLE WEBSITE OR OTHERWISE DISCLOSING THAT INFORMATION TO THE
13 PUBLIC.

14 (5) A QUALIFIED PURCHASER THAT WISHES TO RECEIVE NOTICE UNDER
15 SUBSECTION (1) SHALL REGISTER WITH THE COMMISSION. THE COMMISSION
16 SHALL MAKE AVAILABLE TO A MANUFACTURER A LIST OF QUALIFIED
17 PURCHASERS THAT HAVE REGISTERED WITH THE COMMISSION UNDER THIS
18 SUBSECTION FOR THE PURPOSE OF PROVIDING NOTICE UNDER SUBSECTION
19 (1).

20 (6) A MANUFACTURER THAT VIOLATES THIS SECTION IS SUBJECT TO AN
21 ADMINISTRATIVE FINE OF \$100,000.00 PER DAY FOR EVERY DAY THAT THE
22 INFORMATION IS NOT PROVIDED IN ACCORDANCE WITH THIS SECTION.

23 (7) AS USED IN THIS SECTION AND SECTIONS 17748F AND 17748G:

24 (A) "COMMISSION" MEANS THE DRUG CONSUMER PROTECTION COMMISSION
25 CREATED IN SECTION 17748G(1).

26 (B) "COURSE OF TREATMENT" MEANS THE RECOMMENDED DAILY DOSAGE
27 UNITS OF A PRESCRIPTION DRUG PURSUANT TO ITS PRESCRIBING LABEL AS

1 APPROVED BY THE FDA FOR A COURSE OF TREATMENT THAT IS 30 DAYS OR
2 LESS.

3 (C) "EXCESSIVE PRICE" MEANS A PRICE THAT IS DEFINED AS
4 UNLAWFUL UNDER SECTION 3(1)(Z) OF THE MICHIGAN CONSUMER PROTECTION
5 ACT, 1976 PA 331, MCL 445.903.

6 (D) "QUALIFIED PURCHASER" MEANS ANY OF THE FOLLOWING PERSONS
7 THAT PURCHASE THE PRESCRIPTION DRUG OR PROVIDE REIMBURSEMENT FOR
8 THE PRESCRIPTION DRUG:

9 (i) AN INSURER AS THAT TERM IS DEFINED IN SECTION 106 OF THE
10 INSURANCE CODE OF 1956, 1956 PA 218, MCL 500.106.

11 (ii) A HEALTH MAINTENANCE ORGANIZATION, AS THAT TERM IS
12 DEFINED IN SECTION 3501 OF THE INSURANCE CODE OF 1956, 1956 PA 218,
13 MCL 500.3501.

14 (iii) A PHARMACY BENEFIT MANAGER.

15 (iv) A DEPARTMENT OF THIS STATE.

16 (E) "UNCONSCIONABLE" MEANS ANY OF THE FOLLOWING:

17 (i) EXCESSIVE AND NOT JUSTIFIED BY THE COST OF PRODUCING THE
18 PRESCRIPTION DRUG OR THE COST OF THE APPROPRIATE EXPANSION OF
19 ACCESS TO THE PRESCRIPTION DRUG TO PROMOTE PUBLIC HEALTH.

20 (ii) RESULTS IN CONSUMERS FOR WHOM THE PRESCRIPTION DRUG IS
21 PRESCRIBED HAVING NO MEANINGFUL CHOICE ABOUT WHETHER TO PURCHASE
22 THE PRESCRIPTION DRUG BECAUSE OF THE IMPORTANCE OF THE PRESCRIPTION
23 DRUG TO THEIR HEALTH AND INSUFFICIENT COMPETITION IN THE MARKET FOR
24 THE PRESCRIPTION DRUG.

25 (F) "WHOLESALE ACQUISITION COST" MEANS THAT TERM AS DEFINED IN
26 42 USC 1395W-3A.

27 SEC. 17748F. (1) BEGINNING OCTOBER 1, 2018, A MANUFACTURER OF

1 A PRESCRIPTION DRUG THAT IS MADE AVAILABLE IN THIS STATE SHALL
2 NOTIFY THE COMMISSION IF THE MANUFACTURER IS INTRODUCING A NEW
3 PRESCRIPTION DRUG INTO THE MARKET AT A WHOLESALE ACQUISITION COST
4 THAT EXCEEDS THE THRESHOLD SET FOR A SPECIALTY DRUG UNDER THE
5 MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF
6 2003, PUBLIC LAW 108-173. THE MANUFACTURER SHALL PROVIDE THE NOTICE
7 IN WRITING AND WITHIN 3 DAYS AFTER THE PRESCRIPTION DRUG IS
8 COMMERCIALY AVAILABLE. HOWEVER, A MANUFACTURER MAY PROVIDE THE
9 NOTICE PENDING THE APPROVAL OF THE FDA IF COMMERCIAL AVAILABILITY
10 IS EXPECTED WITHIN 3 DAYS AFTER THE FDA'S APPROVAL.

11 (2) SUBJECT TO SUBSECTION (3), WITHIN 30 DAYS OF PROVIDING THE
12 NOTICE REQUIRED UNDER SUBSECTION (1), THE MANUFACTURER SHALL REPORT
13 ALL OF THE FOLLOWING INFORMATION TO THE COMMISSION IN A FORM AND
14 MANNER REQUIRED BY THE COMMISSION:

15 (A) IF THE PRESCRIPTION DRUG WAS NOT DEVELOPED BY THE
16 MANUFACTURER, THE DATE THE PRESCRIPTION DRUG WAS ACQUIRED AND THE
17 PURCHASE PRICE.

18 (B) A DESCRIPTION OF THE MARKETING AND PRICING PLANS THAT ARE
19 USED TO LAUNCH THE NEW PRESCRIPTION DRUG IN THE UNITED STATES AND
20 INTERNATIONALLY.

21 (C) THE ESTIMATED VOLUME OF PATIENTS THAT MAY BE PRESCRIBED
22 THE PRESCRIPTION DRUG.

23 (D) WHETHER THE PRESCRIPTION DRUG WAS GRANTED BREAKTHROUGH
24 THERAPY DESIGNATION OR PRIORITY REVIEW BY THE FDA BEFORE FINAL
25 APPROVAL.

26 (3) IF THE INFORMATION DESCRIBED IN SUBSECTION (2) IS
27 AVAILABLE IN THE PUBLIC DOMAIN, THE MANUFACTURER MAY LIMIT THE

1 INFORMATION IT INCLUDES IN ITS REPORT TO THE COMMISSION UNDER
2 SUBSECTION (2) .

3 (4) THE COMMISSION SHALL POST ON A PUBLICLY AVAILABLE WEBSITE
4 THE INFORMATION RECEIVED BY IT UNDER SUBSECTION (2) ON AT LEAST A
5 QUARTERLY BASIS. THE COMMISSION SHALL POST THE INFORMATION IN A
6 MANNER THAT DISCLOSES THE INFORMATION FOR EACH PRESCRIPTION DRUG.

7 (5) A MANUFACTURER THAT VIOLATES THIS SECTION IS SUBJECT TO AN
8 ADMINISTRATIVE FINE OF \$100,000.00 PER DAY FOR EVERY DAY THAT THE
9 INFORMATION IS NOT PROVIDED IN ACCORDANCE WITH THIS SECTION.

10 SEC. 17748G. (1) THE DRUG CONSUMER PROTECTION COMMISSION IS
11 CREATED WITHIN THE DEPARTMENT.

12 (2) THE COMMISSION CONSISTS OF THE FOLLOWING 13 MEMBERS
13 APPOINTED BY THE GOVERNOR AFTER CONSIDERING THE RECOMMENDATIONS OF
14 THE SENATE MAJORITY LEADER, THE SENATE MINORITY LEADER, THE SPEAKER
15 OF THE HOUSE OF REPRESENTATIVES, AND THE HOUSE MINORITY LEADER:

16 (A) SIX INDIVIDUALS WHO REPRESENT CONSUMER HEALTH ADVOCACY
17 GROUPS.

18 (B) ONE INDIVIDUAL WHO REPRESENTS PHARMACY BENEFIT MANAGERS.

19 (C) THREE INDIVIDUALS WHO REPRESENT HEALTH INSURERS, HEALTH
20 MAINTENANCE ORGANIZATIONS, OR OTHER PERSONS WHO PROVIDE
21 PRESCRIPTION DRUG BENEFITS.

22 (D) THE DIRECTOR OF THE DEPARTMENT OR HIS OR HER DESIGNEE.

23 (E) THE DIRECTOR OF THE DEPARTMENT OF HEALTH AND HUMAN
24 SERVICES OR HIS OR HER DESIGNEE.

25 (F) THE DIRECTOR OF THE DEPARTMENT OF INSURANCE AND FINANCIAL
26 SERVICES OR HIS OR HER DESIGNEE.

27 (3) THE MEMBERS FIRST APPOINTED TO THE COMMISSION MUST BE

1 APPOINTED WITHIN 15 DAYS AFTER THE EFFECTIVE DATE OF THIS SECTION.

2 (4) MEMBERS OF THE COMMISSION SHALL SERVE FOR TERMS OF 4 YEARS
3 OR UNTIL A SUCCESSOR IS APPOINTED, WHICHEVER IS LATER, EXCEPT THAT
4 OF THE MEMBERS FIRST APPOINTED 1 SHALL SERVE FOR 1 YEAR, 3 SHALL
5 SERVE FOR 2 YEARS, AND 3 SHALL SERVE FOR 3 YEARS.

6 (5) IF A VACANCY OCCURS ON THE COMMISSION, THE GOVERNOR SHALL
7 MAKE AN APPOINTMENT FOR THE UNEXPIRED TERM IN THE SAME MANNER AS
8 THE ORIGINAL APPOINTMENT.

9 (6) THE GOVERNOR MAY REMOVE A MEMBER OF THE COMMISSION FOR
10 INCOMPETENCE, DERELICTION OF DUTY, MALFEASANCE, MISFEASANCE, OR
11 NONFEASANCE IN OFFICE, OR ANY OTHER GOOD CAUSE.

12 (7) THE GOVERNOR SHALL CALL THE FIRST MEETING OF THE
13 COMMISSION. AT THE FIRST MEETING, THE COMMISSION SHALL ELECT FROM
14 AMONG ITS MEMBERS A CHAIRPERSON AND OTHER OFFICERS AS IT CONSIDERS
15 NECESSARY OR APPROPRIATE. AFTER THE FIRST MEETING, THE COMMISSION
16 SHALL MEET AT LEAST QUARTERLY, OR MORE FREQUENTLY AT THE CALL OF
17 THE CHAIRPERSON OR IF REQUESTED BY 4 OR MORE MEMBERS.

18 (8) A MAJORITY OF THE MEMBERS OF THE COMMISSION CONSTITUTE A
19 QUORUM FOR THE TRANSACTION OF BUSINESS AT THE MEETING OF THE
20 COMMISSION. A MAJORITY OF THE MEMBERS PRESENT AND SERVING ARE
21 REQUIRED FOR OFFICIAL ACTION OF THE COMMISSION.

22 (9) THE BUSINESS THAT THE COMMISSION MAY PERFORM MUST BE
23 CONDUCTED AT A PUBLIC MEETING OF THE COMMISSION HELD IN COMPLIANCE
24 WITH THE OPEN MEETINGS ACT, 1976 PA 267, MCL 15.261 TO 15.275.

25 (10) EXCEPT AS OTHERWISE PROVIDED IN SECTION 17748E(4), A
26 WRITING PREPARED, OWNED, USED, IN THE POSSESSION OF, OR RETAINED BY
27 THE COMMISSION IS SUBJECT TO DISCLOSURE UNDER THE FREEDOM OF

1 INFORMATION ACT, 1976 PA 442, MCL 15.231 TO 15.246.

2 (11) MEMBERS OF THE COMMISSION SHALL SERVE WITHOUT
3 COMPENSATION. HOWEVER, MEMBERS OF THE COMMISSION MAY BE REIMBURSED
4 FOR THEIR ACTUAL AND NECESSARY EXPENSES INCURRED IN THE PERFORMANCE
5 OF THEIR OFFICIAL DUTIES AS MEMBERS OF THE COMMISSION.

6 (12) UPON RECEIVING A REPORT FILED UNDER SECTION 17748E OR
7 17748F, THE COMMISSION SHALL REVIEW THE CONTENTS OF THE REPORT TO
8 DETERMINE WHETHER A MANUFACTURER IS CHARGING AN EXCESSIVE PRICE FOR
9 A PRESCRIPTION DRUG OR WHETHER A MANUFACTURER'S INCREASE IN THE
10 WHOLESALE ACQUISITION COST OF A PRESCRIPTION DRUG IS
11 UNCONSCIONABLE. IN MAKING ITS DETERMINATION, THE COMMISSION MAY
12 HOLD PUBLIC HEARINGS TO HEAR FROM CONSUMERS OF THE PRESCRIPTION
13 DRUG AND CONSULT WITH SCIENTISTS, HEALTH RESEARCHERS, AND ANY
14 INDIVIDUAL WITH KNOWLEDGE OR EXPERTISE IN THE PRICING OF
15 PRESCRIPTION DRUGS OR THE PHARMACEUTICAL INDUSTRY.

16 (13) IF THE COMMISSION DETERMINES THAT A MANUFACTURER HAS
17 CHARGED AN EXCESSIVE PRICE FOR A PRESCRIPTION DRUG OR THAT THE
18 INCREASE IN THE WHOLESALE ACQUISITION COST OF A PRESCRIPTION DRUG
19 IS UNCONSCIONABLE, THE COMMISSION SHALL SUBMIT A WRITTEN SUMMARY OF
20 ITS FINDINGS TO THE OFFICE OF THE ATTORNEY GENERAL AND REQUEST THAT
21 THE ATTORNEY GENERAL INVESTIGATE UNDER SECTION 3J OF THE MICHIGAN
22 CONSUMER PROTECTION ACT, 1976 PA 331, MCL 445.903J.

23 Enacting section 1. This amendatory act takes effect 90 days
24 after the date it is enacted into law.

25 Enacting section 2. This amendatory act does not take effect
26 unless Senate Bill No. ____ or House Bill No. 5690 (request no.
27 04293'17) of the 99th Legislature is enacted into law.