

# HOUSE BILL No. 5388

October 31, 2007, Introduced by Reps. Simpson, Brown, Byrum, McDowell, Bieda, Donigan, Vagnozzi, Valentine, Corriveau, Polidori, Leland, Hopgood, Dean, Miller, Alma Smith, Ebli, Lemmons, Wojno, Kathleen Law, Constan, Jackson, Accavitti, Hammel and Scott 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 section 17790.

## THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1        SEC. 17790. (1) A MANUFACTURER, INCLUDING ANY EMPLOYEE OR  
2        AGENT OF THE MANUFACTURER, SHALL KEEP A DETAILED RECORD OF THE  
3        VALUE, NATURE, AND PURPOSE OF ANY GIFTS, FEES, PAYMENTS, SUBSIDIES,  
4        OR OTHER ECONOMIC BENEFITS PROVIDED IN CONNECTION WITH  
5        PHARMACEUTICAL DETAILING, MARKETING, ADVERTISING, OR OTHER  
6        PROMOTIONAL ACTIVITIES DIRECTED TO A PHARMACIST OR DISPENSING  
7        PRESCRIBER OR HIS OR HER DESIGNEE.

8        (2) BY DECEMBER 31, 2008 AND EACH YEAR THEREAFTER, A  
9        MANUFACTURER SHALL SUBMIT A WRITTEN REPORT TO THE DEPARTMENT THAT

1 DISCLOSES THE VALUE, NATURE, AND PURPOSE OF ANY GIFTS, FEES,  
2 PAYMENTS, SUBSIDIES, OR OTHER ECONOMIC BENEFITS PROVIDED IN  
3 CONNECTION WITH PHARMACEUTICAL DETAILING, MARKETING, ADVERTISING,  
4 OR OTHER PROMOTIONAL ACTIVITIES DIRECTED TO A PHARMACIST OR  
5 DISPENSING PRESCRIBER, OR HIS OR HER DESIGNEE. THE REPORT SHALL BE  
6 ON A FORM AND IN A MANNER AS PRESCRIBED BY THE DEPARTMENT. THE  
7 DEPARTMENT SHALL ASSESS A FILING FEE FOR THIS REPORT THAT COVERS  
8 THE DEPARTMENT'S ADMINISTRATIVE COST OF MAINTAINING THESE REPORTS.  
9 ON OR BEFORE MARCH 31, 2009, AND EACH YEAR THEREAFTER, THE  
10 DEPARTMENT SHALL REPORT TO THE LEGISLATURE AND THE GOVERNOR ON THE  
11 DISCLOSURES MADE UNDER THIS SECTION. EACH MANUFACTURER SHALL ALSO  
12 DISCLOSE TO THE DEPARTMENT, ON OR BEFORE SEPTEMBER 31, 2008, AND  
13 ANNUALLY THEREAFTER, THE NAME AND ADDRESS OF THE INDIVIDUAL  
14 RESPONSIBLE FOR THE MANUFACTURER'S COMPLIANCE WITH THE PROVISIONS  
15 OF THIS SECTION.

16 (3) THE DEPARTMENT SHALL MAKE THE REPORTS SUBMITTED PURSUANT  
17 TO THIS SECTION AVAILABLE TO THE PUBLIC ON THE DEPARTMENT'S  
18 WEBSITE.

19 (4) EACH OF THE FOLLOWING IS EXEMPT FROM DISCLOSURE UNDER THIS  
20 SECTION:

21 (A) FREE SAMPLES OR COMPLEMENTARY STARTER DOSES OF  
22 PRESCRIPTION DRUGS THAT ARE INTENDED TO BE DISTRIBUTED TO PATIENTS.

23 (B) PAYMENT OF REASONABLE COMPENSATION AND REIMBURSEMENT OF  
24 EXPENSES INCURRED IN CONNECTION WITH BONA FIDE CLINICAL TRIALS. AS  
25 USED IN THIS SUBDIVISION, "CLINICAL TRIAL" MEANS AN APPROVED  
26 CLINICAL TRIAL CONDUCTED IN CONNECTION WITH A RESEARCH STUDY  
27 DESIGNED TO ANSWER SPECIFIC QUESTIONS ABOUT VACCINES, NEW

1 THERAPIES, OR NEW WAYS OF USING KNOWN TREATMENTS.

2 (C) ANY GIFT, FEE, PAYMENT, SUBSIDY, OR OTHER ECONOMIC BENEFIT  
3 THE VALUE OF WHICH IS LESS THAN \$25.00.

4 (5) A MANUFACTURER WHO NEGLECTS OR REFUSES TO FILE A REPORT  
5 UNDER THIS SECTION IS SUBJECT TO AN ADMINISTRATIVE FINE OF NOT MORE  
6 THAN \$10,000.00. A MANUFACTURER WHO INTENTIONALLY PROVIDES A FALSE  
7 REPORT IS SUBJECT TO AN ADMINISTRATIVE FINE OF NOT MORE THAN  
8 \$500,000.00.

9 Enacting section 1. This amendatory act does not take effect  
10 unless all of the following bills of the 94th Legislature are  
11 enacted into law:

12 (a) Senate Bill No.\_\_\_\_ or House Bill No. 5389(request no.  
13 02306'07).

14 (b) Senate Bill No.\_\_\_\_ or House Bill No. 5387(request no.  
15 02307'07).