

HOUSE BILL No. 5394

October 31, 2007, Introduced by Reps. McDowell, Brown, Byrum, Simpson, Bieda, Donigan, Vagnozzi, Valentine, Corriveau, Polidori, Leland, Hopgood, Dean, Miller, Alma Smith, Ebli, Lemmons, Wojno, Kathleen Law, Constan, Accavitti and Hammel 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 part 96A.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

PART 96A. CLINICAL TRIALS - HUMAN SUBJECT RESEARCH

SEC. 9661. (1) A PERSON WHO VIOLATES THIS PART BY FAILING TO
REPORT A CLINICAL TRIAL CONDUCTED OR SPONSORED TO THE DEPARTMENT AS
REQUIRED UNDER SECTION 9653 OR FAILS TO REPORT IN THE FORM
PRESCRIBED UNDER SECTION 9655 IS SUBJECT TO A CIVIL FINE AS
FOLLOWS:

(A) FIRST VIOLATION -- A FINE OF NOT MORE THAN \$250,000.00.

(B) SECOND VIOLATION -- A FINE OF NOT MORE THAN \$500,000.00.

(C) THIRD AND SUBSEQUENT VIOLATIONS -- A FINE OF NOT MORE THAN
\$1,000,000.00.

1 (2) THE DIRECTOR OF THE DEPARTMENT SHALL ADVISE THE ATTORNEY
2 GENERAL OF THE FAILURE OF A PERSON TO PAY A CIVIL FINE IMPOSED
3 UNDER THIS SECTION. THE ATTORNEY GENERAL SHALL BRING A CIVIL ACTION
4 IN A COURT OF COMPETENT JURISDICTION TO RECOVER THE FINE AND COSTS
5 AND FEES INCLUDING ATTORNEY FEES. CIVIL PENALTIES COLLECTED SHALL
6 BE PAID TO THE STATE TREASURY FOR DEPOSIT IN THE GENERAL FUND.

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

10 (a) Senate Bill No.____ or House Bill No. 5395(request no.
11 02308'07).

12 (b) Senate Bill No.____ or House Bill No. 5390(request no.
13 02309'07).

14 (c) Senate Bill No.____ or House Bill No. 5392(request no.
15 02311'07).

16 (d) Senate Bill No.____ or House Bill No. 5393(request no.
17 02312'07).

18 (e) Senate Bill No.____ or House Bill No. 5391(request no.
19 02313'07).