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State of Minnesota
HOUSE OF REPRESENTATIVES

**EIGHTY-FIFTH
SESSION**

HOUSE FILE No. 2289

March 21, 2007

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The bill was read for the first time and referred to the Committee on Health and Human Services

1.1 A bill for an act
1.2 relating to health; requiring disclosure of clinical trials for prescription drugs;
1.3 proposing coding for new law in Minnesota Statutes, chapter 144.

1.4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.5 Section 1. **[144.6601] CITATION.**

1.6 This act may be cited as the "Patient Safety and Drug Review Transparency Act."

1.7 Sec. 2. **[144.6602] DEFINITIONS.**

1.8 Subdivision 1. **Scope of definitions.** The terms used in sections 144.6602 to
1.9 144.6605 have the following meanings, unless the context indicates otherwise.

1.10 Subd. 2 **Clinical trial.** "Clinical trial" means any pharmacological, pharmacokinetic,
1.11 or other study of the safety or efficacy of a pharmaceutical drug, biological product, or
1.12 vaccine that has been approved for sale by the federal Food and Drug Administration,
1.13 whether or not completed in full, except for Phase 1 trials as defined in Code of Federal
1.14 Regulations, title 21, section 312.21(a), or any successor regulations, including, but not
1.15 limited to:

1.16 (1) a clinical investigation that involves any trial to test the safety or efficacy of a
1.17 pharmaceutical drug or biological product with one or more human subjects and that
1.18 is intended to be submitted to, or held for inspection by, the federal Food and Drug
1.19 Administration as part of any application for a research or marketing permit or for any
1.20 other type of application, permit, procedure, or requirement of the Food and Drug
1.21 Administration, including, but not limited to, an abbreviated new drug application, an
1.22 investigational new drug application, a new drug application, nonconfidential additions to

2.1 the drug master file, postmarketing adverse events recording, and compliance with the
2.2 electronic or paper common technical document;

2.3 (2) any pharmacological study subsequent to initial approval for sale by the Food
2.4 and Drug Administration, including studies assessing potential off-label applications and
2.5 new drug trials assessing the efficacy or safety of a drug compared to other therapies; and

2.6 (3) any other study cited or relied upon by a manufacturer for claims made in
2.7 marketing or educational efforts or materials to prescribers or consumers.

2.8 Subd. 3. **Manufacturer.** "Manufacturer" means a manufacturer of prescription
2.9 drugs or biological products or an affiliate of the manufacturer.

2.10 **Sec. 3. [144.6603] DISCLOSURE OF CLINICAL TRIALS OF PRESCRIPTION**
2.11 **DRUGS.**

2.12 Subdivision 1. **Information to be disclosed.** A manufacturer of prescription drugs
2.13 shall make publicly available, in accordance with subdivision 3, the following information
2.14 regarding clinical trials conducted or sponsored by the manufacturer, or any entity on its
2.15 behalf, for each prescription drug the manufacturer sold, delivered, dispensed, offered for
2.16 sale, or gave away in this state:

2.17 (1) the names of all participating organizations and funding sources of the clinical
2.18 trial, including the name and contact information, including institutional affiliation, of all
2.19 sponsors, cosponsors, and administrators, including the name of the principal investigators
2.20 and study centers, of the clinical trial;

2.21 (2) a summary of the purpose of the clinical trial, including the name of the drug
2.22 being tested and its active ingredients; overall design of the study, including statistical
2.23 method to be employed; status or phase type of the trial; inclusion and exclusion criteria;
2.24 treatment methods to be used; all hypotheses tested by the trial; the medical condition or
2.25 conditions being studied; and outcomes that were evaluated;

2.26 (3) the dates during which the trial took place; and

2.27 (4) a summary of information concerning the results and outcomes of the clinical
2.28 trial, which shall also include, but not be limited to, specific data and information about
2.29 the potential or actual adverse effects of the drug, including the frequency, severity, and
2.30 nature of adverse events for any trial participant and the numbers of participants who
2.31 discontinued participation in the trial and the reasons for their discontinuance. For any
2.32 clinical trial that is terminated, a description of the reasons leading to the decision to
2.33 terminate the trial, including whether efficacy, adverse events, or safety issues were factors.

2.34 Subd. 2. **Application.** The disclosure requirement in subdivision 1 shall apply
2.35 to all clinical trials completed or terminated on or after January 1, 1990, including any

3.1 clinical trials completed after a prescription drug has been approved for sale by the federal
3.2 Food and Drug Administration.

3.3 Subd. 3. **Information to be posted.** The information required to be disclosed under
3.4 subdivision 1 shall be posted on the publicly accessible Web site. In order to satisfy the
3.5 requirements of this subdivision, the publicly accessible Web site and manner of posting
3.6 must be acceptable to the commissioner and shall be a free, nonsubscription Web site that
3.7 clearly indicates the location and instructions for downloading the files or information
3.8 submitted under subdivision 1.

3.9 Subd. 4. **Disclosure of terminated trials.** Disclosure of clinical trials under
3.10 subdivision 1 shall include clinical trials that the manufacturer, or an entity on its behalf,
3.11 initiated but terminated prior to completion. For these trials, the manufacturer shall
3.12 include an explanation for the termination of the trial, including, but not limited to,
3.13 potential or actual adverse effects of the drug, including the frequency, severity, and nature
3.14 of adverse events for any trial participant and numbers of participants who discontinued
3.15 participation in the trial and the reasons for their discontinuance.

3.16 **Sec. 4. ~~144.6604~~ FEES.**

3.17 Beginning January 1, 2008, each manufacturer of prescription drugs that are
3.18 provided to state residents through the medical assistance program shall pay a fee of
3.19 \$1,000 per calendar year to the commissioner. Fees collected under this section are
3.20 appropriated to the commissioner to cover the cost of overseeing implementation of
3.21 sections 144.6602 to 144.6605, including, but not limited to, maintaining links to publicly
3.22 accessible Web sites to which manufacturers are posting clinical trial information under
3.23 section 144.6603 and other relevant sites.

3.24 **Sec. 5. ~~144.6605~~ COMPLIANCE DATES.**

3.25 A manufacturer shall post the information required by section 144.6603 as follows:

3.26 (1) for trials completed or terminated before the effective date of sections
3.27 144.6602 to 144.6605, within six months after the effective date of sections 144.6602 to
3.28 144.6605, or six months after the date of approval for sale by the federal Food and Drug
3.29 Administration, whichever is later;

3.30 (2) for trials completed or terminated after the effective date of sections 144.6602 to
3.31 144.6605, within six months after the date of approval for sale by the federal Food and
3.32 Drug Administration, or six months after the date on which the trial was completed,
3.33 whichever is later;

4.1 (3) for trials whose results are being submitted for publication to a peer-reviewed
4.2 medical journal, the dates in clauses (1) and (2) may be extended to facilitate publication.
4.3 The final extended compliance date shall not exceed 12 months after the trial is completed
4.4 or terminated. The manufacturer shall post the required information not later than the
4.5 earlier of:

4.6 (i) 30 days after the time of publication; or

4.7 (ii) 30 days after receipt of a rejection for publication unless the paper is submitted
4.8 to another peer-reviewed journal for publication.

4.9 If a manufacturer wishes to use the extended compliance date, it shall post notice on
4.10 a publicly accessible Web site within the time frames specified in items (i) and (ii) that it is
4.11 seeking publication in a peer-reviewed journal and the notice shall include the names and
4.12 affiliations of all authors of the study and the names of the peer-reviewed journals that
4.13 are considering publication of the paper.