

SENATE No. 735

By Mr. Bertonazzi, a petition (accompanied by bill, Senate, No. 735) of Louis P. Bertonazzi for legislation to establish standards of responsibility for vaccine administrators. The Judiciary.

The Commonwealth of Massachusetts

In the Year One Thousand Nine Hundred and Ninety.

AN ACT TO ESTABLISH STANDARDS OF RESPONSIBILITY FOR VACCINE ADMINISTRATORS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Chapter 231 of the General Laws is hereby amended by
2 inserting after section 60I the following section: —

3 Section 60J. The following terms as used in this section shall
4 have the following meanings, except where the context clearly
5 indicates otherwise: —

6 “Vaccine administrator” means any licensed health care
7 professional, organization, or institution, whether public or
8 private (including federal, state, and local departments, agencies,
9 and instrumentalities), who administers a covered vaccine or
10 under whose authority a covered vaccine is administered.

11 “Vaccine-related injury” means any injury, disability, illness,
12 condition, or death associated with a covered vaccine, except that
13 the term does not include an injury, disability, illness, condition,
14 or death associated with an adulterant or contaminant
15 intentionally added to such a vaccine.

16 “Vaccine manufacturer” means any individual or any
17 corporation, organization, or institution, whether public or
18 private (including federal, state, and local departments, agencies,
19 and instrumentalities), which manufactures, imports, processes,
20 or distributes under its label a covered vaccine.

21 “Covered vaccine” means any vaccine for which an individual
22 may receive compensation under subtitle II of Title XXI of the
23 Public Health Service Act.

24 (a) No action shall be filed by any individual, or by any
25 individual's parent, guardian, or personal representative, against
26 any vaccine manufacturer or administrator at common law or
27 otherwise, for a vaccine-related injury unless such action is
28 permitted under subtitle 2 of Title XXI of the Public Health
29 Service Act. Any action filed in violation of this clause shall be
30 dismissed, with prejudice, on the motion of any party under law.

31 (b) No vaccine administrator shall be liable in a civil action for
32 damages arising from a vaccine-related injury for failure to
33 provide adequate warnings to the injured party (or the injured
34 party's legal representative) of the potential dangers resulting from
35 the administration of the vaccine, if prior to the administration
36 of the vaccine:

37 (1) the vaccine administrator provided to the legal
38 representative of the injured party the vaccine materials developed
39 by the Secretary pursuant to subtitle II of Title XXI of the Public
40 Health Service Act; or

41 (2) the vaccine administrator otherwise provided written
42 information to the legal representative of the injured party, as
43 required under Subtitle II of Title XXI of the Public Health
44 Service Act, relating to:

45 (i) the frequency, severity, and potential long-term effects
46 of the disease to be prevented by the vaccine,

47 (ii) the symptoms or reactions to the vaccine which, if they
48 occur, should be brought to the immediate attention of a health
49 care provider,

50 (iii) precautionary measures a legal representative should
51 take to reduce the risk of any major adverse reactions to the
52 vaccine that may occur,

53 (iv) early warning signs or symptoms to which the legal
54 representative should be alert as possible precursors to such major
55 adverse reactions,

56 (v) a description of the manner in which the legal
57 representative should monitor such major adverse reactions,

58 (vi) a specification of when, how, and to whom the legal
59 representative should report any major adverse reaction,

60 (vii) the contraindications to (and bases for delay of) the
61 administration of the vaccine, and

62 (viii) an identification of the groups, categories, or
63 characteristics of potential recipients of the vaccine who may be
64 at significantly higher risk of major adverse reaction to the vaccine
65 than the general population.

66 (c) No vaccine administrator shall be liable in a civil action for
67 damages arising from a vaccine-related injury on any grounds
68 other than failure to provide adequate warnings to the injured
69 party (or the injured party's legal representative) of the potential
70 damages resulting from the administration of the vaccine, unless:

71 (1) the vaccine administrator administered the vaccine under
72 circumstances that a reasonably prudent administrator would not
73 have administered the vaccine to the injured party; or

74 (2) the vaccine administrator administered the vaccine in a
75 manner different from the manner that the vaccine would have
76 been administered to the injured party by a reasonably prudent
77 administrator under similar circumstances.

