

*Reprinted*

MAR 3 1994

Place On Calendar

HOUSE FILE 2353

BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HSB 513)

Passed House, <sup>(p576)</sup> Date 3-11-94 Passed Senate, <sup>(p.895)</sup> Date 3-29-94  
 Vote: Ayes 97 Nays 0 Vote: Ayes 49 Nays 0  
 Approved April 8, 1994

**A BILL FOR**

1 An Act providing authorization for certain epidemiological  
 2 studies regarding the incidence and prevalence of the human  
 3 immunodeficiency virus infection.

4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 2353

HOUSE FILE 2353

H-5254

1 Amend House File 2353 as follows:  
 2 1. Page 1, line 13, by inserting after the word  
 3 "infection." the following: "Initiation of any new  
 4 epidemiological studies shall be contingent upon the  
 5 receipt of funding sufficient to cover all the costs  
 6 associated with the studies."

By MARTIN of Scott

H-5254 FILED MARCH 9, 1994

*adopted 3-11-94*

*(p576)*

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1 Section 1. Section 141.23A, Code 1993, is amended to read  
2 as follows:

3 141.23A HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIOLOGICAL  
4 BLINDED-STUDY STUDIES.

5 1. Notwithstanding section 141.8 regarding informed  
6 consent and reporting requirements, and section 141.22  
7 regarding informed consent and preliminary and posttest  
8 counseling, the Iowa The department of public health or its  
9 agent with the approval of the state board of health may  
10 conduct through the expenditure of federal grant moneys  
11 allocated for this purpose an epidemiological blinded study of  
12 newborns and nonblinded studies to determine the incidence and  
13 prevalence of the human immunodeficiency virus infection.

14 2. ~~All~~ In blinded studies personal identifiers shall be  
15 permanently stripped from the specimens selected prior to  
16 testing for the human immunodeficiency virus infection. The  
17 informed consent and reporting and counseling requirements of  
18 sections 141.8 and 141.22 do not apply.

19 For the purposes of this section, "blinded epidemiological  
20 blinded-study studies" means a-study studies in which blinded  
21 specimens which were collected for other purposes are selected  
22 according to established criteria, are permanently stripped of  
23 personal identifiers, and are then tested.

24 For the purposes of this section, "nonblinded  
25 epidemiological studies" means studies in which specimens are  
26 collected for the express purpose of testing for the human  
27 immunodeficiency virus infection and persons included in the  
28 nonblinded study are selected according to established  
29 criteria. Sections 141.8 and 141.22 apply to nonblinded  
30 epidemiological studies.

31 EXPLANATION

32 This bill authorizes the Iowa department of public health,  
33 with the approval of the state board of health, to conduct  
34 blinded and nonblinded epidemiological studies to determine  
35 the incidence and prevalence of the human immunodeficiency

1 virus infection. The department is currently limited to  
2 performance of blinded studies on newborns funded through  
3 federal grant moneys.

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*Substituted for  
SF 2062  
3-17-94 (P. 229)*

HOUSE FILE 2353  
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HSB 513)

(As Amended and Passed by the House March 11, 1994)

Passed House, Date 3/11/94 Passed Senate, Date 3/29/94  
Vote: Ayes 97 Nays 0 Vote: Ayes 49 Nays 0  
Approved April 8, 1994

**A BILL FOR**

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House Amendments \_\_\_\_\_

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4 BLINDED-STUDY STUDIES.

5 1. Notwithstanding section 141.8 regarding informed  
6 consent and reporting requirements, and section 141.22  
7 regarding informed consent and preliminary and posttest  
8 counseling, the Iowa Department of Public Health or its  
9 agent with the approval of the state board of health may  
10 conduct through the expenditure of federal grant moneys  
11 allocated for this purpose an epidemiological blinded study of  
12 newborns and nonblinded studies to determine the incidence and  
13 prevalence of the human immunodeficiency virus infection.  
14 Initiation of any new epidemiological studies shall be  
15 contingent upon the receipt of funding sufficient to cover all  
16 the costs associated with the studies.

17 2. All In blinded studies personal identifiers shall be  
18 permanently stripped from the specimens selected prior to  
19 testing for the human immunodeficiency virus infection. The  
20 informed consent and reporting and counseling requirements of  
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28 epidemiological studies" means studies in which specimens are  
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30 immunodeficiency virus infection and persons included in the  
31 nonblinded study are selected according to established  
32 criteria. Sections 141.8 and 141.22 apply to nonblinded  
33 epidemiological studies.

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HSB 513

HUMAN RESOURCES

SENATE/HOUSE FILE <sup>Naw</sup> 2353  
BY (PROPOSED DEPARTMENT OF  
PUBLIC HEALTH BILL)

Passed Senate, Date \_\_\_\_\_ Passed House, Date \_\_\_\_\_  
Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_ Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_  
Approved \_\_\_\_\_

A BILL FOR

1 An Act providing authorization for certain epidemiological  
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4 BLINDED-STUDY STUDIES.

5 1. Notwithstanding-section-141-8-regarding-informed  
6 consent-and-reporting-requirements,-and-section-141-22  
7 regarding-informed-consent-and-preliminary-and-posttest  
8 counseling,-the-iowa The department of public health or its  
9 agent with the approval of the state board of health may  
10 conduct through-the-expenditure-of-federal-grant-moneys  
11 allocated-for-this-purpose-an epidemiological blinded study of  
12 newborns and nonblinded studies to determine the incidence and  
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14 2. All In blinded studies personal identifiers shall be  
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27 immunodeficiency virus infection and persons included in the  
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29 criteria. The informed consent and reporting and counseling  
30 requirements of sections 141.8 and 141.22 apply.

31 EXPLANATION

32 This bill authorizes the Iowa department of public health,  
33 with the approval of the state board of health, to conduct  
34 blinded and nonblinded epidemiological studies to determine  
35 the incidence and prevalence of the human immunodeficiency

1 virus infection. The department is currently limited to  
2 performance of blinded studies on newborns funded through  
3 federal grant moneys.

4 BACKGROUND STATEMENT  
5 SUBMITTED BY THE AGENCY

6 This bill would allow the Iowa department of public health  
7 to conduct, with the approval of the state board of health,  
8 blinded and nonblinded epidemiological studies of human  
9 immunodeficiency virus infection in accordance with the  
10 confidentiality provisions which currently exist. This  
11 amendment was recommended by the Director's Ad Hoc Committee  
12 on the Prevention of HIV Infection and would allow for  
13 additional epidemiological studies to enhance prevention  
14 activities. The current Code language restricts the  
15 department's epidemiological research to a singular newborn  
16 study funded by the centers for disease control.

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HOUSE FILE 2353

AN ACT  
PROVIDING AUTHORIZATION FOR CERTAIN EPIDEMIOLOGICAL STUDIES  
REGARDING THE INCIDENCE AND PREVALENCE OF THE HUMAN IMMUNO-  
DEFICIENCY VIRUS INFECTION.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 141.23A, Code 1993, is amended to read as follows:

141.23A HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIOLOGICAL  
~~BLINDED-STUDY~~ STUDIES.

~~1. Notwithstanding section 141.8 regarding informed consent and reporting requirements, and section 141.22 regarding informed consent and preliminary and posttest counseling, the Iowa~~ The department of public health or its agent with the approval of the state board of health may conduct ~~through the expenditure of federal grant moneys allocated for this purpose an~~ epidemiological blinded study of newborns and nonblinded studies to determine the incidence and prevalence of the human immunodeficiency virus infection. Initiation of any new epidemiological studies shall be contingent upon the receipt of funding sufficient to cover all the costs associated with the studies.

~~2. All~~ In blinded studies personal identifiers shall be permanently stripped from the specimens selected prior to testing for the human immunodeficiency virus infection. The informed consent and reporting and counseling requirements of sections 141.8 and 141.22 do not apply.

For the purposes of this section, "blinded epidemiological blinded-study studies" means a study studies in which blood specimens which were collected for other purposes are selected according to established criteria, are permanently stripped of personal identifiers, and are then tested.

For the purposes of this section, "nonblinded epidemiological studies" means studies in which specimens are collected for the express purpose of testing for the human immunodeficiency virus infection and persons included in the nonblinded study are selected according to established criteria. Sections 141.8 and 141.22 apply to nonblinded epidemiological studies.

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HAROLD VAN MAANEN  
Speaker of the House

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LEONARD L. BOSWELL  
President of the Senate

I hereby certify that this bill originated in the House and is known as House File 2353, Seventy-fifth General Assembly.

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ELIZABETH ISAACSON  
Chief Clerk of the House

Approved April 8, 1994

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TERRY E. BRANSTAD  
Governor