

# SENATE BILL 572

J1, J2, C3

7lr1349  
CF HB 584

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By: ~~Senator Simonaire~~ Senators Simonaire, Middleton, Astle, Benson, Feldman, Hershey, Jennings, Klausmeier, Mathias, Oaks, Reilly, and Rosapepe

Introduced and read first time: February 2, 2017

Assigned to: Finance

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Committee Report: Favorable with amendments

Senate action: Adopted with floor amendments

Read second time: March 24, 2017

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## CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **Investigational Drugs, Biological Products, and Devices – Right to Try Act**

3 FOR the purpose of authorizing a manufacturer of an investigational drug, biological  
4 product, or device to provide the investigational drug, biological product, or device to  
5 certain patients; specifying the manner in which an investigational drug, biological  
6 product, or device may be provided to certain patients; authorizing a manufacturer  
7 of an investigational drug, biological product, or device to require an eligible patient  
8 to pay certain costs, subject to certain limitations; ~~establishing that the heirs of~~  
9 ~~certain patients are not liable for certain debts~~ requiring a manufacturer of an  
10 investigational drug, biological product, or device to notify a certain patient and a  
11 certain health care provider of certain side effects or risks; requiring the Office of the  
12 Attorney General to develop an informed consent form that meets certain  
13 requirements; providing for the construction of certain provisions of this Act;  
14 ~~establishing that a certain manufacturer may enforce a certain claim against the~~  
15 ~~estate of a certain patient, but not the patient's heirs or legatees, except under~~  
16 ~~certain circumstances;~~ prohibiting a health occupations board, under certain  
17 circumstances, from revoking, failing to renew, suspending, or taking certain action  
18 against a health care provider's license based solely on a certain recommendation of  
19 the health care provider; prohibiting the Department of Health and Mental Hygiene  
20 from taking action against a health care provider's Medicare certification based  
21 solely on a certain recommendation of the health care provider or certain treatment  
22 provided by a health care provider; prohibiting an official, employee, or agent of the  
23 State from blocking or attempting to block a certain patient's access to an  
24 investigational drug, biological product, or device; establishing that this Act does not

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 create a certain cause of action; providing for the effect of certain provisions of this  
 2 Act; defining certain terms; and generally relating to the provision of investigational  
 3 drugs, biological products, and devices in the State.

4 BY adding to

5 Article – Health – General

6 Section 21-2B-01 through ~~21-2B-07~~ 21-2B-06 to be under the new subtitle  
 7 “Subtitle 2B. Right to Try Act”

8 Annotated Code of Maryland

9 (2015 Replacement Volume and 2016 Supplement)

10 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,  
 11 That the Laws of Maryland read as follows:

12 **Article – Health – General**

13 **SUBTITLE 2B. RIGHT TO TRY ACT.**

14 **21-2B-01.**

15 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS  
 16 INDICATED.

17 (B) “CARRIER” HAS THE MEANING STATED IN § 15-10A-01(C) OF THE  
 18 INSURANCE ARTICLE.

19 ~~(B)~~ (C) “ELIGIBLE PATIENT” MEANS AN INDIVIDUAL WHO:

20 (1) HAS A TERMINAL ILLNESS, ATTESTED TO BY THE INDIVIDUAL’S  
 21 TREATING PHYSICIAN;

22 (2) HAS CONSIDERED ALL OTHER TREATMENT OPTIONS CURRENTLY  
 23 APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

24 (3) HAS RECEIVED A RECOMMENDATION FROM THE INDIVIDUAL’S  
 25 TREATING PHYSICIAN FOR THE USE OF AN INVESTIGATIONAL DRUG, BIOLOGICAL  
 26 PRODUCT, OR DEVICE;

27 (4) (I) HAS GIVEN INFORMED CONSENT FOR THE USE OF THE  
 28 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE; OR

29 (II) IF THE INDIVIDUAL IS A MINOR OR LACKS THE MENTAL  
 30 CAPACITY TO PROVIDE INFORMED CONSENT, HAS A PARENT OR LEGAL GUARDIAN  
 31 WHO HAS GIVEN INFORMED CONSENT ON THE INDIVIDUAL’S BEHALF FOR THE USE  
 32 OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE;

1           (5) IS INELIGIBLE FOR OR UNABLE TO PARTICIPATE IN A CLINICAL  
2 TRIAL; AND

3           (6) HAS DOCUMENTATION FROM THE INDIVIDUAL'S TREATING  
4 PHYSICIAN THAT THE INDIVIDUAL MEETS THE REQUIREMENTS OF ITEMS (1)  
5 THROUGH (5) OF THIS SUBSECTION.

6       ~~(D)~~ (D) "HEALTH OCCUPATIONS BOARD" MEANS A BOARD ESTABLISHED  
7 UNDER THE HEALTH OCCUPATIONS ARTICLE THAT ISSUES LICENSES TO PRACTICE  
8 A HEALTH OCCUPATION IN THE STATE.

9       ~~(D)~~ (E) "INFORMED CONSENT" MEANS A WRITTEN DOCUMENT PREPARED  
10 USING THE INFORMED CONSENT FORM DEVELOPED BY THE OFFICE OF THE  
11 ATTORNEY GENERAL IN ACCORDANCE WITH § 21-2B-02(D)(1) OF THIS SUBTITLE  
12 THAT:

13           (1) IS SIGNED BY THE PATIENT OR A PARENT OR LEGAL GUARDIAN OF  
14 THE PATIENT;

15           (2) IS ATTESTED TO BY THE PATIENT'S TREATING PHYSICIAN AND A  
16 WITNESS; AND

17           (3) AT A MINIMUM:

18           (I) EXPLAINS THE CURRENTLY APPROVED PRODUCTS AND  
19 TREATMENTS FOR THE DISEASE OR CONDITION FROM WHICH THE PATIENT  
20 SUFFERS;

21           (II) ATTESTS TO THE FACT THAT THE PATIENT CONCURS WITH  
22 THE PATIENT'S TREATING PHYSICIAN IN BELIEVING THAT ALL CURRENTLY  
23 APPROVED AND CONVENTIONALLY RECOGNIZED TREATMENTS ARE UNLIKELY TO  
24 PROLONG THE PATIENT'S LIFE;

25           (III) IDENTIFIES CLEARLY THE SPECIFIC PROPOSED  
26 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT THE PATIENT IS  
27 SEEKING TO USE;

28           (IV) INFORMS THE PROVIDER AND ELIGIBLE PATIENT OF ANY  
29 KNOWN OR ANTICIPATED SIDE EFFECTS, RISKS, OR REPORTED PATIENT  
30 DISCOMFORT THAT IS LIKELY RELATED TO THE TREATMENT;

31           ~~(V)~~ (V) DESCRIBES THE BEST AND WORST POTENTIAL  
32 OUTCOMES OF USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR

1 DEVICE WITH A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME,  
 2 INCLUDING THE POSSIBILITY THAT NEW, UNANTICIPATED, DIFFERENT, OR WORSE  
 3 SYMPTOMS MIGHT RESULT AND THAT DEATH COULD BE HASTENED BY THE  
 4 PROPOSED TREATMENT, BASED ON THE TREATING PHYSICIAN'S KNOWLEDGE OF  
 5 THE PROPOSED TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE  
 6 PATIENT'S CONDITION;

7 ~~(v)~~ (VI) MAKES CLEAR THAT THE PATIENT'S ~~HEALTH~~  
 8 ~~INSURANCE~~ CARRIER AND HEALTH CARE PROVIDER ARE NOT OBLIGATED TO PAY  
 9 FOR ANY CARE OR TREATMENTS THAT ~~MAY BE~~ ARE NECESSARY AS A RESULT OF THE  
 10 USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE ~~UNLESS~~  
 11 ~~THEY ARE SPECIFICALLY REQUIRED TO DO SO BY~~ EXCEPT AS REQUIRED BY FEDERAL  
 12 OR STATE LAW OR CONTRACT;

13 ~~(vi)~~ (VII) MAKES CLEAR THAT THE PATIENT'S ELIGIBILITY FOR  
 14 HOSPICE CARE MAY BE WITHDRAWN IF THE PATIENT BEGINS CURATIVE TREATMENT  
 15 WITH THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND THAT  
 16 HOSPICE CARE MAY BE REINSTATED IF THIS TREATMENT ENDS AND THE PATIENT  
 17 MEETS HOSPICE ELIGIBILITY REQUIREMENTS; AND

18 ~~(vii)~~ (VIII) STATES THAT THE PATIENT UNDERSTANDS THAT THE  
 19 PATIENT ~~IS~~ MAY BE LIABLE FOR ALL EXPENSES RELATING TO THE USE OF THE  
 20 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND THAT THIS  
 21 LIABILITY EXTENDS TO THE PATIENT'S ESTATE, BUT NOT THE HEIRS OR LEGATEES  
 22 OF THE PATIENT; ~~UNLESS A CONTRACT BETWEEN THE PATIENT AND THE~~  
 23 ~~MANUFACTURER OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR~~  
 24 ~~DEVICE STATES OTHERWISE.~~

25 ~~(e)~~ (F) "INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE"  
 26 MEANS A DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT:

27 (1) HAS SUCCESSFULLY COMPLETED PHASE I OF A CLINICAL TRIAL  
 28 BUT HAS NOT YET BEEN APPROVED FOR GENERAL USE BY THE UNITED STATES  
 29 FOOD AND DRUG ADMINISTRATION; AND

30 (2) REMAINS UNDER INVESTIGATION OR IN A CLINICAL TRIAL  
 31 APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

32 ~~(F)~~ (G) "TERMINAL ILLNESS" MEANS A DISEASE OR CONDITION THAT,  
 33 WITHOUT LIFE-SUSTAINING PROCEDURES, WILL RESULT IN DEATH OR A STATE OF  
 34 PERMANENT UNCONSCIOUSNESS FROM WHICH RECOVERY IS UNLIKELY WITHIN 12  
 35 MONTHS.

1 (A) A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL  
2 PRODUCT, OR DEVICE MAY:

3 (1) PROVIDE THE MANUFACTURER'S INVESTIGATIONAL DRUG,  
4 BIOLOGICAL PRODUCT, OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT  
5 COMPENSATION; OR

6 (2) SUBJECT TO SUBSECTION (B) OF THIS SECTION, REQUIRE AN  
7 ELIGIBLE PATIENT TO PAY THE COSTS OF OR ASSOCIATED WITH THE MANUFACTURE  
8 OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE PROVIDED TO  
9 THE ELIGIBLE PATIENT.

10 (B) (1) ANY PAYMENT REQUIRED BY A MANUFACTURER UNDER  
11 SUBSECTION (A)(2) OF THIS SECTION SHALL BE LIMITED TO THE RECOVERY OF THE  
12 COSTS OF OR ASSOCIATED WITH THE MANUFACTURE OF THE SPECIFIC  
13 INVESTIGATIONAL DRUG OR BIOLOGICAL PRODUCT DOSAGES OR DEVICES  
14 PROVIDED TO THE ELIGIBLE PATIENT.

15 (2) A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL  
16 PRODUCT, OR DEVICE MAY NOT PROFIT FROM PROVIDING AN INVESTIGATIONAL  
17 DRUG, BIOLOGICAL PRODUCT, OR DEVICE PROVIDED TO AN ELIGIBLE PATIENT.

18 (C) AFTER THE DATE THAT AN ELIGIBLE PATIENT BEGINS TAKING THE  
19 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE AND DURING THE TIME  
20 THE ELIGIBLE PATIENT IS TAKING THE INVESTIGATIONAL DRUG, BIOLOGICAL  
21 PRODUCT, OR DEVICE, THE MANUFACTURER SHALL NOTIFY THE ELIGIBLE PATIENT  
22 AND THE ELIGIBLE PATIENT'S HEALTH CARE PROVIDER OF ANY SIDE EFFECTS OR  
23 RISKS ASSOCIATED WITH THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR  
24 DEVICE THAT ARE REQUIRED TO BE DISCLOSED TO THE U. S. FOOD AND DRUG  
25 ADMINISTRATION DURING THE DRUG APPROVAL PROCESS.

26 (D) (1) THE OFFICE OF THE ATTORNEY GENERAL SHALL DEVELOP AN  
27 INFORMED CONSENT FORM THAT:

28 (I) COMPLIES WITH THE REQUIREMENTS OF ~~§ 21-2B-01(D)(3)~~  
29 § 21-2B-01(E)(3) OF THIS SUBTITLE;

30 (II) INCLUDES INSTRUCTIONS FOR THE PHYSICIAN OR PATIENT  
31 ON HOW TO COMPLETE THE FORM; AND

32 (III) PROVIDES SPACES FOR A PHYSICIAN TO INCLUDE THE  
33 INFORMATION RELATING TO A PARTICULAR PATIENT AND THE PHYSICIAN'S  
34 RECOMMENDATION FOR THE PATIENT.

1           **(2) THIS SUBSECTION MAY NOT BE CONSTRUED TO PROHIBIT A**  
 2 **TREATING PHYSICIAN OR A MANUFACTURER OF AN INVESTIGATIONAL DRUG,**  
 3 **BIOLOGICAL PRODUCT, OR DEVICE FROM INCLUDING ADDITIONAL INFORMATION**  
 4 **OR ADVISEMENTS WITH THE INFORMED CONSENT FORM DEVELOPED UNDER**  
 5 **PARAGRAPH (1) OF THIS SUBSECTION.**

6 **21-2B-03.**

7 ~~**IF AN ELIGIBLE PATIENT DIES WHILE BEING TREATED WITH AN**~~  
 8 ~~**INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, THE ELIGIBLE**~~  
 9 ~~**PATIENT'S HEIRS ARE NOT LIABLE MANUFACTURER OF THE INVESTIGATIONAL**~~  
 10 ~~**DRUG, BIOLOGICAL PRODUCT, OR DEVICE MAY ENFORCE A CLAIM AGAINST THE**~~  
 11 ~~**ESTATE OF THE ELIGIBLE PATIENT, BUT NOT THE ELIGIBLE PATIENT'S HEIRS OR**~~  
 12 ~~**LEGATEES, FOR ANY OUTSTANDING DEBT RELATED TO THE TREATMENT OR LACK OF**~~  
 13 ~~**INSURANCE COVERAGE FOR THE TREATMENT, UNLESS A CONTRACT BETWEEN THE**~~  
 14 ~~**ELIGIBLE PATIENT AND THE MANUFACTURER STATES OTHERWISE.**~~

15 ~~**21-2B-04.**~~

16           **(A) A HEALTH OCCUPATIONS BOARD MAY NOT REVOKE, FAIL TO RENEW,**  
 17 **SUSPEND, OR TAKE ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE**  
 18 **BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATION TO AN**  
 19 **ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN**  
 20 **INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, ~~PROVIDED THE~~**  
 21 ~~**RECOMMENDATION IS CONSISTENT WITH MEDICAL STANDARDS OF CARE.**~~

22           **(B) THE DEPARTMENT MAY NOT TAKE ACTION AGAINST A HEALTH CARE**  
 23 **PROVIDER'S MEDICARE CERTIFICATION BASED SOLELY ON THE HEALTH CARE**  
 24 **PROVIDER'S RECOMMENDATION THAT AN ELIGIBLE PATIENT HAVE ACCESS TO AN**  
 25 **INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE OR THE HEALTH CARE**  
 26 **PROVIDER'S TREATMENT OF AN ELIGIBLE PATIENT WITH AN INVESTIGATIONAL**  
 27 **DRUG, BIOLOGICAL PRODUCT, OR DEVICE.**

28 ~~**21-2B-05.**~~ **21-2B-04.**

29           **(A) AN OFFICIAL, EMPLOYEE, OR AGENT OF THE STATE MAY NOT BLOCK OR**  
 30 **ATTEMPT TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN INVESTIGATIONAL**  
 31 **DRUG, BIOLOGICAL PRODUCT, OR DEVICE.**

32           **(B) THIS SECTION DOES NOT PROHIBIT A LICENSED HEALTH CARE**  
 33 **PROVIDER FROM PROVIDING COUNSEL, ADVICE, OR A RECOMMENDATION THAT IS**  
 34 **CONSISTENT WITH MEDICAL STANDARDS OF CARE.**

1 ~~21-2B-06.~~ 21-2B-05.

2       **THIS SUBTITLE DOES NOT CREATE A PRIVATE CAUSE OF ACTION AGAINST A**  
3 **MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR**  
4 **DEVICE OR AGAINST ANOTHER PERSON INVOLVED IN THE CARE OF AN ELIGIBLE**  
5 **PATIENT USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE**  
6 **FOR ANY HARM TO THE ELIGIBLE PATIENT RESULTING FROM THE INVESTIGATIONAL**  
7 **DRUG, BIOLOGICAL PRODUCT, OR DEVICE IF THE MANUFACTURER OR OTHER**  
8 **PERSON IS COMPLYING IN GOOD FAITH WITH THIS SUBTITLE AND HAS EXERCISED**  
9 **REASONABLE CARE.**

10 ~~21-2B-07.~~ 21-2B-06.

11       **THIS SUBTITLE DOES NOT AFFECT THE COVERAGE REQUIREMENTS UNDER**  
12 **TITLE 15, SUBTITLE 8 OF THE INSURANCE ARTICLE.**

13       SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
14 October 1, 2017.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.