

SENATE BILL 63

J1, J2, C3

(PRE-FILED)

6lr0497
CF HB 56

By: **Senator Simonaire**

Requested: July 22, 2015

Introduced and read first time: January 13, 2016

Assigned to: Finance

A BILL ENTITLED

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; establishing that the heirs of
7 certain patients are not liable for certain debts under certain circumstances;
8 prohibiting a health occupations board, under certain circumstances, from revoking,
9 failing to renew, suspending, or taking certain action against a health care provider's
10 license based solely on a certain recommendation of the health care provider;
11 prohibiting the Department of Health and Mental Hygiene from taking action
12 against a health care provider's Medicare certification based solely on a certain
13 recommendation of the health care provider; prohibiting an official, employee, or
14 agent of the State from blocking or attempting to block a certain patient's access to
15 an investigational drug, biological product, or device; establishing that this Act does
16 not create a certain cause of action; providing for the effect of certain provisions of
17 this Act; defining certain terms; and generally relating to the provision of
18 investigational drugs, biological products, and devices in the State.

19 BY adding to

20 Article – Health – General

21 Section 21–2B–01 through 21–2B–07 to be under the new subtitle “Subtitle 2B. Right
22 to Try Act”

23 Annotated Code of Maryland

24 (2015 Replacement Volume)

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

27 **Article – Health – General**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 **(3) AT A MINIMUM:**

2 **(I) EXPLAINS THE CURRENTLY APPROVED PRODUCTS AND**
3 **TREATMENTS FOR THE DISEASE OR CONDITION FROM WHICH THE PATIENT**
4 **SUFFERS;**

5 **(II) ATTESTS TO THE FACT THAT THE PATIENT CONCURS WITH**
6 **THE PATIENT'S TREATING PHYSICIAN IN BELIEVING THAT ALL CURRENTLY**
7 **APPROVED AND CONVENTIONALLY RECOGNIZED TREATMENTS ARE UNLIKELY TO**
8 **PROLONG THE PATIENT'S LIFE;**

9 **(III) IDENTIFIES CLEARLY THE SPECIFIC PROPOSED**
10 **INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT THE PATIENT IS**
11 **SEEKING TO USE;**

12 **(IV) DESCRIBES THE BEST AND WORST POTENTIAL OUTCOMES**
13 **OF USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE WITH A**
14 **REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME, INCLUDING THE**
15 **POSSIBILITY THAT NEW, UNANTICIPATED, DIFFERENT, OR WORSE SYMPTOMS MIGHT**
16 **RESULT, AND THAT DEATH COULD BE HASTENED BY THE PROPOSED TREATMENT,**
17 **BASED ON THE TREATING PHYSICIAN'S KNOWLEDGE OF THE PROPOSED TREATMENT**
18 **IN CONJUNCTION WITH AN AWARENESS OF THE PATIENT'S CONDITION;**

19 **(V) MAKES CLEAR THAT THE PATIENT'S HEALTH INSURANCE**
20 **CARRIER AND HEALTH CARE PROVIDER ARE NOT OBLIGATED TO PAY FOR ANY CARE**
21 **OR TREATMENTS THAT MAY BE NECESSARY AS A RESULT OF THE USE OF THE**
22 **INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE UNLESS THEY ARE**
23 **SPECIFICALLY REQUIRED TO DO SO BY LAW OR CONTRACT;**

24 **(VI) MAKES CLEAR THAT THE PATIENT'S ELIGIBILITY FOR**
25 **HOSPICE CARE MAY BE WITHDRAWN IF THE PATIENT BEGINS CURATIVE TREATMENT**
26 **WITH THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, AND THAT**
27 **HOSPICE CARE MAY BE REINSTATED IF THIS TREATMENT ENDS AND THE PATIENT**
28 **MEETS HOSPICE ELIGIBILITY REQUIREMENTS; AND**

29 **(VII) STATES THAT THE PATIENT UNDERSTANDS THAT THE**
30 **PATIENT IS LIABLE FOR ALL EXPENSES RELATING TO THE USE OF THE**
31 **INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, AND THAT THIS**
32 **LIABILITY EXTENDS TO THE PATIENT'S ESTATE UNLESS A CONTRACT BETWEEN THE**
33 **PATIENT AND THE MANUFACTURER OF THE INVESTIGATIONAL DRUG, BIOLOGICAL**
34 **PRODUCT, OR DEVICE STATES OTHERWISE.**

1 (E) "INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE" MEANS
2 A DRUG, BIOLOGICAL PRODUCT, OR DEVICE THAT:

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

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

8 (F) "TERMINAL ILLNESS" MEANS A DISEASE OR CONDITION THAT, WITHOUT
9 LIFE-SUSTAINING PROCEDURES, WILL RESULT IN DEATH, OR A STATE OF
10 PERMANENT UNCONSCIOUSNESS FROM WHICH RECOVERY IS UNLIKELY, WITHIN 12
11 MONTHS.

12 21-2B-02.

13 A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT,
14 OR DEVICE MAY:

15 (1) PROVIDE THE MANUFACTURER'S INVESTIGATIONAL DRUG,
16 BIOLOGICAL PRODUCT, OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT
17 COMPENSATION; OR

18 (2) REQUIRE AN ELIGIBLE PATIENT TO PAY THE COSTS OF, OR THE
19 COSTS ASSOCIATED WITH, THE MANUFACTURE OF THE INVESTIGATIONAL DRUG,
20 BIOLOGICAL PRODUCT, OR DEVICE PROVIDED TO THE ELIGIBLE PATIENT.

21 21-2B-03.

22 IF AN ELIGIBLE PATIENT DIES WHILE BEING TREATED WITH AN
23 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, THE ELIGIBLE
24 PATIENT'S HEIRS ARE NOT LIABLE FOR ANY OUTSTANDING DEBT RELATED TO THE
25 TREATMENT OR LACK OF INSURANCE COVERAGE FOR THE TREATMENT.

26 21-2B-04.

27 (A) A HEALTH OCCUPATIONS BOARD MAY NOT REVOKE, FAIL TO RENEW,
28 SUSPEND, OR TAKE ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE
29 BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATION TO AN
30 ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN
31 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, PROVIDED THE
32 RECOMMENDATION IS CONSISTENT WITH MEDICAL STANDARDS OF CARE.

1 **(B) THE DEPARTMENT MAY NOT TAKE ACTION AGAINST A HEALTH CARE**
2 **PROVIDER'S MEDICARE CERTIFICATION BASED SOLELY ON THE HEALTH CARE**
3 **PROVIDER'S RECOMMENDATION THAT AN ELIGIBLE PATIENT HAVE ACCESS TO AN**
4 **INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.**

5 **21-2B-05.**

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

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

12 **21-2B-06.**

13 **THIS SUBTITLE DOES NOT CREATE A PRIVATE CAUSE OF ACTION AGAINST A**
14 **MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR**
15 **DEVICE OR AGAINST ANOTHER PERSON INVOLVED IN THE CARE OF AN ELIGIBLE**
16 **PATIENT USING THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE,**
17 **FOR ANY HARM TO THE ELIGIBLE PATIENT RESULTING FROM THE INVESTIGATIONAL**
18 **DRUG, BIOLOGICAL PRODUCT, OR DEVICE IF THE MANUFACTURER OR OTHER**
19 **PERSON IS COMPLYING IN GOOD FAITH WITH THIS SUBTITLE AND HAS EXERCISED**
20 **REASONABLE CARE.**

21 **21-2B-07.**

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

24 **SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect**
25 **October 1, 2016.**