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3lr1663 CF 3lr2933

### By: Senators Madaleno, Forehand, Garagiola, and Rosapepe Introduced and read first time: February 1, 2013 Assigned to: Finance

## A BILL ENTITLED

#### 1 AN ACT concerning

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## Tobacco–Related Disease Products Research, Development, and Commercialization Program

4 FOR the purpose of establishing the Tobacco-Related Disease Products Research,  $\mathbf{5}$ Development, and Commercialization Program; specifying the purpose of the 6 Program; establishing the Tobacco-Related Disease Products Research, 7 Development, and Commercialization Fund as a special, nonlapsing fund; 8 specifying the purpose of the Fund; requiring the Maryland Biotechnology 9 Center in the Department of Business and Economic Development to administer the Fund; requiring the State Treasurer to hold the Fund and the Comptroller 10 to account for the Fund; specifying the contents of the Fund; specifying the 11 12purpose for which the Fund may be used; providing for the investment of money 13 in and expenditures from the Fund; establishing certain criteria and certain award amounts for grants awarded under the Program; requiring certain 1415recipients of Program funds to pay a certain royalty; authorizing the 16 Department to adopt certain regulations; exempting the Fund from a certain 17provision of law requiring interest on State money in special funds to accrue to the General Fund of the State; requiring the Governor to make a certain 1819appropriation from the Cigarette Restitution Fund each year under certain 20circumstances; defining certain terms; and generally relating to the Tobacco-Related 21Disease Products Research. Development. and 22Commercialization Program.

- 23 BY adding to
- 24 Article Economic Development
- Section 5–1401 through 5–1406 to be under the new subtitle "Subtitle 14.
   Tobacco–Related Disease Products Research, Development, and Commercialization Program"
- 28 Annotated Code of Maryland
- 29 (2008 Volume and 2012 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 BY repealing and reenacting, with amendments,

- 2 Article State Finance and Procurement
- 3 Section 6–226(a)(2)(ii)69. and 70. and 7–317(g)
- 4 Annotated Code of Maryland
- 5 (2009 Replacement Volume and 2012 Supplement)
- 6 BY adding to
- 7 Article State Finance and Procurement
- 8 Section 6–226(a)(2)(ii)71.
- 9 Annotated Code of Maryland
- 10 (2009 Replacement Volume and 2012 Supplement)

## 11 Preamble

12 WHEREAS, The United States Surgeon General has determined that cigarette 13 smoking causes lung cancer, heart disease, and other serious diseases and that there 14 are hundreds of tobacco-related deaths in the United States each year; and

15 WHEREAS, Because cigarette smoking presents serious public health concerns, 16 leading United States tobacco product manufacturers entered into a settlement 17 agreement on November 23, 1998, entitled the "Master Settlement Agreement" with 18 the State of Maryland; and

WHEREAS, The Master Settlement Agreement obligates these manufacturers
to pay substantial sums to the State of Maryland, in return for a release of past,
present, and certain future claims against them as described in the Agreement; and

WHEREAS, The Master Settlement Agreement has resulted in approximately
 \$1.5 billion in payments to the State of Maryland from leading United States tobacco
 product manufacturers; and

WHEREAS, The State of Maryland received approximately \$150 million in fiscal year 2012 through the Master Settlement Agreement and annual payments are anticipated for at least the next 15 years; and

WHEREAS, The Biotechnology Industry Organization reports that 16 states have used funds from the Master Settlement Agreement to support the biotechnology industry in those states; and

31 WHEREAS, Although the biotechnology industry is a pillar of job creation in 32 the State, to date Maryland has not used any funds from the Master Settlement 33 Agreement to support its biotechnology industry; and

34 WHEREAS, Small biotechnology companies have access to only approximately 35 3% of the \$27 billion in yearly grant funding for research and development provided 36 through the National Institutes of Health; now, therefore,

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$\frac{1}{2}$	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
3	Article – Economic Development
4 5	SUBTITLE 14. TOBACCO-RELATED DISEASE PRODUCTS RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION PROGRAM.
6	5-1401.
7 8	(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
9 10 11	(B) "FUND" MEANS THE TOBACCO-RELATED DISEASE PRODUCTS RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION FUND ESTABLISHED UNDER § 5-1403 OF THIS SUBTITLE.
$12 \\ 13 \\ 14$	(C) "PROGRAM" MEANS THE TOBACCO-RELATED DISEASE PRODUCTS RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION PROGRAM ESTABLISHED UNDER § 5-1402 OF THIS SUBTITLE.
15	5–1402.
$\frac{16}{17}$	(A) THERE IS A TOBACCO-RELATED DISEASE PRODUCTS RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION PROGRAM IN THE DEPARTMENT.
18 19 20	(B) THE PURPOSE OF THE PROGRAM IS TO PROMOTE THE RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION OF INNOVATIVE PRODUCTS AND TECHNOLOGIES THAT ADDRESS TOBACCO-RELATED DISEASES.
21	5-1403.
$\frac{22}{23}$	(A) THERE IS A TOBACCO-RELATED DISEASE PRODUCTS RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION FUND IN THE DEPARTMENT.
$24 \\ 25$	(B) THE PURPOSE OF THE FUND IS TO PROVIDE GRANT MONEY TO SUPPORT THE PURPOSES OF THE PROGRAM.
$\frac{26}{27}$	(C) THE MARYLAND BIOTECHNOLOGY CENTER IN THE DEPARTMENT SHALL ADMINISTER THE FUND.
$\frac{28}{29}$	(D) (1) THE FUND IS A SPECIAL, NONLAPSING FUND THAT IS NOT SUBJECT TO § 7–302 OF THE STATE FINANCE AND PROCUREMENT ARTICLE.

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$\frac{1}{2}$	(2) THE STATE TREASURER SHALL HOLD THE FUND SEPARATELY, AND THE COMPTROLLER SHALL ACCOUNT FOR THE FUND.
3	(E) THE FUND CONSISTS OF:
4 5 6	(1) MONEY APPROPRIATED IN THE STATE BUDGET TO THE FUND FROM THE CIGARETTE RESTITUTION FUND ESTABLISHED UNDER § 7–317 OF THE STATE FINANCE AND PROCUREMENT ARTICLE;
7	(2) ROYALTIES RECEIVED UNDER § 5–1405 OF THIS SUBTITLE;
8	(3) INVESTMENT EARNINGS OF THE FUND; AND
9 10	(4) ANY OTHER MONEY FROM ANY OTHER SOURCE ACCEPTED FOR THE BENEFIT OF THE FUND.
11 12 13	(F) THE FUND SHALL BE USED TO COVER THE COSTS OF THE PROGRAM, INCLUDING ANY GRANTS THAT ARE AWARDED TO ELIGIBLE RECIPIENTS.
$\begin{array}{c} 14 \\ 15 \end{array}$	(G) (1) THE STATE TREASURER SHALL INVEST THE MONEY OF THE FUND IN THE SAME MANNER AS OTHER STATE MONEY MAY BE INVESTED.
16 17	(2) ANY INVESTMENT EARNINGS OF THE FUND SHALL BE PAID INTO THE FUND.
18 19	(H) EXPENDITURES FROM THE FUND MAY BE MADE ONLY IN ACCORDANCE WITH THE STATE BUDGET.
20	5–1404.
21 22 23 24 25 26	(A) IN CONSULTATION WITH THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE, THE MARYLAND BIOTECHNOLOGY CENTER IN THE DEPARTMENT SHALL AWARD GRANTS TO APPLICANTS FOR RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION OF INNOVATIVE PRODUCTS AND TECHNOLOGIES THAT ADDRESS TOBACCO-RELATED DISEASES, INCLUDING THERAPEUTICS, DIAGNOSTICS, AND MEDICAL DEVICES.
27 28	(B) THE DEPARTMENT SHALL AWARD GRANTS TO APPLICANTS ON A COMPETITIVE BASIS, WITH PRIORITY GIVEN TO THE FOLLOWING CRITERIA:
29 30	(1) THE TECHNICAL AND SCIENTIFIC MERIT OF THE APPLICANT'S PROPOSAL AND ITS POTENTIAL ABILITY TO ADDRESS THE UNMET MEDICAL

NEEDS OF THE CITIZENS OF MARYLAND, INCLUDING THE NEEDS OF SMOKERS,
 FORMER SMOKERS, AND NONSMOKERS EXPOSED TO SECONDHAND SMOKE;

3 (2) THE DEGREE OF THE ASSOCIATION BETWEEN CIGARETTE 4 SMOKING AND THE DISEASE BEING ADDRESSED BY THE APPLICANT'S 5 PROPOSAL;

6 (3) THE AMOUNT OF TIME THE PROPOSAL IS LIKELY TO TAKE TO 7 RESULT IN A LATE-STAGE CLINICAL TRIAL OR A MARKETED PRODUCT, WITH 8 PRIORITY GIVEN TO:

9 (I) IN THE CASE OF THERAPEUTICS, PROPOSALS 10 REASONABLY LIKELY TO RESULT IN A LATE–STAGE CLINICAL TRIAL WITHIN 3 11 YEARS FROM THE END OF THE PROJECT PERIOD; OR

(II) IN THE CASE OF DEVICES AND DIAGNOSTICS,
PROPOSALS REASONABLY LIKELY TO RESULT IN A MARKETED PRODUCT WITHIN
3 YEARS OF THE END OF THE PROJECT PERIOD;

15(4) THE APPLICANT'S TRACK RECORD IN BRINGING PRODUCTS TO16MARKET;

17(5) THE APPLICANT'S TRACK RECORD IN LEVERAGING OTHER18FUNDING SOURCES, INCLUDING PRIVATE CAPITAL; AND

19(6) THE POTENTIAL FOR THE CREATION OF NEW JOBS IN THE20STATE THAT CAN BE SUSTAINED WITHOUT CONTINUED STATE FUNDING,21INCLUDING MANUFACTURING JOBS.

22 (C) AN APPLICANT MAY NOT RECEIVE MORE THAN ONE GRANT AWARD 23 PER FISCAL YEAR.

24 (D) GRANT AWARDS SHALL BE IN THE FOLLOWING AMOUNTS:

25 (1) **\$200,000** FOR A SINGLE COMPANY; OR

26 (2) \$300,000 FOR A COMPANY COLLABORATING WITH A 27 NONPROFIT MEDICAL RESEARCH INSTITUTE OR CARE FACILITY IN THE STATE.

28 **5–1405.** 

29 (A) (1) PROGRAM RECIPIENTS WHO DEVELOP OR IMPROVE A 30 PRODUCT OR SERVICE WITH MONEY FROM THE FUND, WHICH RESULTS IN A

1 2	MARKETED PRODUCT OR SERVICE, SHALL PAY THE STATE A ROYALTY OF 3% OF NET SALES OF THE PRODUCT OR SERVICE.
3 4 5	(2) THE TOTAL AMOUNT OF A ROYALTY PAID BY A PROGRAM RECIPIENT UNDER THIS SECTION MAY NOT BE MORE THAN 300% OF THE AMOUNT OF THE GRANT RECEIVED UNDER THE PROGRAM.
6 7	(B) ROYALTIES RECEIVED UNDER THIS SECTION SHALL BE DEPOSITED IN THE FUND AND USED TO PROVIDE FUTURE AWARDS UNDER THE PROGRAM.
8	5–1406.
9 10	THE DEPARTMENT MAY ADOPT REGULATIONS TO IMPLEMENT THE PROVISIONS OF THIS SECTION.
11	<b>Article – State Finance and Procurement</b>
12	6–226.
$\frac{13}{14}$	(a) (2) (ii) The provisions of subparagraph (i) of this paragraph do not apply to the following funds:
15	69. the Maryland Legal Services Corporation Fund; [and]
$\begin{array}{c} 16 \\ 17 \end{array}$	70. Mortgage Loan Servicing Practices Settlement Fund; AND
18 19	71. TOBACCO–RELATED DISEASE PRODUCTS RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION FUND.
20	7–317.
$\begin{array}{c} 21 \\ 22 \end{array}$	(g) (1) Amounts may only be expended from the Fund through appropriations in the State budget bill as provided in this subsection.
23 24 25 26	(2) The Governor shall include in the annual budget bill appropriations from the Fund equivalent to the lesser of \$100,000,000 or 90% of the funds estimated to be available to the Fund in the fiscal year for which the appropriations are made.
27 28 29 30	(3) For each fiscal year for which appropriations are made, at least 50% of the appropriations shall be made for those purposes enumerated in subsection $(f)(1)(i)$ , $(ii)$ , and $(iii)1$ through 9 of this section subject to the requirement of subsection $(e)(2)$ of this section.

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1 (4) **(I)** For each fiscal year for which appropriations are made, at 2 least 30% of the appropriations shall be made for the purposes of the Maryland 3 Medical Assistance Program.

4 (II) FROM THE APPROPRIATIONS MADE UNDER 5 SUBPARAGRAPH (I) OF THIS PARAGRAPH, \$3,000,000 SHALL BE APPROPRIATED 6 TO THE TOBACCO-RELATED DISEASE PRODUCTS RESEARCH, DEVELOPMENT, 7 AND COMMERCIALIZATION FUND ESTABLISHED UNDER § 5–1403 OF THE 8 ECONOMIC DEVELOPMENT ARTICLE.

9 (5) For each fiscal year for which appropriations are made, 0.15% of 10 the Fund shall be appropriated for the purposes of enforcement of Title 16, Subtitle 5 11 of the Business Regulation Article.

12 (6) Any additional appropriations, not subject to paragraph (3), 13 paragraph (4), or paragraph (5) of this subsection, may be made for any lawful 14 purpose.

15 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect16 July 1, 2013.