

HOUSE BILL NO. 565

INTRODUCED BY K. MCCARTHY

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A BILL FOR AN ACT ENTITLED: "AN ACT ESTABLISHING THE BIOSCIENCE DISCOVERY, EVALUATION, AND DEVELOPMENT PROGRAM; REQUIRING THE GOVERNOR'S OFFICE OF ECONOMIC DEVELOPMENT TO ADMINISTER THE PROGRAM; PROVIDING FOR A PROGRAM ADVISORY BOARD; PROVIDING AN APPROPRIATION; PROVIDING RULEMAKING AUTHORITY; AND PROVIDING AN EFFECTIVE DATE."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Legislative findings.** The legislature finds that:

- (1) additional resources are needed to assist in improving the evaluation process for bioscience research discoveries with commercial potential and accelerating the translational development of these discoveries;
- (2) advancing bioscience research discoveries toward commercialization would support the development of new bioscience products and services in Montana;
- (3) the development of products and services from research discoveries that originate in Montana will help to create new bioscience companies and additional primary jobs in Montana;
- (4) the bioscience discovery, evaluation, and development program will help support partnership efforts between the bioscience industry and research institutions to build infrastructure that supports the commercialization of therapeutics, diagnostic products, devices, or instruments that improve human health; and
- (5) it is in the best interests of the state's economic growth to dedicate financial resources to facilitate the development of new bioscience research discoveries in Montana and promote Montana-based bioscience technologies.

NEW SECTION. **Section 2. Definitions.** As used in [sections 1 through 3], the following definitions

apply:

- (1) "Bioscience" means technologies based on life sciences ~~that involve the development of therapeutics, diagnostics, or devices.~~
- (2) "Early-stage bioscience company" means a company with less than 100 employees that is engaged in the development of ~~novel biomedical therapies, diagnostics, or devices~~ BREAKTHROUGH PRODUCTS AND



1 TECHNOLOGIES TO COMBAT DISEASES, PRODUCE BIOFUELS, ADVANCE BIOLOGICAL AND MEDICAL RESEARCH, OR IMPROVE
 2 PUBLIC HEALTH.

3 (3) "Office" means the governor's office of economic development.

4 (4) "Program" means the bioscience discovery, evaluation, and development program.

5 (5) "Proof-of-concept study" means a rigorous study that determines the commercialization potential of
 6 a technology and that can be used to determine whether or not to move a technology forward at a decision point.

7 (6) "Research institution" means a public or private entity that conducts ~~biomedical~~ BIOSCIENCE research.

8 (7) "Technology transfer office" means an office at a public or private research institution that is
 9 responsible for the translational development and commercialization of potentially promising technologies.

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 11 NEW SECTION. Section 3. Bioscience discovery, evaluation, and development program -- grant

12 criteria -- rulemaking. (1) There is a bioscience discovery, evaluation, and development program administered
 13 by the governor's office of economic development.

14 (2) The office shall establish a VOLUNTARY FIVE-MEMBER program advisory board to aid in the
 15 implementation of the program, including but not limited to the review of program grant applications and the
 16 evaluation of progress made by the recipients of program grants.

17 (3) (a) The office must use ~~at least 50%~~ of program funds appropriated by the legislature to award grants
 18 to technology transfer offices, GRANT AND SPONSORED PROGRAM OFFICES, and early-stage bioscience companies
 19 located in Montana for the purpose of supporting development of bioscience discoveries through rigorous
 20 proof-of-concept studies.

21 (b) Grants must be:

22 (i) provided in amounts of ~~\$25,000 to \$50,000~~ UP TO \$35,000;

23 (ii) matched equally by nonstate funds; and

24 (iii) evaluated by the program advisory board.

25 (c) To be eligible for grant support, technology transfer offices ~~at research institutions~~, GRANT AND
 26 SPONSORED PROGRAM OFFICES, or early-stage bioscience companies shall submit to the office:

27 (i) an executive summary that provides an overview of the technology to be tested, including a market
 28 assessment;

29 (ii) a description of the proposed proof-of-concept studies, including experimental design with methods
 30 and qualifications of personnel involved;

- 1 (iii) evidence of nonstate matching funds at least equal to the amount applied for under the program;
- 2 (iv) an analysis of how the scope of work proposed will enhance the commercialization potential of the
- 3 technology or why the proposed scope of work is required to support the acquisition of subsequent funding; AND
- 4 (V) EVIDENCE OF A DEMONSTRATED EFFORT TO SECURE FOLLOW-ON FUNDING FROM NONSTATE SOURCES, SUCH
- 5 AS FEDERAL SMALL BUSINESS INNOVATION RESEARCH PHASE 1 AWARDS, VENTURE CAPITAL, OR ANGEL INVESTMENT.
- 6 ~~(4) The office may use up to 50% of program funds provided by the legislature to support:~~
- 7 ~~(a) partnership efforts between the bioscience industry and research institutions;~~
- 8 ~~(b) preclinical evaluation of discoveries;~~
- 9 ~~(c) securing provisional patents;~~
- 10 ~~(d) market assessments of technologies; and~~
- 11 ~~(e) staff and operations in the administration of the program.~~

12 ~~(5)~~(4) Grantees shall provide the office with a final report describing the outcomes of the studies upon

13 completion of work supported by the grant.

14 ~~(6)~~(5) The office shall develop reasonable outcome measures to determine the success of the program

15 and report to the economic affairs interim committee by September 15 immediately preceding each regular

16 legislative session.

17 ~~(7)~~(6) In consultation with the advisory board, the office shall adopt rules to implement the program.

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19 NEW SECTION. Section 4. Appropriation. There is appropriated from the state general fund to the

20 governor's office of economic development ~~\$1 million~~ \$350,000 in each year of the biennium beginning July 1,

21 2013, for the purposes described in [sections 1 through 3].

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23 NEW SECTION. Section 5. Codification instruction. [Sections 1 through 3] are intended to be codified

24 as an integral part of Title 90, chapter 3, and the provisions of Title 90, chapter 3, apply to [sections 1 through 3].

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26 NEW SECTION. Section 6. Effective date. [This act] is effective July 1, 2013.

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