

114TH CONGRESS
1ST SESSION

S. 2443

To support the establishment of a Standards Coordinating Body in
Regenerative Medicine and Advanced Therapies.

IN THE SENATE OF THE UNITED STATES

JANUARY 12, 2016

Ms. BALDWIN introduced the following bill; which was read twice and referred
to the Committee on Health, Education, Labor, and Pensions

A BILL

To support the establishment of a Standards Coordinating
Body in Regenerative Medicine and Advanced Therapies.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Advancing Standards
5 in Regenerative Medicine Act”.

1 **SEC. 2. SUPPORT FOR THE ESTABLISHMENT OF A STAND-**
2 **ARDS COORDINATING BODY IN REGENERA-**
3 **TIVE MEDICINE AND ADVANCED THERAPIES.**

4 Subchapter A of chapter V of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
6 ed by inserting after section 506F the following:

7 **“SEC. 506G. COORDINATING BODY IN REGENERATIVE MEDI-**
8 **CINE AND ADVANCED THERAPIES.**

9 “(a) IN GENERAL.—The Secretary, in consultation
10 with stakeholders, including regenerative medicine product
11 manufacturers and clinical trial sponsors, contract manu-
12 facturers, academic institutions, standard setting organi-
13 zations, the National Institute of Standards and Tech-
14 nology, and other relevant Federal agencies, as appro-
15 priate, shall facilitate establishment of a public-private
16 Standards Coordinating Body in Regenerative Medicine
17 and Advanced Therapies.

18 “(b) FUNCTION OF STANDARDS COORDINATING
19 BODY.—Upon establishment of the Standards Coordi-
20 nating Body in Regenerative Medicine and Advanced
21 Therapies under subsection (a), the Secretary shall—

22 “(1) identify opportunities for the development
23 of laboratory regulatory science research and docu-
24 mentary standards that the Secretary determines
25 would support the development, evaluation, and re-
26 view of regenerative medicine products; and

1 “(2) work with such Standards Coordinating
2 Body, as appropriate, in the development of stand-
3 ards described in paragraph (1).

4 “(c) GUIDANCE.—The Secretary shall issue guidance,
5 as appropriate, on how standards may be used in regu-
6 latory review for regenerative medicine and advanced
7 therapies.

8 “(d) DEFINITION.—For purposes of this section, the
9 term ‘regenerative medicine and advanced therapies’ in-
10 cludes cell therapy, gene therapy, gene-modified cell ther-
11 apy, therapeutic tissue engineering products, and human
12 cell and tissue products, and combination products using
13 any such therapies or products.

14 “(e) NO ADDITIONAL FUNDS.—The Secretary shall
15 carry out this section using funds otherwise made avail-
16 able to the Food and Drug Administration. No additional
17 funds are authorized to be appropriated to carry out this
18 section.”.

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