114TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Ms. BALDWIN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Advancing Standards in Regenerative Medicine Act".

SEC. 2. SUPPORT FOR THE ESTABLISHMENT OF A STANDARDS COORDINATING BODY IN REGENERATIVE MEDICINE AND ADVANCED THERAPIES.

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

"SEC. 506G. COORDINATING BODY IN REGENERATIVE MEDICINE AND ADVANCED THERAPIES.

''(a) IN GENERAL.—The Secretary, in consultation with stakeholders, including regenerative medicine product manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, standard setting organizations, the National Institute of Standards and Technology, and other relevant Federal agencies, as appropriate, shall facilitate establishment of a public-private Standards Coordinating Body in Regenerative Medicine and Advanced Therapies.

''(b) FUNCTION OF STANDARDS COORDINATING BODY.—Upon establishment of the Standards Coordinating Body in Regenerative Medicine and Advanced Therapies under subsection (a), the Secretary shall—

''(1) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would support the development, evaluation, and review of regenerative medicine products; and

''(2) work with such Standards Coordinating Body, as appropriate, in the development of standards described in paragraph (1).

''(c) GUIDANCE.—The Secretary shall issue guidance, as appropriate, on how standards may be used in regulatory review for regenerative medicine and advanced therapies.

''(d) DEFINITION.—For purposes of this section, the term 'regenerative medicine and advanced therapies' includes cell therapy, gene therapy, gene-modified cell therapy, therapeutic tissue engineering products, and human cell and tissue products, and combination products using any such therapies or products.

''(e) NO ADDITIONAL FUNDS.—The Secretary shall carry out this section using funds otherwise made available to the Food and Drug Administration. No additional funds are authorized to be appropriated to carry out this section.''.