AMENDMENT TO H.R. 4866

OFFERED BY M__. _____

Page 2, line 12, strike ''180 days'' and insert ''one year''.

Page 3, line 16, strike ''scalable''.

Page 3, line 18, strike ''biopharmaceutical'' and insert ''pharmaceutical''.

Page 4, line 5, after ''implementation of'' insert ''advanced manufacturing and''.

Page 4, line 7, strike ''the potential to participate in and lead a'' and insert ''experience in participating in and leading a''.

Page 4, line 10, strike ''biopharmaceutical'' and insert ''pharmaceutical''.

Page 4, lines 16 and 17, strike ''technical assistance for continuous manufacturing'' and insert ''technical assistance, which may include regulatory and quality metric guidance as applicable, for advanced manufacturing and continuous manufacturing''.

Page 5, lines 1 and 2, strike ''standardize systems and approaches'' and insert ''develop best practices''.

Page 5, lines 4 and 5, amend subparagraph (E) to read as follows:

''(E) to assess and respond to the workforce needs for continuous manufacturing, including the development of training programs if needed.

Page 6, strike lines 1 through 7 and insert the following paragraphs:

''(3) to develop, along with industry partners (which may include large and small biopharmaceutical manufacturers, generic and nonprescription manufacturers, and contract manufacturers) and another institution or institutions designated under this section, if any, a roadmap for developing a continuous manufacturing workforce;

''(4) to develop, along with industry partners and other institutions designated under this section, a roadmap for strengthening existing, and developing new, relationships with other institutions; and

''(5) to provide an annual report to the Food and Drug Administration regarding the institution's activities under this section, including a description of how the institution continues to meet and make progress on the criteria listed in subsection (c).

Page 6, line 10, after ''funding'' insert '', through grants, contracts, or cooperative agreements,''.

Page 6, lines 17 and 18, strike subparagraph (B) (and make such conforming changes as may be necessary).

Page 6, after line 20, insert the following new paragraph (and redesignate the subsequent paragraph accordingly):

''(2) CONSISTENCY WITH FDA MISSION.—As a condition on receipt of funding under this subsection, a National Center of Excellence shall agree to consider any input from the Secretary regarding the use of funding that would—

''(A) help to further the advancement of continuous manufacturing through the National Center of Excellence; and

''(B) be relevant to the mission of the Food and Drug Administration.

Page 8, line 6, strike ''in collaboration with'' and insert ''in consultation with''.

Page 8, line 17, after ''how'' insert ''advanced manufacturing and''.

Page 8, after line 20, insert the following new subparagraph (and make such conforming changes as may be necessary):

''(C) appropriate feedback solicited from the public, which may include other institutions, large and small biopharmaceutical manufacturers, generic and nonprescription manufacturers, and contract manufacturers.

Page 8, lines 19 and 20, strike '', review, and approval process for drugs and biological products'' and insert ''of pharmaceuticals and regulatory responsibilities of the Food and Drug Administration''.

Page 8, after line 21, insert the following new paragraph (and make such conforming changes as may be necessary):

''(1) ADVANCED MANUFACTURING.—The term 'advanced manufacturing' means an approach for the manufacturing of pharmaceuticals that incorporates novel technology, or uses an established technique or technology in a new or innovative way (such as continuous manufacturing where the input materials are continuously transformed within the process by two or more unit operations) that en-

hances drug quality or improves the manufacturing process.

Page 8, strike lines 22 through 25 (the ''biological product'' definition) (and make such conforming changes as may be necessary).

Page 9, strike lines 11 through 13 (the ''drug'' definition) (and make such conforming changes as may be necessary).