AMENDMENT NO._____ Calendar No._____

Purpose: To improve the bill.

IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.

S. 1895

To lower health care costs.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Sen. BURR

Viz:

At the appropriate place in title II, insert the following:

SEC. 2___. MISBRANDED DRUGS AND DEVICES.

Paragraph (a) of section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended to read as follows:

"(a)(1)(A) If its labeling is false or misleading in any particular.

"(B) Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs or devices for coverage, or reimbursement,

shall not be considered to be false or misleading under this paragraph, or a violation of section 505 of this Act or section 351 of the Public Health Service Act, if the health care economic information relates to an indication approved, cleared, or licensed under section 505, 513, 510, or 515 of this Act or under section 351(a) or (k) of the Public Health Service Act for such drug or device, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 of this Act or under section 351 of the Public Health Service Act, or a device approved, cleared, or classified under section 510, 513, or 515. The requirements set forth in section 505(a), 510(k), 513(f)(2), or 515(c), or in subsections (a) and (k) of section 351 of the Public Health Service Act shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this subparagraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this subparagraph shall be made available to the Secretary upon request.

"(C) Medical product development information provided to a payor, formulary committee, or other similar

entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement, shall not be considered to be false or misleading under this subparagraph, or a violation of section 505 of this Act or section 351 of the Public Health Service Act, if the medical product development information relates to an investigational new drug or device or the investigational use of an approved drug or cleared device, and is based on information unbiased, factual, accurate, and non-misleading, and includes, where applicable a conspicuous and prominent statement describing any material differences between the medical product development information and the proposed labeling submitting with the application for the requested indication or use of the drug or device under section 505 of this Act or under section 351 of the Public Health Service Act, or device under section 510, 513, or 515 in cases that such drug or device is approved, cleared, or classified for another indication. Information provided to any payor, formulary committee, or other such similar entity, shall include a conspicuous and prominent statement consistent with subparagraph (2)(B)(ii) that such drug or device is not approved, cleared, or licensed by the Secretary.

"(2)(A) For purposes of subparagraph (1)(B), the term 'health care economic information' means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug or device. Such analysis may be comparative to the use of another drug or device to another health care intervention, or to no intervention, and may include information related to the duration of treatment, health care setting, burden of illness, dosing regiments, patient populations, surrogate or intermediate endpoints, clinical outcomes assessments and real world evidence, comparative effectiveness, adherence, and other such information as the Secretary may determines appropriate.

"(B)(i) For purposes of subparagraph (1)(C), the term 'medical product development information' means information related to an investigational new drug or device or the investigational use of an approved drug or cleared device, and may include the following information—

"(I) product information; information about the indication or indications sought; an anticipated timeline for possible approval, clearance, or licensure

of the product or of the new use; product pricing information; patient utilization projections; product-related programs or services; results from studies, including clinical studies of drugs or devices or bench tests that describe performance; and

"(II) other information as the Secretary may determine appropriate, including any updated information related to product development.

"(ii) The information described in subclause (i) shall be accompanied by a clear statement that such product is not approved or safety and effectiveness is not yet confirmed, applicable information related to the stage of product development or clinical studies, study design, or other supplemental information that the Secretary determines appropriate to include related to the unapproved product or unapproved use or uses of such approved product.

"(C)(i) The information described in clause (A) does not include any analysis that relates only to an indication that is not approved under section 505 of this Act or under section 351 of the Public Health Service Act for such drug.

"(ii) The information described in subparagraph (2)(B) shall not include—

"(I) study characterizations or characterizing conclusions; or

"(II) information representing that an unapproved product is approved, cleared, or licensed, or has otherwise been determined to be safe or effective, or information representing that an unapproved use of an approved, cleared, or licensed product is safe or effective for the use for which it is being studied.".