AMENDMENT

OFFERED BY MR. GRIFFITH OF VIRGINIA

At the end of title VIII, add the following:

SEC. 803. COMMUNICATIONS REGARDING INTENDED USES OF DRUGS AND DEVICES; SCIENTIFIC EXCHANGE.

The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 201 of such Act (21 U.S.C. 321) the following:

"SEC. 201A. INTENDED USES OF DRUGS AND DEVICES.

''(a) INTENDED USE.—For purposes of this Act, including sections 301(d), 502(f)(1), 505, 510, 513, and 515, and for purposes of section 351 of the Public Health Service Act, the intended use of a drug or device shall not be determined by reference to—

''(1) actual or constructive knowledge of the manufacturer or sponsor that such drug or device will be used in a manner that varies from the use approved, cleared, or licensed for marketing under section 505, 510, 513, or 515 of this Act or section 351 of the Public Health Service Act;

''(2) non-public statements about the drug or device that are not reflected in any claim, pro-

motional statement or material, or circumstances surrounding the distribution of the drug or device that involve interactions with third parties; or

''(3) communications meeting the criteria under subsection (b) to be considered scientific exchange safe harbor communications.

''(b) SCIENTIFIC EXCHANGE SAFE HARBOR.—

''(1) IN GENERAL.—A communication by a manufacturer or sponsor, or a person acting on behalf of a manufacturer or sponsor, about information that is not included in the drug or device labeling required by this Act, constitutes a scientific exchange safe harbor communication if—

''(A) the communication is not advertising or otherwise promotional in nature;

''(B) the communication is supported by competent and reliable scientific evidence;

''(C) the communication clearly discloses appropriate contextual information about the data presented, including information about limitations of the data, the scientific and analytical methodologies used, and any contradictory data or information known to the manufacturer or sponsor;

''(D) the communication includes a conspicuous and prominent statement about such information not being contained in the drug or device labeling required by this Act; and

''(E) if the communication relates to a use of a drug or device that has not been approved or cleared for marketing under section 505, 510, 513, or 515 of this Act or section 351 of the Public Health Service Act, the manufacturer or sponsor, or person acting on behalf of the manufacturer or sponsor, makes no representation that such use has been demonstrated to be safe or effective.

''(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

''(A) to authorize the Secretary to require that a manufacturer or sponsor submit an application, certification, or other such submission, or to seek the Secretary's review or approval, before, during, or subsequent to engaging in scientific exchange; or

''(B) to limit the ability of a manufacturer or sponsor to engage in communications or ac-

tivities not specified in this subsection, but that are otherwise permissible.''.