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AMENDMENT TO H.R. 3962

OFFERED BY MR. WELCH OF VERMONT AND MR. DEFAZIO OF OREGON

In section 1128H of the Social Security Act, as proprosed to be inserted by section 1451(a), insert after subsection (e) [page 902, after line 19] the following (and redesignate subsequent provisions and cross-references thereto accordingly):

"(f) BAN ON GIFTS.—

"(1) IN GENERAL.—It is unlawful for any applicable manufacturer or distributor to offer or give any gift (as defined in paragraph (2)) to a covered recipient (or to an entity or individual at the request of a covered recipient).

"(2) GIFT.—

"(A) IN GENERAL.—For purposes of paragraph (1) and subject to subparagraph (B), the term "gift" means any payment or transfer of value described in subsection (g)(8) or anything else of value.

"(B) EXCLUSIONS.—Such term does not include the following:

"(i) A payment or transfer of value described in subsection (g)(8)(C), except that for purposes of this clause, in applying clause (i) of such subsection, '$5' shall be deemed to be '$10'.

"(ii) A gift provided to a covered recipient if the covered recipient reimburses the manufacturer for the cost at fair market value.

"(iii) Charitable contributions to a nonprofit covered recipient—

"(I) to fund health care provided to a patient for free or on an income-sensitive sliding scale basis;

"(II) for a charitable fundraising event sponsored by a health care provider to benefit third-parties; or

"(III) to fund a fellowship or internship for a medical student or resident, as long as the fellowship or internship is not identified with the applicable manufacturer.

"(iv) Payment to the sponsor of a significant educational, medical, scientific, or

policy-making conference or seminar, provided—

"(I) the payment is not made directly to a health care provider, unless the provider is the sponsor;

"(II) funding is used solely for bona fide educational purposes; and

"(III) all program content is objective, free from industry control, and does not promote specific products.

"(v) Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided—

"(I) there is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities; and

"(II) the content of the presentation, including slides and written materials, is determined by the health care professional.

"(vi) For a bona fide clinical trial—

"(I) direct salary support per principal investigator and other health care professionals per year; and

"(II) expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.

"(vii) For a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry—

"(I) gross compensation;

"(II) direct salary support per health care professional; and

"(III) expenses paid on behalf of each health care professional.

"(viii) Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device

if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the applicable manufacturer.

"(ix) The provision, distribution, dissemination, or receipt of educational materials and consultation, including videos and other items, for the purpose of technical training of individual health care professionals on the effective use of a covered drug, device, biological, or medical supply.

"(x) Royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right.

"(xi) Other reasonable fees, payments, subsidies, or other economic benefits provided by an applicable manufacturer of covered drugs, devices, biologicals, or medical supplies at fair market value.

"(xii) Samples of a covered drug, device, biological, or medical supply provided to a health care provider for free distribution to patients.

"(xiii) The provision of reasonable quantities of medical device demonstration or evaluation units to a health care provider to assess the appropriate use and function of the product and determine whether and when to use or recommend the product in the future.

"(xiv) The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals and other items that serve a genuine educational function provided to a health care provider for the benefit of patients.

"(xv) Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

"(xvi) Rebates and discounts for covered drugs, devices, biologicals, or medical supplies provided in the normal course of business.

"(xvii) Labels approved by the federal Food and Drug Administration for covered drugs, devices, biologicals, or medical supplies.

"(3) OTHER DEFINITIONS.—For purposes of this subsection:

"(A) BONA FIDE CLINICAL TRIAL.—The term 'bona fide clinical trial' means a clinical trial that has been reviewed by the Food and Drug Administration,that constitutes "research" as such term is defined in section 46.102 of title 45 of the Code of Federal Regulations, and that reasonably can be considered to be of interest to scientists or health care professionals working in the particular field of inquiry.

"(B) CLINICAL TRIAL.—The term 'clinical trial' means any study assessing the safety or efficacy of covered drugs, devices, biologicals, or medical supplies administered alone or in combination with other covered drugs, devices,

biologicals, or medical supplies or other therapies, or assessing the relative safety or efficacy of covered drugs, devices, biologicals, or medical supplies in comparison with other covered drugs, devices, biologicals, or medical supplies or other therapies.

"(C) SIGNIFICANT EDUCATIONAL, SCIENTIFIC, OR POLICY-MAKING CONFERENCE OR SEMINAR.—The term 'significant educational, scientific, or policy-making conference or seminar' means an educational, scientific, or policy-making conference or seminar that—

"(i) is accredited by the Accreditation Council for Continuing Medical Education or a comparable organization; and

"(ii) offers continuing medical education credit, features multiple presenters on scientific research, or is authorized by the sponsoring association to recommend or make policy.

"(4) CLARIFICATION.—Nothing in this subsection shall preclude the disclosure or reporting requirements under this section for those items not subject to paragraph (1).".

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