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111TH CONGRESS
2D SESSION

H. R. 4615

To amend the Federal Food, Drug, and Cosmetic Act to require dentists to provide patients with a fact sheet before performing any dental restoration work, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 4, 2010

Ms. WATSON (for herself, Mr. STARK, Mr. CUMMINGS, Ms. KILPATRICK of Michigan, Ms. WOOLSEY, Mrs. NAPOLITANO, Ms. JACKSON LEE of Texas, Mr. KENNEDY, Ms. BORDALLO, Ms. CHU, Mr. HONDA, Mr. FALEOMAVAEGA, and Mr. PAYNE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require dentists to provide patients with a fact sheet before performing any dental restoration work, and for other purposes.

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 ''Consumers Have Options for Molar Protection Act of 2009'' or the ''CHOMP Act of 2009''.

SEC. 2. PROVISION OF FACT SHEET TO PATIENTS PRIOR TO DENTAL RESTORATION WORK.

(a) IN GENERAL.—Chapter III of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

"SEC. 311. PROVISION OF FACT SHEET TO PATIENTS PRIOR TO DENTAL RESTORATION WORK.

''(a) REQUIREMENT.—A dentist shall—

''(1) before performing any dental restoration work—

''(A) provide the patient with the fact sheet developed by the Secretary under subsection (b); and

''(B) obtain the patient's signature acknowledging receipt of the fact sheet; and

''(2) place a copy of the signed acknowledgment in the patient's record.

''(b) FACT SHEET.—

''(1) DEVELOPMENT.—The Secretary shall develop not later than 1 year after the date of the enactment of this section, and periodically review and update as scientifically warranted, a fact sheet describing and comparing the risks and efficacy of the various types of dental restorative materials that may be used to repair a patient's oral condition or defect.

''(2) CONTENTS.—The fact sheet developed under paragraph (1) shall include each of the following:

''(A) A description of the groups of materials that are available to the dental profession for restoration of an oral condition or defect.

''(B) A comparison of the relative benefits and detriments of each group of materials.

''(C) A comparison of the cost considerations associated with each group of materials.

''(D) A reference to encourage discussion between the patient and dentist regarding dental restorative materials and to inform the patient of his or her options.

''(3) AVAILABILITY.—The Secretary shall make the fact sheet developed under paragraph (1) available to all licensed dentists in the United States.

''(c) PENALTY.—

''(1) IN GENERAL.—Whoever violates subsection (a) shall be fined not more than $5,000.

''(2) CALCULATION.—In calculating the maximum authorized amount of a fine under paragraph (1), the number of violations shall be calculated by multiplying $5,000 by the number of dental restora-

tive materials placed into a patient's mouth in violation of subsection (a).

''(d) DEFINITIONS.—In this section:

''(1) The term 'dental restoration work'—

''(A) means the placement of a dental restorative material into a patient's mouth; and

''(B) excludes any surgical, endodontic, periodontic, or orthodontic dental procedure in which a dental restorative material is not used.

''(2) The term 'dental restorative material' means any structure or device placed into a patient's mouth with the intent that it remain there for an indefinite period beyond the completion of the dental procedure.

''(3) The term 'patient' means the patient or the patient's parent, legal guardian, or other authorized representative.''.

(b) APPLICABILITY.—The requirement of section 311(a) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies with respect to any dental restoration work (as defined in such section) on or after the date that is 2 years after the date of the enactment of this Act.

SEC. 3. LABELING OF DENTAL RESTORATIVE MATERIALS.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(aa) If it is a dental restorative material (as defined in section 311(d)), and its labeling fails to include text (developed by the Secretary) describing the health risks associated with the material.''.

(b) DEVELOPMENT OF TEXT.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall develop text to be included in the labeling of dental restorative material, as required by section 502(aa) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) APPLICABILITY.—The requirement of section 502(aa) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies with respect to any dental restorative material that is introduced or delivered for introduction into interstate commerce on or after the date that is 1 year after the date of the enactment of this Act.

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