

AMENDMENT TO _____
OFFERED BY M__ . _____

In section 2 of the bill, in findings (12), (30), and (43), strike the term “Food and Drug Administration” each place it appears and insert “Secretary of Health and Human Services”.

In section 2 of the bill, in findings (36), (44), (45), and (46), strike the term “Food and Drug Administration” each place it appears and insert “Department of Health and Human Services”.

In section 3 of the bill

(1) strike the term “Food and Drug Administration” each place it appears and insert “Secretary of Health and Human Services”; and

(2) in paragraph (1), strike “under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),”.

In the heading of title I of the bill, strike “**AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION**” and insert “**AUTHORITY OF THE SECRETARY OF HEALTH AND HUMAN SERVICES**”.

Amend section 101 of the bill to read as follows:

1 **SEC. 101. AUTHORITY OF THE SECRETARY OF HEALTH AND**
2 **HUMAN SERVICES.**

3 (a) ESTABLISHMENT OF CENTER.—There is estab-
4 lished within the Department of Health and Human serv-
5 ices the Tobacco Harm Reduction Center (in this section
6 referred to as the “Center”).

7 (b) CENTER HEAD.—

8 (1) IN GENERAL.—The Center shall be headed
9 by an Administrator to be appointed by the Presi-
10 dent with the advice and consent of the Senate who
11 shall have the authority provided under this Act,
12 perform the functions that relate to the subject mat-
13 ter of this Act, and have the authority to promulgate
14 regulations for the efficient enforcement of this Act.

15 (2) NO DELEGATION OF AUTHORITY.—Neither
16 the Secretary of Health and Human Services, the
17 Administrator, nor any other person is authorized to
18 delegate the functions or responsibilities assigned to
19 the Administrator under this Act to any other de-
20 partment, agency, bureau, center, administration, or
21 administrator.

22 (c) DEFINITION OF TOBACCO PRODUCTS.—In this
23 Act:

1 (1) The term “tobacco product” means any
2 product made or derived from tobacco that is in-
3 tended for human consumption, including any com-
4 ponent, part, or accessory of a tobacco product (ex-
5 cept for raw materials other than tobacco used in
6 manufacturing a component, part, or accessory of a
7 tobacco product).

8 (2) The term “tobacco product” does not in-
9 clude an article that is a drug under subsection
10 (g)(1) of section 201 of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 321), a device under
12 subsection (h) of such section, or a combination
13 product described in section 503(g) of that Act (21
14 U.S.C. 353(g)).

15 (3) A tobacco product may not be marketed in
16 combination with any other article or product regu-
17 lated under the Federal Food, Drug, and Cosmetic
18 Act (including a drug, biologic, food, cosmetic, med-
19 ical device, or a dietary supplement).

20 (d) EXCLUSION OF OTHER REGULATORY PRO-
21 GRAMS.—No tobacco product or nicotine-containing prod-
22 uct shall be regulated as a food, drug, or device under
23 subsection (f), (g), or (h) of section 201, or chapter IV
24 or V, of the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C 321(f), (g), or (h), 341 et seq., and 351 et seq.),

1 except that any tobacco product commercially distributed
2 domestically and any nicotine-containing product commer-
3 cially distributed domestically shall be subject to chapter
4 V of such Act if the manufacturer or a distributor of such
5 product markets it with an explicit claim that the product
6 is intended for use in the cure, mitigation, treatment, or
7 prevention of disease in man or other animals, within the
8 meaning of section 201(g)(1)(C) or section 201(h)(2) of
9 such Act.

Revise all amendments in the bill to the Federal Food, Drug, and Cosmetic Act to be freestanding provisions consistent with the authority of the Tobacco Harm Reduction Center described in the preceding amendment.

Revise all references in the bill to the Food and Drug Administration or the Commissioner of Food and Drugs to refer to the Department of Health and Human Services, the Secretary of Health and Human Services, the Tobacco Harm Reduction Center, or the Administrator of the Tobacco Harm Reduction Center, as appropriate consistent with the preceding amendments.