

AMENDMENT TO H.R. 4771

OFFERED BY MR. PITTS OF PENNSYLVANIA

Page 2, lines 9 through 11, strike clauses (li) and (lii) (and redesignate the subsequent subsections accordingly).

Page 4, lines 11 and 12, strike “and the limitations under section 201(i)(6)”.

Page 5, after line 24, insert the following (and make such conforming changes as may be necessary:

1 “(III) is not anabolic or
2 androgenic.”.

Page 6, line 13, strike “the list of anabolic steroids” and insert “the definition of anabolic steroids”.

Page 6, line 20 through 24, strike subparagraph (B) and insert the following:

3 “(B) adding such drug or other substance
4 to the definition of anabolic steroids will assist
5 in preventing abuse or misuse of the drug or
6 other substance.

Page 7, after line 10, insert the following (and redesignate the subsequent paragraphs accordingly):

1 “(3) The Attorney General shall transmit notice
2 of an order proposed to be issued under paragraph
3 (1) to the Secretary of Health and Human Services.
4 In issuing an order under paragraph (1), the Attor-
5 ney General shall take into consideration any com-
6 ments submitted by the Secretary in response to a
7 notice transmitted pursuant to this paragraph.

Page 7, line 18, strike “the list of anabolic steroids”
and insert “the definition of anabolic steroids”.

Page 8, lines 15 and 16, strike “unless it bears a
label clearly identifying” and insert “that does not bear
a label clearly identifying”.

Beginning on page 8, line 20, strike paragraph (2)
and insert the following:

8 “(2)(A) A product described in subparagraph
9 (B) is exempt from the International Union of Pure
10 and Applied Chemistry nomenclature requirement of
11 this subsection if such product is labeled in the man-
12 ner required under the Federal Food, Drug, and
13 Cosmetic Act.

14 “(B) A product is described in this subpara-
15 graph if the product—

1 “(i) is the subject of an approved applica-
2 tion as described in section 505(b) or (j) of the
3 Federal Food, Drug, and Cosmetic Act; or

4 “(ii) is exempt from the provisions of sec-
5 tion 505 of such Act relating to new drugs be-
6 cause—

7 “(I) it is intended solely for investiga-
8 tional use as described in section 505(i) of
9 such Act; and

10 “(II) such product is being used ex-
11 clusively for purposes of a clinical trial
12 that is the subject of an effective investiga-
13 tional new drug application.

