AMENDMENT TO
RULES COMMITTEE PRINT 115-76
OFFERED BY MR. BARTON OF TEXAS

At the end of title III, insert the following new section:

SEC. 304. HIGH-QUALITY, EVIDENCE-BASED OPIOID ANALGESIC PRESCRIBING GUIDELINES AND REPORT.

(a) GUIDELINES.—The Commissioner of Food and Drugs shall develop high-quality, evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain in the relevant therapeutic areas where such guidelines do not exist.

(b) PUBLIC INPUT.—In developing the guidelines under subsection (a), the Commissioner of Food and Drugs shall—

(1) conduct a public workshop, open to representatives of State medical societies and medical boards, various medical specialties including pain medicine specialty societies, patient groups, pharmacists, universities, and others; and

(2) provide a period for the submission of comments by the public.

(c) REPORT.—Not later than the date that is 2 years after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and post on the public website of the Food and Drug Administration, a report on how the guidelines under subsection (a) will be utilized to protect the public health.

(d) UPDATES.—The Commissioner of Food and Drugs shall periodically—

(1) update the guidelines under subsection (a), informed by public input described in subsection (b); and

(2) submit to the committees specified in subsection (c) and post on the public website of the Food and Drug Administration an updated report under subsection (c).

(e) STATEMENT TO ACCOMPANY GUIDELINES AND RECOMMENDATIONS.—The Commissioner of Food and Drugs shall ensure that any opioid analgesic prescribing guidelines and other recommendations developed under this section are accompanied by a clear statement that such guidelines or recommendations, as applicable—

(1) are intended to help inform clinical decision-making by prescribers and patients; and

(2) should not be used by other parties, including pharmacy benefit management companies, retail or community pharmacies, or public and private payors, for the purposes of restricting, limiting, delaying, or denying coverage for or access to a prescription issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

(f) DEFINITION.—In this section, the term ''evidence-based'' means informed by a robust and systemic review of treatment efficacy and clinical evidence.