PUBLICCITIZEN
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July 9, 2015

Dear Members of the United States House of Representatives:

Public Citizen, a patient advocacy organization with more than 400,000 members and supporters nationwide, continues to strongly oppose H.R. 6, the 21st Century Cures Act, because the legislation still carries several provisions that would undermine public health and threaten patient safety. Our most serious concerns, summarized in our May 13 letter to you,[1] relate to provisions that would lower standards for Food and Drug Administration (FDA) approval of medical devices and drugs (particularly with respect to antibiotics), scale back the requirements of the Physician Payment Sunshine Act, and extend marketing exclusivity for certain drugs.

We continue to urge you to oppose H.R. 6. Unfortunately, the following proposed amendments, which would have mitigated some of the damage that would result if H.R. 6 is enacted, were not made in order by the House Rules Committee.

For your information, we would have favored the following amendments offered:

(1) Amendment #2, offered by Representative Fitzpatrick. This amendment would have struck Subtitle M, which has several provisions that would undermine medical device safety, including the following:

- Section 2221 of Subtitle M would allow companies to make changes to even the highest-risk devices (such as brain stents and artificial heart valves) without first notifying the FDA or documenting that the modified device remains safe and effective. Instead, device manufacturers would pay a third-party contractor to certify that the manufacturer had an adequate "quality system," after which the manufacturer would be authorized to determine for itself whether each device remained safe and effective following a change. Changes to high-risk devices can be dangerous and alter device effectiveness and should not be exempted from FDA oversight.
- Section 2222 of Subtitle M would undermine FDA approval standards for high-risk devices by allowing the FDA to approve such devices based solely on low-quality evidence derived from medical anecdotes or articles from medical journals. Medical anecdotes (commonly referred to as "case histories") lack any control group and may include only one or a few patients, clearly constituting insufficient evidence for evaluating the safety and effectiveness of medical devices. Medical journal articles often leave out critical information or rely on mistakes, misrepresentations, or fraud, meaning the FDA may not learn of such problems before it approves a device if it relies solely on these published articles to support approval.

(2) Amendment #9, offered by Representative Fitzpatrick. This amendment would have struck Section 2221 of Subtitle M, discussed above.

(3) Amendment #20, offered by Representative Gosar. This amendment would have struck Section 2151 from Subtitle I, which would allow the FDA to grant a six-month extension of marketing

[1] Public Citizen. Letter to United States House of Representatives regarding the 21st Century Cures Act. May 13, 2015. http://www.citizen.org/documents/2258.pdf. Accessed July 9, 2015.

exclusivity if an existing drug is approved to treat a rare disease. This provision would increase health care costs and limit patient access to new drugs.

(4) Amendment #7, offered by Representative Fitzpatrick. This amendment would have strengthened the 510(k) premarket notification clearance process for medical devices. First, it would have prohibited finding a new medical device substantially equivalent to a predicate device if the predicate has been removed from the market by the Secretary of Health and Human Services or determined to be misbranded or adulterated by judicial order. The amendment also would have permitted the FDA to reject a claim of substantial equivalency for a medical device whose predicate has been corrected or removed from the market by its sponsor.

(5) Amendment #22, offered by Representatives Schakowsky and Welch. This amendment would have added a new section requiring drug manufacturers seeking FDA approval for a drug to disclose the costs of research and development for that particular drug, as well as how much was funded by the National Institutes of Health. It also would have required the Secretary of Health and Human Services to make this information public. These provisions would have provided transparency to research and development costs for new drugs and facilitated policymakers' assessments of drug pricing issues.

(6) Amendment #34, offered by Representative Welch. This amendment would have closed loopholes that inhibit the development of generic drugs, resulting in significant savings for patients and private and government health insurers.

(7) Amendment #3, offered by Representative Fitzpatrick. This amendment would have directed the Government Accountability Office to investigate and issue a report on the FDA's implementation of medical device safety reporting regulations, focusing on reporting problems involving power morcellators.

Amendments 2, 9, and 20 in particular would have removed some of the most troubling provisions of H.R. 6.

Thank you for considering our view on these important matters.

Sincerely,

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