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July 1, 2016

Dear Members of the U.S. Congress Conference Committee for the Comprehensive Addiction and Recovery Act:

Public Citizen, a consumer advocacy organization with more than 400,000 members and supporters nationwide, strongly urges you to oppose Section 803 of the proposed House bill amending S. 524, legislation designed to address the opioid addiction/abuse epidemic.

While we recognize the strong need to address opioid abuse in this country as a serious public health crisis, Section 803 (“Excluding abuse-deterrent formulations of prescription drugs from the Medicaid additional rebate requirement for new formulations of prescription drugs”) is an expensive handout to the pharmaceutical industry that would do little to address the opioid epidemic.

Section 803 would increase payments under Medicaid programs to opioid manufacturers for “abuse-deterrent” formulations of opioid drugs by reimbursing for these drugs as if they were new drugs, rather than reformulations of older opioids. The provision would yield approximately \$75 million in additional Medicaid payments to manufacturers of abuse-deterrent opioids.

Such additional Medicaid payments are not needed to encourage manufacturers to develop these drugs. Manufacturers already are heavily promoting abuse-deterrent opioids as the future of opioid pain relief, and state lawmakers are being pressed to pass laws designed to increase the use of these products.^{1,2}

New abuse-deterrent formulations also do not warrant expensive payments because they offer little proven benefit over older opioids; they merely have properties that *may*, to varying degrees, deter certain types of abuse (e.g., crushing and snorting an opioid to achieve a euphoric “high.”) Individuals still can easily become addicted to the abuse-deterrent opioids by taking them as prescribed, and the Food and Drug Administration will approve abuse-deterrent formulations without studies showing that they actually prevent drug abuse or reduce addiction rates.³ Indeed, the new formulations may even fuel the opioid epidemic if promotion of their abuse-deterrent features leads to an overall increase in inappropriate opioid prescribing.

¹ American Legislative Exchange Council. State factor: Optimizing the abuse-deterrent opioids market. January 27, 2016. www.alec.org/publication/2016opioids/.

² Center for Lawful Access and Abuse Deterrence. Abuse-deterrent medications. <http://claad.org/abuse-deterrent-medications/>. Accessed June 30, 2016.

³ Food and Drug Administration. Abuse-Deterrent Opioids – Evaluation and Labeling (Guidance for Industry). April 2015. <http://1.usa.gov/1aiRdmE>. Accessed June 30, 2016.

We urge you to oppose Section 803, as it is a misguided handout to an industry that needs no additional incentives to develop and market new abuse-deterrent opioids. Such a handout is particularly unnecessary because the drugs have not yet shown value for public health.

Thank you for considering our comments on this important public health issue.

Sincerely,



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