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May 13, 2015

Dear Members of the United States House of Representatives:

Public Citizen, a patient advocacy organization with more than 350,000 members and supporters nationwide, writes to express serious concerns with the latest draft version of the 21st Century Cures Act, released today. The bill has been scaled back from the original publicly released draft but still carries seven provisions that would undermine public health and threaten patient safety. As the bill enters markup, we urge you to support amending the bill to remove at least these seven provisions.

One of the bill's most troubling provisions would open a gaping hole in the Physician Payment Sunshine Act for educational gifts (Section 3041). This provision would exempt drug and medical-device manufacturers from reporting speaker fees or gifts to doctors that are intended for "continuing medical education" purposes. These could include hefty fees and other valuable payments and gifts, such as expensive admission into medical conferences at lavish resorts. Another irrational amendment in the same section would define an existing exception for "educational materials that directly benefit patients" to include medical textbooks and journals. These items directly benefit doctors, not patients, and they are costly items that should be reported. All these speaker fees, travel expenses, and gifts together constitute a substantial proportion of the industry payments that are routinely intended to influence physician prescribing behavior. Exempting them from reporting would seriously undermine the intended benefits of the Physician Payment Sunshine Act.

A second dangerous provision would speed the rise of resistant superbugs by paying a bonus to hospitals to use new antibiotics (Section 2123). New antibiotics are a precious, limited resource: The more these drugs are used, the faster bacteria will adapt and become resistant to them, thus hastening the development of superbugs. To preserve these drugs, hospitals should be given incentives to *avoid* using new antibiotics when not medically necessary and to treat with older antibiotics before using newer ones. Yet this provision in the 21st Century Cures Act does the opposite, encouraging overuse of new antibiotics by paying a financial bonus to hospitals each time they use one.

A third unacceptable provision is found in a small paragraph that would broadly exempt much publicly funded research from primary oversight by the agency entrusted with protecting human subjects (Section 2261; see proposed Sec. 491A(d)(1)(A)(iv) of Part H of title IV of the Public Health Service Act). The provision would strip the Office for Human Research Protections (OHRP) of authority to fully regulate clinical trials that are also regulated by the Food and Drug Administration (FDA) (including all publicly funded trials that involve FDA-regulated medical products, such as drugs or medical devices). Instead, human subjects protection regulations would be enforced by the FDA only. Protection of human subjects is not part of the core mission of the FDA, as it is for OHRP, and for decades the FDA has been far less likely to take action to enforce human subjects protections. This provision, therefore, would threaten the safety and welfare of human subjects who participate in an enormous proportion of publicly funded clinical trials. If there is a desire to consolidate oversight for protection of research subjects, then OHRP — not the FDA — should be vested with primary oversight responsibility.

Fourth, a major section of the bill would create a new pathway for approving antibiotics that would largely eliminate the need for Phase III clinical trials for approval of new antibiotics (Section 2121). Large, well-designed, randomized, controlled Phase III clinical trials are the gold standard for assessing drug safety and effectiveness, developed by scientific consensus over decades. These large trials are a

critical step in weeding out unsafe or ineffective drugs, and should be required for all drugs, including antibiotics. Yet the proposed pathway would force the FDA to enter into a written agreement early in the clinical development program that will provide for approvals based on Phase II clinical studies alone, with additional evidence required only if deemed necessary. Under this arrangement, Phase III testing will become the rare exception, rather than the rule.

Fifth, the bill 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 (Section 2222). 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 never learn of problems if it relies solely on these published articles to support approval.

Sixth, the bill would allow companies to make changes to even the highest-risk devices (like brain stents or artificial heart valves) without first notifying the FDA or documenting that the modified device remains safe and effective (Section 2221). 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, as illustrated by recent cases of massive bone and tissue damage caused by material changes in certain metal-on-metal hip implants.[1] These changes should not be exempted from FDA oversight.

Seventh, the bill provides an additional 6 months exclusivity for new indications for orphan drugs (Section 2151). This provision will increase healthcare costs and limit patient access to new drugs.

Each of these provisions would undermine public health and threaten the health and well-being of patients or human research subjects. Therefore, we urge you to support amending the bill to remove at least these provisions and, if such amendments fail to be adopted, to vote against the bill.

Thank you for considering our view on these important matters.

Sincerely,

Sarah Sorscher, J.D., M.P.H.
Attorney
Public Citizen's Health Research Group

Michael Carome, M.D.
Director
Public Citizen's Health Research Group

Vijay Das
Healthcare Policy Advocate
Public Citizen's Congress Watch

Lisa Gilbert
Director
Public Citizen's Congress Watch

[1] Meier B, Concerns over "metal on metal" hip implants. New York Times. March 3, 2010. http://www.nytimes.com/2010/03/04/health/04metalhip.html. Accessed May 13, 2015.