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NEWS

US device industry and FDA "colluded" on legislation to weaken regulatory oversight

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US Food and Drug Administration officials had multiple meetings with leaders of the medical device industry to craft legislation that critics say will severely weaken regulatory oversight of the industry, an investigation by the online news service Inside Health Policy has found.

The revelations, discovered in emails and documents obtained under the Freedom of Information Act, have led to renewed calls by professional and public interest watchdog groups to defeat companion legislation to the proposed 21st Century Cures Act, which has been referred to the Senate. They have also called to oppose the approval of Robert Califf as a nominee for the role of FDA commissioner because he took part in meetings with the Advanced Medical Technology Association (AdvaMed), a trade association for medical technology companies.

The bill, which was passed in the US House of Representatives in July,[1] is set to substantially boost funding for the National Institutes of Health, but critics have long said that it will undermine the US drug and device approval process.

Michael Carome, director of the health research group at Public Citizen, a public interest organization, described as "unseemly and inappropriate" the meetings between the FDA and the device industry to craft the language in the act.

Carome said that Califf's "participation in this collusion with industry" should, at a minimum, put Califf's nomination as FDA commissioner on hold pending an investigation. Carome said, "The attitudes [Califf] has developed over his decades long history of extensive financial ties to pharmaceutical and medical device companies leave him all too willing to promote the interests of regulated industries over those of public health and patient safety."

The National Physicians Alliance, together with Public Citizen and six other organizations, wrote a letter to the House of Representatives on 19 May, stating that the 21st Century Cures Act "fails to ensure a . . . scientifically based approach" to drug and device approval and that it will allow "unsafe and ineffective drugs and medical devices to enter the market."

The organizations said that the new act would severely weaken the level of evidence used by the FDA to approve medical devices, allowing the agency to approve devices on the basis of animal studies, anecdotal evidence, uncontrolled case histories, surrogate markers, and peer reviewed medical journal articles. They objected to the inclusion of published peer reviewed articles on the grounds that they often "leave out critical information because of space limitations" and because they "do not examine raw data or inspect clinical trial sites."

Another concern among the organizations is an exemption in the legislation to the Physician Payments Sunshine Act that will allow payments to doctors such as speakers' fees to remain secret if used for continuing medical education. They also cited a provision in the new act that will allow manufacturers to pay a third party to certify that companies have an adequate "quality system" to evaluate even the highest risk devices, after which "the manufacturer would be authorized to determine for itself whether each device remained safe and effective following important changes [to their devices]."

JC Scott, senior executive vice president of government affairs at AdvaMed, told *The BMJ*, "Nothing in the legislation—which passed the US House with overwhelming bipartisan support—would impact the stringent, risk based regulatory framework FDA has in place to ensure the safety and effectiveness of medical technology. Instead, the proposal clarifies that, if appropriate, FDA may take certain data sources into account when evaluating a submission."

The FDA defended its meetings with the industry, telling *The BMJ* that "FDA officials routinely meet with a diverse group of stakeholders." The agency said that it had met with 12 representatives of public interest and professional organizations who attended a meeting on 28 October, after the bill was referred to the Senate in July.

Diana Zuckerman, president of the National Center for Health Research, whose organization requested the October meeting, told *The BMJ* that none of the more than two dozen non-profit organizations that are members of the Patient, Consumer, and Public Health Coalition had been invited by the FDA to help develop any provisions of the 21st Century Cures Act or its Senate companion bill.

She said, "There's a world of difference between talking about approval standards in general and crafting specific legislative language. It is outrageous that FDA officials and regulated industry are sitting down to craft legislative language to give to congressional staff."

FierceBiotech, an online news source, cited a study showing that reliance on "mid-stage data," allowed under the proposed act, paint a "grim picture of the bill's potential."[2] The study, published in *The BMJ*, reviewed three Alzheimer's drugs that did well during early and mid-stage studies but failed in eventual phase III trials owing to safety and efficacy problems.[3]

1 McCarthy M. Controversial bill to boost US medical research funding is passed in House of Representatives. *BMJ* 2015;351:h3831.
2 Garde D. What if 21st Century Cures had been around before bapineuzumab blew up? *FierceBiotech* 2015 Nov 24. www.fiercebiotech.com/story/what-if-21st-century-cures-had-been-around-bapineuzumab-blew/2015-11-24.
3 Zuckerman DM, Jury NJ, Silcox CE. 21st Century Cures Act and similar policy efforts: at what cost? *BMJ* 2015;351:h6122.

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