



All Members of the U.S. House of Representatives
cc: Staff Legislative Directors & Health Legislative Aides

June 17, 2015

Dear Representatives:

On May 21, 2015 the 21st Century Cures Act (H.R. 6) was passed unanimously by the Energy and Commerce committee and is now before you in the House. This ambitious legislation aims to advance the discovery, development, and delivery of new drugs and devices. While H.R. 6 has the laudable goal of promoting new medical treatments, many physicians are deeply concerned about potentially serious harms and unintended consequences of this proposed legislation. We write to urge caution, thoughtful review, and concrete revisions.

The National Physicians Alliance (NPA) represents physicians across medical specialties. The organization works to secure high quality, evidence-based health care for our patients. This requires defense of the Food and Drug Administration as a strong, effective regulatory agency—one that we as prescribers can trust. Physicians depend on the FDA to determine whether new drugs and devices are both safe and effective before they are brought to market. NPA’s FDA Task Force has followed the development of the 21st Century Cures Act, and believe this legislation would actually take us backwards by dangerously lowering standards for FDA approval, thereby diminishing the safety and efficacy of medical products.

While we do agree with the bill’s call to increase the budget of the National Institutes of Health to spur development of much needed drugs, devices, and diagnostics, we recognize that this is not an appropriations bill: actual funding would require separate legislation. On balance, a worthy call for new funding of NIH (independent of appropriations power) does not offset the negative elements of the Act.

H.R. 6 has many provisions that focus on shortening the interval for drug and device approval as a way of stimulating new medical developments. As background, the FDA now approves medications more quickly than any other regulatory agency in the world. The agency evaluates nearly all new drug applications within 6-10 months. The new proposal would encourage use of preclinical (non-human) data, shorter or smaller clinical trials, reliance on evidence from clinical experience, and increased use of intermediary “surrogate” endpoints to determine efficacy. The problem is not simply that none of these methods has been shown to be as reliable in predicting clinical outcomes as randomized controlled clinical trials. It is that drugs and devices approved on this standard of evidence have been found to compromise patient safety.

As well stated in the June 5 2015 New England Journal of Medicine article [The 21st Century Cures Act – Will It Take Us Back In Time?](#): “Patients and physicians would not benefit from legislation that

instead of catapulting us into the future, could actually bring back some of the problems we thought we had left behind in the 20th Century.”

<http://www.nejm.org/doi/full/10.1056/NEJMp1506964>

In their thoughtful New York Times Op-Ed of June 11 2015, “[Don’t Weaken the FDA’s Drug Approval Process](#),” the authors (including former FDA Commissioner David Kessler) write that during the AIDS crisis, the FDA “transformed itself into a more flexible and creative institution that has introduced new ways to speed lifesaving treatments to patients.” In doing so, the agency also maintained that drug companies “still have to show that the new drugs were safe and effective under the usual criteria required by the agency.” By contrast, the 21st Century Cures Act would lower the standards of approval for many medical products. The authors conclude that “the FDA has the expertise and legal and regulatory tools to expedite cures and better treatments. Congress should be wary of changing standards that paved the way for the development and approval of breakthrough drugs for AIDS and other diseases and that, importantly, have been proven to be effective and safe.” We agree.

http://www.nytimes.com/2015/06/11/opinion/dont-weaken-the-fdas-drug-approval-process.html?_r=0

Patients with unmet medical needs already have tools to obtain investigational drugs prior to approval through compassionate use pathways. In fact, the FDA has recently sped up this process, making it far easier for doctors to order such drugs for individual needs. The reality is that to speed along significant new drug and device development, we need more basic research and coordination of these efforts. The problem is not in the regulatory process. Changing that process to make the FDA less accountable and less dependable will not lead to significant “breakthrough” developments, but will instead harm our patients. We do not need to release another thalidomide onto the drug market. We need a regulatory agency that ensures adequate data from clinical trials in humans. Without this standard, we all—patients, doctors, and policymakers—will become guinea pigs deprived of informed consent.

We urge you to withhold support for the 21st Century Cures Act unless provisions in it are substantially changed and would like to discuss proposals for revision with you.

Respectfully,



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