

The 21<sup>st</sup> Century Cures Act directs leadership at the NIH, USDA, and FDA “to reduce administrative burden ... while maintaining the integrity ... of research findings and protection of ... animals.”

In response to this directive, some groups have proposed recommendations that would gut current minimal protections for animals—reducing the frequency of IACUC inspections from semiannual to annual; eliminating the current requirement for annual USDA inspections of laboratories; and diluting IACUCs’ protocol review requirements.

The proposed changes would have catastrophic implications for animal welfare.

- Semiannual inspections have highlighted serious deficiencies in critical aspects of animal care—including provision of food, water, and post-operative pain relief; acceptability of euthanasia methods; and deviations from IACUC-approved protocols that jeopardized or compromised animal well-being.
- USDA inspections have likewise encouraged laboratories to strengthen SOPs and bolster employee training to ensure compliance with basic regulations—for instance, training workers to handle animals humanely to avoid inflicting spinal injuries on rabbits, pigs, dogs, and monkeys; or ensuring that facilities clip animals’ toenails before they curl around to pierce the paw pad. Such incompetence and neglect is not limited to a subset of bad actors; it permeates the field.
- On the issue of IACUC review of protocols, the groups suggest conducting a single member or administrative expedited review for studies deemed to be minimally invasive. However, the December 2014, audit of the USDA Office of the Inspector General documented that laboratories sometimes report animals in the wrong pain category. Even in NIH’s own laboratories, experiments in which baby monkeys were *permanently* removed from their mothers were placed in “Column C,” indicating experiments involving no pain or distress. In light of these documented failures to appropriately classify experiments in categories that have been in place for decades, it scarcely makes sense to introduce new categories with which IACUCs’ responsibilities to review protocols would effectively be eviscerated.

In 1985, members of Congress from both sides of the aisle worked together to strengthen protections for animals in laboratories to address deep-seated ethical concerns held by the American public regarding the use of animals in experiments. Polling by the Pew Research Center has found that 50 percent of U.S. adults oppose the use of animals in experiments, and other surveys suggest that the support of the shrinking group that continues to accept animal experimentation is contingent on the existence and enforcement of stringent regulations aimed at protecting animals.

In stark contrast to the public’s expectations, multiple federal audits document abject failures on the part of laboratories to comply with minimal animal welfare regulations and guidelines. Experimenters grumble about so-called “regulatory burden,” but the real burden is suffered by animals in laboratories who are forced to live in artificial conditions and deprived of everything that would make their lives worth living.

Meanwhile, mounting evidence gathered over the past decade has highlighted the failure of animal experiments to produce human-relevant data. The NIH reports that 95 percent of all drugs that are shown to be safe and effective in preclinical studies, including in animal tests, fail or cause harm in clinical trials. A review published in the *British Medical Journal* found that “even the most promising findings from animal-based research often fail in human trials and are rarely adopted into clinical practice.”

If we are serious about reducing administrative burden, we should place more stringent requirements at the points where projects are funded and protocols approved—to ensure that money is only disbursed and projects only greenlighted when there is confidence that something useful will come from the work.

By shifting away from projects involving animals and increasing investments in human-relevant projects, we can successfully comply with the directive of the Cures Act to maintain the integrity of research findings while also protecting animals.