

Our patients need better antibiotics AND better clinical trials.

Our patients need better diagnostic tools and truly novel drugs and devices, but these drugs and devices should be thoroughly tested before being released to the public.

Currently proposed legislation such as H.R. 3742, the Antibiotic Development to Advance Patient Treatment (ADAPT) Act and H.R. 4187, the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act that aim to hasten the development and approval of antibiotics also run the risk of actually harming patients.

On behalf of the National Physicians Alliance (NPA) FDA Task Force, we are concerned that the primary beneficiaries of such legislation will not be patients, but rather the pharmaceutical and clinical laboratory industries. The NPA FDA Task Force's mission is to support the FDA in promoting the development of significant medical advances while ensuring adequate testing of new drugs and devices.

On behalf of the National Physicians Alliance, we ask that you support legislation that honors the following principles:

- **Clinical trials should focus on meaningful clinical outcomes**, such as improvements in symptoms, function, and survival. Allowing alternative, or “surrogate” endpoints will not necessarily lead to positive results with meaningful outcomes when the drugs or devices are released to the public.
- **Approval of new drugs should be based on clinical trials conducted on humans.** Results in animal studies or mathematical modeling cannot substitute for adequate scientific human trials with traditional, clinically-relevant patient-centered endpoints.
- **Studies should be done in populations of direct concern for the drugs being tested;** drugs designed for very ill patients should be tested in those patients. Current patients with existing options should not be put at risk.
- **Current law already allows for fast-tracking, single studies, and expedited review of new drugs with added benefits over available therapies.** There is no need for another regulatory pathway that lowers standards for approval without benefit for patients. Expedited pathways should focus resources on drugs that are a real advance, meaning superior to existing drugs in efficacy in the setting of antibiotic resistance, or, if not more effective, causing fewer side effects where current therapies already exist. Simply showing drugs are somewhat less effective (“non-inferior”) to already existing alternatives does not warrant an expedited review.
- **Approval for drugs should be based on added benefits and/or safety.**



With this framework in mind, we want to express concern over recent bills designed to speed up antibiotic approval in particular.

We agree that antibiotic resistance is a growing problem and share the World Health Organization position that our response must be multifaceted: we must work globally to fight root causes, including reducing overuse and inappropriate selection of antibiotics as well as curtailing the use of antibiotics in animal feed. We also see the need for putting new antibiotics in the pipeline if they meet acceptable criteria.

Without significant public health benefit, it is not acceptable to lower the standards for clinical trials only to incentivize more rapid delivery of new drugs to market.

For these reasons, we have major concerns with the following bills currently before Congress:

1. ADAPT – HR 3742, the Antibiotic Development to Advance Patient Treatment Act of 2013

ADAPT would allow the FDA to approve drugs based on alternative endpoints in place of traditional, clinically-relevant endpoints. It would also allow changes in drug susceptibility criteria to be made by a private group tied in with the drug industry, presenting a true conflict of interest. It is important to emphasize that the FDA already has the authority to approve drugs in a limited subset of patients under its basic labeling regulations.

2. DISARM – HR 4187, Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms

DISARM would increase the rate of reimbursement for hospitals for fast-tracked antibiotics regardless of whether those drugs have demonstrated added benefits for patients. The bill would also extend the drugs' patent period, thereby barring generic entry of these drugs for a longer period of time. The bill would therefore shift the cost burden onto the consumer for these new drugs approved through fast-track pathways that do not guarantee added benefits for patients.

3. STAAR – S. 2236, Strategies to Address Antimicrobial Resistance

STAAR would form an Antibiotic Resistance Advisory Group. We support the formation of such a group, but believe it must by statute be free of conflicts of interest with pharmaceutical companies. Merely disclosing conflicts is not sufficient to avoid conflicts of interest. STAAR should focus on linking resistance in the test tube to clinically-relevant patient-centered outcomes in clinical trials of antibiotics.

We ask that you join us in defending the regulatory credibility and power of the FDA.

Drug and device companies may see regulation as a roadblock to discovery and growth; we see it as a critical line of defense for public health. Well-done, scientifically-based regulation provides the best pathway to achieving real and lasting innovation. As physicians, we have to know we can trust the label "FDA-approved."

For more information please visit [NPAlliance.org/FDA-TaskForce](https://npalliance.org/FDA-TaskForce)
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The National Physicians Alliance is a non-partisan, non-profit organization that offers a professional home to physicians across medical specialties. We create research, advocacy, and education programs that promote health and foster active engagement of physicians with their communities. The NPA accepts no funding from pharmaceutical or medical device companies.