In This Issue of JAMA

August 15, 2017
Volume 318, Number 7
Pages 585-676

Research

Approval of High-Risk Medical Device Supplements 619

The US Food and Drug Administration (FDA) requires manufacturers of high-risk medical devices to show that modifications to the devices are safe and effective. In a descriptive study of 83 clinical studies supporting the approval of 78 applications to the FDA for changes in the design, performance, or intended uses of a high-risk medical device, Zheng and colleagues found that less than half of the studies were randomized, blinded, or controlled, and most primary outcomes were based on surrogate end points that may not be valid predictors of clinical events. In an Editorial on this and another article in this issue, Califf suggests that substantial progress in balancing safety with access to effective therapies will result from major changes to the system of drug and device approval.

Editorial 614 Related Article 626
Author Audio Interview jama.com CME jamanetwork.com/learning

Quality of Evidence for Drugs Granted Accelerated Approval 626

Under its accelerated approval provision, the FDA may consider studies with surrogate measures of clinical outcomes in the approval of drugs for serious or life-threatening conditions, but after approval sponsors must conduct confirmatory trials with clinical end points such as overall survival. In a study of 22 drugs granted accelerated approval, Naci and colleagues found that many confirmatory trials had not been completed or had failed to show clinical benefit, and all but one of the primary end points of 18 completed confirmatory studies were surrogate measures.

Editorial 614 Related Article 619
Author Audio Interview jama.com CME jamanetwork.com/learning

An Intensive Lifestyle Intervention for Glycemic Control 637

Patients with type 2 diabetes mellitus can achieve glycemic control with pharmacological therapy, weight reduction, and modifications to diet and physical activity. In this preliminary randomized clinical trial of 98 adults with non-insulin-dependent type 2 diabetes, Johansen and colleagues found that participants who received a diet and exercise intervention plus standard care had a greater mean reduction in hemoglobin A_{1c} level than participants who received standard care alone. Further research is needed to assess the clinical benefits of the intervention.

Humanities

Opinion

LETTERS

Editor in Chief
Howard Bauchner, MD

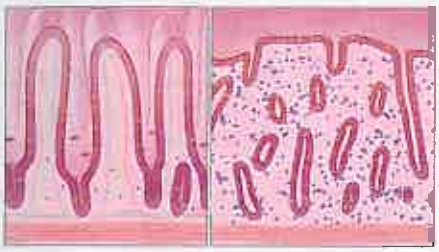
134 YEARS
OF CONTINUOUS
PUBLICATION

In This Issue of JAMA

August 15, 2017
Volume 318, Number 7
Pages 585-676

Clinical Review & Education

Celiac Disease and Nonceliac Gluten Sensitivity 647



Celiac disease is a chronic, small intestinal immune-mediated enteropathy initiated by exposure to dietary gluten in genetically predisposed individuals. Leonard and colleagues review the clinical management of celiac disease and nonceliac gluten sensitivity.

CME jamanetwork.com/learning

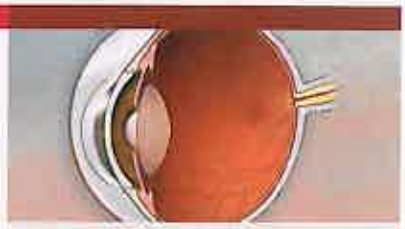
Engaging Patients in Decisions for Screening or Treatment 657

Patient decision aids are printed booklets, videos, or web-based tools to facilitate discussions about the benefits and harms of interventions for specific health conditions. In this JAMA Clinical Evidence Synopsis of 105 trials, Stacey and colleagues conclude that patient decision aids can help patients understand their options, assess risks, and make decisions consistent with their values. In an Editorial, Montori and colleagues discuss the limitations of available research and suggest that important questions about the effectiveness of patient decision aids have not been adequately addressed.

Editorial 617

From The Medical Letter: Bezlotoxumab for *C difficile* Infection 659

This *Medical Letter on Drugs and Therapeutics* article discusses the use of bezlotoxumab in adults with *Clostridium difficile* infection at high risk for recurrent disease.



Online @ jama.com

Editor's Audio Summary
Edward H. Livingston, MD, summarizes and comments on this week's issue.

Online First Articles
Visit jamanetwork.com/journals/jama/newonline for just-published opinion and Medical News articles.

Author Audio Interview

AUDIO Rita F. Redberg, MD, MSc, Aaron S. Kesselheim, MD, JD, MPH, and Robert M. Califf, MD, discuss their articles characterizing studies used for the approval of high-risk medical devices and accelerated approval of drugs by the FDA.