

The Food and Drug Amendments of 2022 grant the FDA explicit legal authority to require initiation of confirmatory studies prior to accelerated approval, setting of enrolment targets, and biannual (twice yearly) reporting of study progress. The legislation also codifies an expedited withdrawal procedure that can be triggered if the sponsor fails to conduct the required postapproval study, the confirmatory study does not confirm benefit, other evidence shows the product is not safe and effective, or the sponsor disseminates false or misleading promotional materials.

These provisions are important reforms to the accelerated approval programme, which we believe could be further modernised. In addition to study progress reporting, the FDA could require an annual review of the overall benefit–risk balance of accelerated approvals (as is done by the European Medicines Agency for conditional marketing authorisation). In addition, as underscored by the aducanumab approval (for which <1% of study participants were Black), the FDA could make accelerated approval conditional on adequately inclusive clinical trials, and, if such studies are not completed before approval, the FDA should require that successful completion of postapproval requirements is defined as enrolment of participants representative of the national disease population. Ultimately, these reforms would advance timely evidence generation, the safety of medications available on the market, and equity in clinical trials for medicines receiving accelerated approval.

Q-DT reports personal fees from Astellas, Bayer, and Janssen, and a grant from Pfizer, unrelated to this Correspondence. All other authors declare no competing interests.

*Thomas J Hwang, Quoc-Dien Trinh, Ariadna Tibau, Kerstin N Vokinger
thomas_hwang@dfci.harvard.edu

Division of Urological Surgery (TJH, Q-DT) and Center for Surgery and Public Health (Q-DT), Brigham and Women's Hospital, Harvard Medical

School, Boston 02115, MA, USA; Cancer Innovation and Regulation Initiative, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute and Brigham and Women's Hospital, Boston, MA, USA (TJH, KNV); Department of Oncology (AT) and Department of Medicine (AT), Hospital de la Santa Creu i Sant Pau, Autonomous University of Barcelona, Barcelona, Spain; Institute of Law, University of Zurich, Zurich, Switzerland (KNV)

- 1 Congress.gov. Food and drug amendments of 2022. June 8, 2022. <https://www.congress.gov/bill/117th-congress/house-bill/7667> (accessed June 25, 2022).
- 2 Centers for Medicare and Medicaid Services. Medicare program: Medicare part B monthly actuarial rates, premium rates, and annual deductible beginning January 1, 2022. Nov 17, 2021. <https://www.federalregister.gov/documents/2021/11/17/2021-25050/medicare-program-medicare-part-b-monthly-actuarial-rates-premium-rates-and-annual-deductible> (accessed June 25, 2022).
- 3 Naci H, Smalley KR, Kesselheim AS. Characteristics of preapproval and postapproval studies for drugs granted accelerated approval by the US Food and Drug Administration. *JAMA* 2017; **318**: 626–36.
- 4 Beaver JA, Pazdur R. "Dangling" accelerated approvals in oncology. *N Engl J Med* 2021; **384**: e68.
- 5 Carpenter D, Kesselheim AS, Joffe S. Reputation and precedent in the bevacizumab decision. *N Engl J Med* 2011; **365**: e3.

Department of Error

Burton R, Sheron N. *Complex relationship between health and moderate alcohol use*. *Lancet* 2022; **400**: 141–43—In this Comment, the email has been corrected. This correction has been made to the online version as of July 18, 2022.

Samarasekera U, Leandro Mena: *advancing sexual health in the USA*. *Lancet* 2022; **400**: 89—In this Profile, the abbreviation for the state Mississippi in the fourth paragraph has been corrected. This correction has been made to the online version as of July 18, 2022.

GBD 2020 Alcohol Collaborators. *Population-level risks of alcohol consumption by amount, geography, age, sex, and year: a systematic analysis for the Global Burden of Disease Study 2020*. *Lancet* 2022; **400**: 185–235—Appendices 1 and 2 of this Article have been corrected as of July 19, 2022.