

**EDITOR**

PETER VAN DOREN

MANAGING EDITOR

THOMAS A. FIREY

DESIGN AND LAYOUT

DAVID HERBICK DESIGN

CIRCULATION MANAGER

ALAN PETERSON

REGULAR CONTRIBUTORS

SAM BATKINS, IKE BRANNON, ART CARDEN, THOMAS A. HEMPHILL, DAVID R. HENDERSON, DWIGHT R. LEE, GEORGE LEEF, PIERRE LEMIEUX, PHIL R. MURRAY

EDITORIAL ADVISORY BOARD

CHRISTOPHER C. DEMUTH
Distinguished Fellow, Hudson Institute

SUSAN E. DUDLEY
Research Professor and Director of the Regulatory Studies Center, George Washington University

WILLIAM A. FISCHEL
Professor of Economics, Dartmouth College

H.E. FRECH III
Professor of Economics, University of California, Santa Barbara

ROBERT W. HAHN
Professor and Director of Economics, Smith School, Oxford University

SCOTT E. HARRINGTON
Alan B. Miller Professor, Wharton School, University of Pennsylvania

JAMES J. HECKMAN
Henry Schultz Distinguished Service Professor of Economics, University of Chicago

ANDREW N. KLEIT
MICASU Faculty Fellow, Pennsylvania State University

MICHAEL C. MUNGER
Professor of Political Science, Duke University

ROBERT H. NELSON
Professor of Public Affairs, University of Maryland

SAM PELTZMAN
Ralph and Dorothy Keller Distinguished Service Professor Emeritus of Economics, University of Chicago

GEORGE L. PRIEST
John M. Olin Professor of Law and Economics, Yale Law School

PAUL H. RUBIN
Professor of Economics and Law, Emory University

JANE S. SHAW
Board Member, John William Pope Center for Higher Education Policy

RICHARD L. STROUP
Professor Emeritus of Economics, Montana State University

W. KIP VISCUSI
University Distinguished Professor of Law, Economics, and Management, Vanderbilt University

RICHARD WILSON
Mallinckrodt Professor of Physics, Harvard University

CLIFFORD WINSTON
Senior Fellow in Economic Studies, Brookings Institution

BENJAMIN ZYCHER
John G. Searle Chair, American Enterprise Institute

PUBLISHER

PETER GOETTLER
President and CEO, Cato Institute

REGULATION was first published in July 1977 “because the extension of regulation is piecemeal, the sources and targets diverse, the language complex and often opaque, and the volume overwhelming.” REGULATION is devoted to analyzing the implications of government regulatory policy and its effects on our public and private endeavors.

FOR THE RECORD**Prescription for Lower Drug Prices: More OTC Transitions**

In their recent *Regulation* article, David Hyman and Bill Kovacic discuss the pros and cons of having the U.S. Food and Drug Administration consider the effects of regulation on prices as well as on safety and efficacy. (“Risky Business: Should the FDA Pay Attention to Drug Prices?” Winter 2017–2018.) The cons they mention include lack of statutory authority and expertise.

One topic their article doesn’t discuss is FDA regulation of the transition of drugs from prescription to over-the-counter (OTC) status. The FDA’s statutory authority here is clear and its claim of expertise is complete. The effect on prices is also clear: every study of the matter shows substantial price reductions when drugs move to OTC. Of course, total cost—including the cost of physician visits and the value of the time and trouble of securing prescriptions—declines even further when the drug moves to OTC.

With the pressure mounting for action to restrain drug prices, you might think that speeding up and broadening the OTC transition would be on the FDA’s priority list or the priority list of its critics. But the topic is little discussed by anyone. This neglected area deserves more scrutiny.

The FDA has required prescriptions for certain drugs since the 1930s. The legal basis for this requirement is the agency’s statutory authority to regulate drug labels. It decided that adequate instructions for consumer use could not be written for some drugs and that the words “For sale by prescription only” would meet the statutory labeling requirement. This history is important because the ostensible rationale is about consumer information and safety, and the FDA is supposed to weigh the adequacy of one sales channel or the other in meeting information and safety goals. In practice, however, it is the producer of a drug, not the FDA, that initiates the process for prescription–OTC switches.

Why should the FDA wait for someone else to initiate this process? The FDA claims competence to decide when an adequate consumer label can be written. I suggest the FDA should periodically review existing drugs for eligibility for OTC sales. I further suggest that when any prescription drug passes certain milestones— x million prescriptions sold over y years with a risk profile similar to, say, ibuprofen or aspirin—there should be a rebuttable presumption that the drug becomes OTC-eligible. It would then be up to the drug’s producer or producers to take advantage of the opportunity.

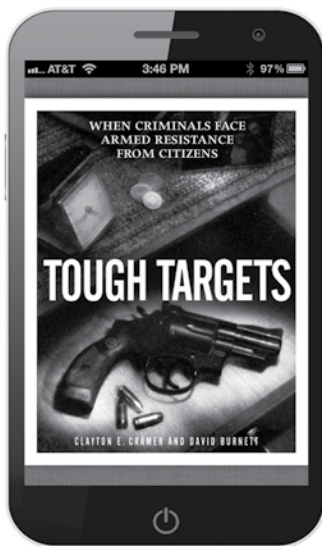
Moving more drugs to OTC status is no free lunch, but it is as close to one as consumers are likely to get in the health care sector. And the FDA doesn’t need any new statutory authority or new kinds of expertise to make it happen.

—SAM PELTZMAN

Ralph & Dorothy Keller Distinguished Service Professor of Economics Emeritus, Booth School of Business, University of Chicago

Cato at your Fingertips

The Cato Institute's acclaimed research on current and emerging public policy issues—and the innovative insights of its *Cato@Liberty* blog—now have a new home: Cato's newly designed, mobile-friendly website. With over 2.2 million downloads annually of its respected Policy Analysis reports, White Papers, journals, and more—and it's all free—the quality of Cato's work is now only matched by its immediate accessibility.



Visit today at Cato.org and at Cato.org/blog.

CATO
INSTITUTE