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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
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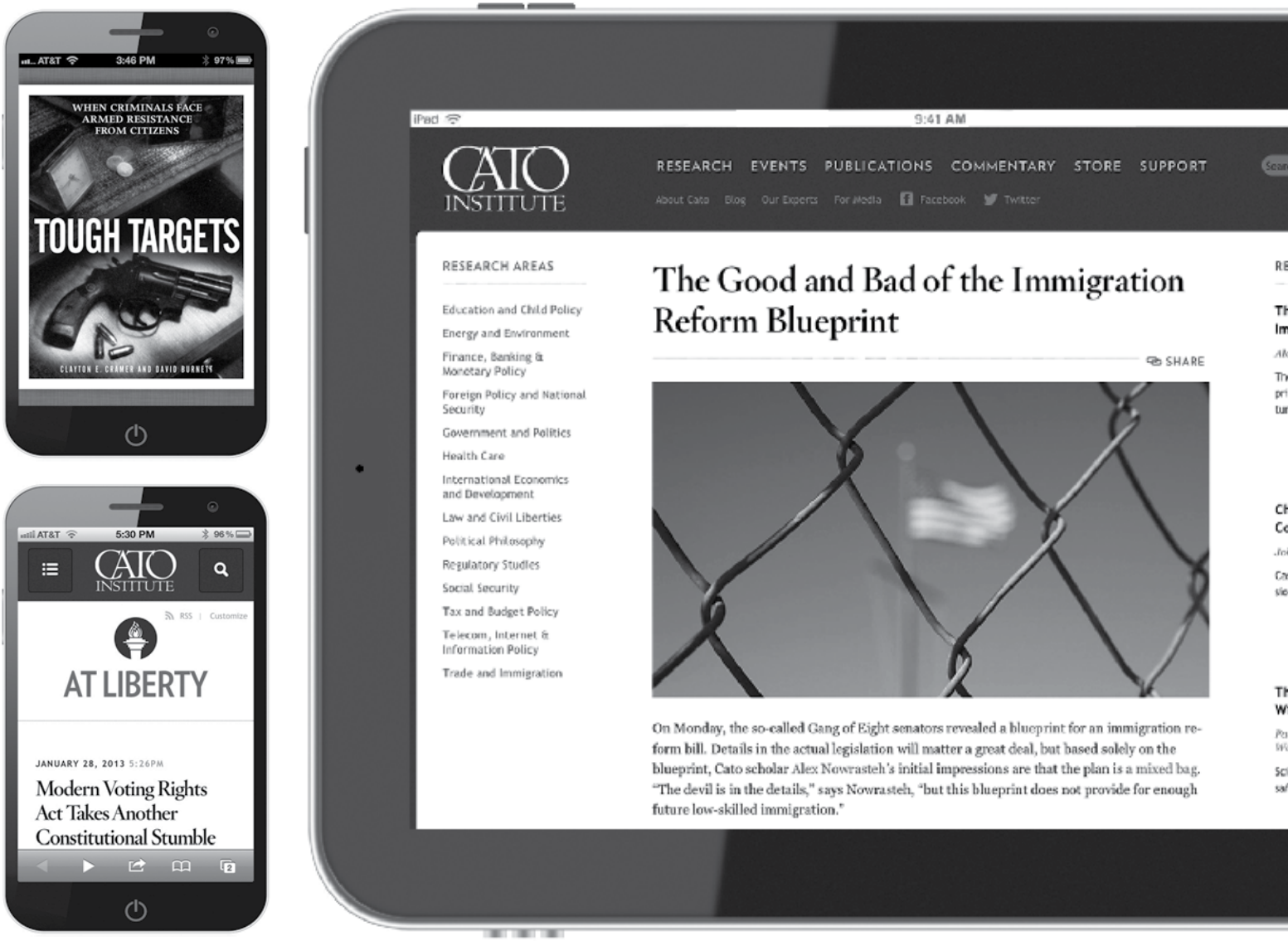

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