FACT SHEET
The Cody Miller Patient Medication Information Act of 2015

The Cody Miller Act requires the Food and Drug Administration (FDA) to implement regulations on patient medication information, a process that was first attempted more than 30 years ago. These regulations would ensure that the information dispensed with any prescription medication is consumer-friendly, accurate, and consistent between pharmacies.

Medication mistakes continue as the FDA continues to delay implementing regulations on the content and dissemination of consumer-friendly medication information.

Medication Mistakes. Pharmacy package inserts and drug labels are often the primary source of prescription drug information that patients and caregivers rely on as they administer medications at home. However, they often are not standardized and are not designed for consumers. This can result in:

- ***Inconsistencies***: A *Consumer Reports* study found that information gathered on the same drug at five different pharmacies "had incomplete or hard-to-read package inserts—and in 4 of 5 cases, a dangerous omission that violated an FDA regulation."[1]
- ***Misunderstanding***: Older adults have particular difficulty with reading and understanding health information,[2] and 30 percent report that they did not have a conversation about side effects of new drugs with their doctor or pharmacist.[3]
- ***Adverse Events***: The Institute of Medicine Reported that over 500,000 adverse drug events occur in the outpatient setting each year.[4] A 2010 study from the Centers for Disease Control and Prevention found that over 5,000 people died from non-opioid unintentional prescription pharmaceutical drug overdoses[5].

Failed Regulation. While the FDA strictly regulates the prescribing information meant for doctors and requires the *Drug Facts* label on over the counter medications, patient information about a medication and its potential risks is largely unregulated.

In 1980, the FDA finalized requirements for manufacturers to provide FDA-approved medication information meant for consumers, but these regulations were revoked two years later. The FDA attempted to issue regulations again in 1995 that would have set standards for the content and format of medication information, but in 1996, Congress prevented finalization of these regulations and instead required a market-based plan.

A 2008 study found that the quality of medication information provided at the pharmacy did not meet the FDA's expectations, as the length, consistency, and quality varied widely between pharmacies. As a consequence, the FDA has been working on developing regulations to require clearer patient information to accompany prescriptions.

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[1] http://www.consumerreports.org/cro/2011/06/can-you-read-this-drug-label/index.htm
[2] http://nnlm.gov/outreach/consumer/hlthlit.html
[3] Testimony of Dr. Doris Peters, Associate Director, Consumer Reports Health Ratings Center, Before the Senate Aging Committee hearing entitled "protecting Seniors from Medication Labeling Mistakes," December 11, 2013.
[4] http://iom.nationalacademies.org/en/Reports/2006/Preventing-Medication-Errors-Quality-Chasm-Series.aspx
[5] http://jama.jamanetwork.com/article.aspx?articleid=1653518