New Clinical Information and Physician Prescribing: How Do Pediatric Labeling Changes Affect Prescribing to Children? *

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Abstract

This paper investigates the how physician prescribing responds to new scientific information added to drug labeling. To examine this issue, we focus on how pediatric labeling changes, induced by a 1997 policy change, affected physician prescribing to children. The 1997 policy, known as pediatric exclusivity, gave drug sponsors a six month exclusivity extension for conducting additional pediatric studies of already marketed drugs. New data from the pediatric studies could help inform physician prescribing to children and reduce inappropriate off label prescribing, however, there is little evidence about how the studies and subsequent labeling changes actually impact physician prescribing. Using data from the FDA, the National Ambulatory Medical Care Survey, and IMS Health, we use a difference in difference strategy to examine how pediatric prescriptions respond to different types of labeling changes in comparison to prescriptions of comparator drugs (without labeling changes) in the same ATC class. Our results show that the new information when added to a drug’s label does impact physician prescribing to children. We find that most pediatric exclusivity label changes lead to reductions in prescribing to children. In particular, evidence that a drug is not effective for children when added to a drug’s label produces the largest drop in pediatric prescriptions. This evidence suggests that pediatric labeling changes have in some cases reduced previous patterns of inefficient off label prescribing.

Keywords: Innovation Policy, Market Incentives; Pharmaceuticals; Pediatric Exclusivity; FDA regulation

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