

## Health Blog

WSJ's blog on health and the business of health.

SEPTEMBER 21, 2010, 3:08 PM ET

### Need for Speed: How to Get Faster Drug Reviews in Europe

By Amy Dockser Marcus

The drive to encourage drug development in rare and neglected diseases is picking up steam.

In the U.S., when a company receives FDA approval for a drug that targets a neglected disease, it gets a [voucher that can be used to get priority review](#) from the FDA on another, larger market drug, which would speed up the approval review process and could lead to the more lucrative medicine hitting the market sooner.



In the [latest issue of the Lancet](#), researchers from Duke and the Spanish patent office are now calling for a similar “priority review voucher” system in Europe. They estimate that adopting a voucher system in Europe could speed up the approval process by six months, which could translate into an estimated \$300 million in value.

“The potential to get decisions faster has great value and can be used for a worthy cause,” says [David B. Ridley](#), co-author of the Lancet article and one of the Duke researchers who came up with the original idea.

The concept became law in the U.S. in 2007, and the first voucher was awarded to Novartis in 2009 after the FDA approved Coartem, a malaria drug. In August, a bill was introduced in the Senate to extend the priority review vouchers to include some pediatric rare diseases, such as cancer and muscular dystrophy. The legislation was one of the key topics at last week’s pediatric cancer summit run by the Pediatric Cancer Caucus, which works with legislators.

No one knows how many vouchers might ultimately be given out every year in the U.S. Ridley told the Health Blog he hopes to see 2 to 3 a year eventually but that the process will take a while since the idea is to support new drug development. The legislation hasn't been written yet in Europe.

Nancy Goodman, who lost a 10-year-old son to cancer in 2009 and whose [Kids v Cancer](#) group helped drive the effort to expand vouchers to include pediatric rare diseases, says about the potential number of vouchers, "That's the million dollar question." But even one voucher a year, she adds, would represent "a sea-change for kids with cancer and rare diseases."

*Photo: Associated Press*