

United States. That's where we're going to have some real challenges. The second piece is that we're going to have a lot of health care workers that are going to be put at risk for influenza by going to work. We will run out of N95 respirators very quickly. We will not have vaccine available in a timely manner in our hospitals. We won't have anywhere near enough antiviral drugs. I think we've not really tested our system yet.

**JAMA:** How do we prepare for all of these issues? Is this a matter of stockpiling drugs or gathering more equipment now?

**DR OSTERHOLM:** This is the zillion dollar question. We're never going to be able to stockpile enough drugs for this country for any kind of crisis. One of the things we have to understand is our national vulnerability to this new global sourcing of some critical medical supplies and products. That kind of research has not been ongoing. If you can only do 10 things out of 1000, what are the 10 things that are

going to have the most impact? Most of what we're going to have to understand is how to move civil society through day after day when we have a major pandemic. During the 2014-15 Ebola epidemic in West Africa, it only took 2 cases of Ebola in the United States to cause a crisis.

**JAMA:** You've mentioned so many things we need to combat a potential epidemic or pandemic. What barriers are currently standing in our way?

**DR OSTERHOLM:** I would like to say that these barriers are just short-lived challenges, but we have a science literacy issue today where so much antiscience has become the mainstay for how we make decisions. You can't do anything about improving your status and response to any of these issues if you don't have a population that is willing to support them. We used to talk about vaccine hesitancy where people were reluctant to get vaccines. Today it's much greater than that.

It's a hesitancy to adopt any kind of science-based approach.

**JAMA:** Is there a top myth about flu or flu pandemics that you'd like to dispel?

**DR OSTERHOLM:** I think people believe that because you can go on the internet and order something from Amazon and it's here tomorrow, that anything we need in the medical care field will be available in equal speed. We don't have stockpiles of anything beyond a limited supply the US government has of some medical products, which would be quickly exhausted if we are in a real pandemic. We have to anticipate these things, and we have to have plans. Right now, anticipation is the word that probably applies to the next 12 hours. What we need to understand is that it has to apply to the next 10 to 15 years. ■

Listen to our podcast to hear Dr Osterholm speak about flu pandemic preparedness, flu vaccines, and much more.

**Note:** Source references are available through embedded hyperlinks in the article text online.

## The JAMA Forum

# Extending the User Fee Approach to Pharmaceuticals

David M. Cutler, PhD

A central theme in economics is that people who benefit the most from a good or service should pay more for it. If a government decides to build a highway connecting 2 cities, charging a toll to users of the highway is preferred to financing the road through general taxation.

I think of the highway toll example in considering the pharmaceutical industry. The federal government provides many services that disproportionately benefit pharmaceutical firms. Most of these services are paid for by the public at large, through income and other taxes. In effect, we charge everyone for benefits realized by a few. Far more efficient would be to follow the highway example and charge pharmaceutical companies for the services they disproportionately receive. In this piece, I outline and propose user fees for 3 specific public policies.

### Precedent for the User Fee Approach

A precedent for the user-fee model is the Prescription Drug User Fee Act, or PDUFA. In the late 1980s, pharmaceutical firms

Proposed User Fees for Pharmaceutical Companies	
Area	Approximate Annual Fee, US \$ Million
Current program	
US Food and Drug Administration approvals (Prescription Drug User Fee Act payments)	916
Potential new programs	
National Institutes of Health training fee	125
Academic detailing fee	500
Comparative effectiveness fee (Patient-Centered Outcomes Research Institute)	500
<b>Total</b>	<b>1 125</b>

and groups advocating on behalf of people with certain diseases (especially groups representing people with HIV/AIDS) were upset that review times for drug candidates at the US Food and Drug Administration (FDA) were so long—29 months on average. Such long review times meant lost sales for pharmaceutical companies

and delayed access to potentially lifesaving medications for patients.

In response, the FDA and pharmaceutical companies agreed to create PDUFA. Under PDUFA, pharmaceutical companies pay money to the FDA, which allows the FDA to hire additional examiners. The FDA agreed to standards for review times, and the US Congress agreed that it would not reduce the federal contribution to the FDA. PDUFA is generally viewed as a success; review times have decreased to just more than 1 year, and pharmaceutical payments total nearly \$1 billion annually.

### Extending PDUFA

The table outlines 3 additional areas to which the principles of benefit-related payment could be applied. I provide rough estimates of the amounts that might be collected, although the proper amount for each would clearly be a matter for discussion.

**Researcher Training Fee.** The National Institutes of Health (NIH) contributes about \$350 million annually in support of the

9000 students each year who graduate with doctoral degrees in the biomedical sciences. About 18% of biomedical PhD graduates are employed in industry, so this is a benefit of about \$63 million annually.

Scientists are somewhat like FDA examiners. Because their training often benefits the pharmaceutical industry, it would be natural to charge the companies for it. This concern is particularly apparent when the NIH confronts funding difficulties. President Trump's first budget proposed reducing NIH spending by 22%. Fortunately, Congress rejected these proposed cuts. Still, the NIH budget is never safe.

The actual fee would need to be higher than \$63 million because of indirect costs of training the PhD-level researchers, such as faculty mentors, space, equipment, and the like. At the low end, one might double the proposed fee to account for these indirect costs. At the high end, the cost could be in the billions of dollars annually, if one wanted to fund entirely new laboratories. In the absence of a better calculation, I estimate costs of \$125 million annually. This proposal could extend to medical device companies as well, though fewer PhD-level researchers are hired by medical device makers than by pharmaceutical companies.

**Academic Detailing Fee.** Pharmaceutical companies spend as much as \$25 billion annually for detailing, visits from pharmaceutical representatives to physicians to encourage use of selected medications. But drugs that are off patent are not detailed, even if they are more effective than on-patent medications. In some cases, firms detail inappropriately, and a remedy of more honest detailing is called for.

Noncommercial or "academic" detailing has been proposed for several decades. The United States uses academic detailing,

which involves trained educators (such as physicians, nurses, and pharmacists) providing clinicians with an accurate, unbiased synthesis of the best evidence for practice in a specific clinical area, only sporadically. But other countries, such as Australia and Canada, use it more. Clinicians value academic detailing, and it has been shown to be effective in clinical trials in reducing inappropriate prescribing. The major issue preventing greater use of academic detailing is lack of funding. The programs that are available run on a shoestring.

A program for academic detailing might be small or large. Perhaps it is best to start small, so a modest proposal might involve a fee of 2% on all current detailing. That would mean that effectively, 1 in 50 detail visits would be noncommercial. With this assessment, the amount collected would be about \$500 million annually.

**Comparative Effectiveness Research Fee.** Research into comparative effectiveness—comparing 2 or more different treatments, such as pharmaceutical management of a disease vs surgical intervention—has been around for decades, but funding for it has been haphazard. Organizations that conduct comparative effectiveness research have seen their budgets challenged when they produce results unfavorable to a particular constituency. In addition, some fear that comparative effectiveness will lead to rationing care.

To its credit, the pharmaceutical industry supports comparative effectiveness research and even funds some research. However, it is not ideal for an industry to fund research on its own effectiveness. The choice of projects may reflect those areas in which research is likely to benefit the industry, not necessarily areas of most benefit to the public. In addition, researchers

who want future funding may tilt their findings to favor the funders.

The natural solution is for pharmaceutical firms to contribute to a general fund for comparative effectiveness research. To be fair to pharma, the research could mostly be directed at clinical settings where pharmaceuticals are one potential treatment option.

As with academic detailing, there is not a single amount for comparative effectiveness research. The federal government allocated \$1 billion annually to comparative effectiveness research after the Great Recession. One could imagine that an amount in the range of \$500 million to \$1 billion annually would be a reasonable successor.

In total, I suggest increased user fees of \$1.1 billion annually for pharmaceutical companies. This amount is of modest size. For example, total industry profits are about 90 times higher. That metric is not necessarily the right one, however. Even if profits were much smaller and the industry had to raise prices in response, it does not make sense to subsidize one industry at the expense of others. User fees are good economics, and that makes for good policy. ■

**Author Affiliation:** Otto Eckstein Professor of Applied Economics in the Department of Economics and Kennedy School of Government at Harvard University.

**Corresponding Author:** David M. Cutler, PhD (dcutler@harvard.edu).

**Published Online:** September 5, 2018, at <https://newsatjama.jama.com/category/the-jama-forum/>.

**Disclaimer:** Each entry in The JAMA Forum expresses the opinions of the author but does not necessarily reflect the views or opinions of JAMA, the editorial staff, or the American Medical Association.

**Additional Information:** Information about The JAMA Forum, including disclosures of potential conflicts of interest, is available at <https://newsatjama.jama.com/about/>.

**Note:** Source references are available through embedded hyperlinks in the article text online.