



BACK TALK

BY SANDER A. FLAUM

Who will pay the piper?

There must be something in the Potomac. Otherwise, why would bright people like Senator Elizabeth Warren, whose politics I rarely agree with but who has at least always struck me as intelligent, propose the legislation they come up with?

I base my concerns about Senator Warren on her recent espousal of the Medical Innovation Act. Here's how it would work: Say you're a large pharma company (that is, you've got a blockbuster bringing in at least \$1 billion yearly) and you get dinged by the FDA for some code infraction. It's not enough that you be publicly tainted and fined. No, Warren proposes that you also be forced to pay an undetermined portion of your profits for the next five years to a fund benefiting the NIH and the FDA.

Brilliant! Although the 2016 budget request for the NIH is \$31.3 billion, up 3.3% from 2015, let's raise even more cash by picking the pockets of productive pharma companies. If this sounds familiar, you may be thinking of the recent uproar when the police in Ferguson, Missouri, were accused by the Justice Department of funding city coffers by selectively fining its African-American citizens.

It's more than luck that despite the best efforts of the current administration and many members of Congress to thwart our industry, the US still leads the world in medical innovation. Staying on top hasn't been stress-free. As the cost of research has soared, drug development has evolved into a three-step process in which basic research, often funded by the NIH, leads to fundamental discoveries, which must then be "translated" by biotechs into investigational compounds. Of these, only a tiny fraction pass muster, and those few are the ones major pharmaceutical companies must then develop and—cross your fingers!—bring to

market. It's expensive and laborious—but astoundingly, it works!

Does Senator Warren seriously think her proposal, which could more accurately be called the "Medical Demotivation Act," will help? Or would its unintended consequences further destabilize the process by which we fund medical research?

The purpose of a fine is to discourage bad behavior, not generate revenue. Warren's proposal basically turns the FDA into a speed trap. She reminds me of those who advocate paying for education with lotteries. Give me a break! I got my MBA a long time ago but even then we knew that money is fungible. For every extra billion dollars her

idea might bring in, it's simply a billion that will flow out into some Senator Pothole's backyard. Congress couldn't keep its hands off the Social Security trust fund. Does anyone seriously think it won't glom on to free pharma money?

I see this bill as simply a way for Senator Warren to make headlines while tossing red meat to her pharma-hating base. If she wants to do something useful, let her look to the House of Representatives, where a genuinely innovative (and bipartisan!) proposal called the 21st Century Cures Act is being debated. It contains a number of proposals aimed at boosting medical innovation instead of stifling it. Although the bill is still in formation, it's great to see lawmakers encouraging the development of sorely needed drugs.

Perhaps not every politician suffers from Potomac brain deflation? What do you say?

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