



The Daily Dish

From Bad to Worse With the IRA

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Nobody has ever confused Eakinomics with a fan of the drug provisions of the Inflation Reduction Act (IRA). Its central feature is price-fixing for drugs in parts B and D of Medicare, cynically labelled “negotiation.” The Centers for Medicare and Medicaid Services (CMS) is armed with confiscatory taxes and the ability to unilaterally ban a firm’s drugs from Medicare. CMS can (and does) essentially dictate the final price. And there is more. A reasonably comprehensive list of gripes is [here](#).

Despite this, periodically a shade of policy optimism sneaks in. In those dangerous moments, however, CMS reliably revisits the IRA to shatter the hope that policy will support innovation, growth, and consumer welfare. Here we go again.

Drugs eligible for “negotiation” are so-called Qualifying Single Source Drugs (QSSD). The average person can think of this as a drug approved by the Food and Drug Administration (FDA), the official arbiter of safety and efficacy. The drug also has to have been on the market for a number of years and not be subject to competition by a generic drug or biosimilar.

A special case of QSSD has been fixed-dose combination (FDC) drugs, a combination of two active drugs. Under current policy, an FDC is treated by CMS as a separate QSSD for purposes of identifying drugs. Now CMS is proposing to treat the FDC and the original drug as a single drug, and use the earliest approval date for the drugs involved as the approval date of the new FDC. This is a terrible idea.

To begin, the FDA treats the new combination FDC as a unique drug, requiring separate clinical trials and the remainder of the approval process. It makes no sense for CMS to arbitrarily ignore this. Also, the second drug is added for a reason. For example, it may allow the drug to be delivered as an injection instead of infused. This is done because patients value the ease of delivery, or side effects can be reduced to allow more to take it. It

also costs a lot of time and money to develop a new delivery mechanism. It makes no sense for CMS to ignore the welfare of patients and not recognize the costs of innovation when setting drug prices.

The cardinal sin of the IRA is price-fixing, and the new policy would essentially bleed a fixed price into even more drugs. This is literally a step from bad to worse. It makes the disregard for patients and innovation incentives even more dramatic. It is not a step that CMS should take.