THE WALL STREET JOURNAL.

http://www.wsj.com/articles/the-coming-government-takeover-of-drug-pricing-1448231481

OPINION | COMMENTARY

The Coming Government Takeover of Drug Pricing

ObamaCare provides the tools for a unilateral move against the industry the left loves to demonize.

PHOTO: GETTY IMAGES/MEDICALRF.COM

By **SCOTT GOTTLIEB**

Nov. 22, 2015 5:31 p.m. ET

Hillary Clinton has plenty of allies as she demonizes drug-company profits and pushes for federal control over how drugs are priced. There's a drug-pricing task force led by

the White House and a similar Democrat-led effort in Congress.

Many of the pharma industry's proponents in Washington and on Wall Street dismiss this as political noise, arguing that new restrictions impeding investment and innovation are unlikely to get through a Republican Congress. But the Affordable Care Act reordered the legal framework to let a president impose price restrictions unilaterally through the Independent Payment Advisory Board and the Center for Medicare and Medicaid Innovation. These executive-branch bodies were crafted to control what procedures doctors perform, but there is reason to believe they can also control drug prices.

The Independent Payment Advisory Board was designed to take decisions about how to reduce Medicare's spending out of any public debate. The board's appointed academicians have no statutory obligation to engage in the public notice and comment that is customary in regulation. IPAB decisions are exempt from judicial review and appeal, and they take effect without Congress.

The board is barred by law from making big changes to the structure of Medicare. As a result, its focus probably will turn to implementing price controls and ways to give Medicare the power to control the use of new technology.

The Center for Medicare and Medicaid Innovation is similarly able to create new payment rules—even if they conflict with existing law—to target medical technology and procedures that seem to be spending outliers, costing Medicare more than some ill-defined norm. Under the ObamaCare statute, CMMI can flout any existing Medicare rule by designing "pilot" programs that needn't be small in scale.

Regarding drug prices, IPAB and CMMI are likely to engage in so-called reference pricing that is the backbone of European-style price controls. Under this construct, the agencies will allow the Medicare program to lump together drugs and other treatments that the agencies' bureaucrats feel are similar enough that they can be used in place of one another—even if a newer but also more expensive treatment might offer benefits over older alternatives.

Think of a new cancer drug that obviates a far less-tolerable form of chemotherapy. Only Medicare says the new drug should be priced the same as old, generic chemo because the Food and Drug Administration says that the two remedies have a similar treatment effect. Medicare has long wanted the authority to say that it would only pay for the "least costly alternative" treatment within a given set of therapeutic options.

The powers of the Independent Payment Advisory Board are only triggered when Medicare's rate of spending growth is projected to rise faster than a peg that's tied to inflation. Medicare's projections show that this threshold will be triggered in 2017, and maybe sooner. So as a new president takes over, he or she will inherit broad authority to unilaterally rewrite Medicare's payment rules.

The effect on the availability of new treatments could be cataclysmic. Drug discovery is a high-risk, high-cost endeavor. Mounting regulation already has stretched the average time to develop a drug to 128 months between synthesizing a pill and winning its approval. Only about 10% of the drugs that go through Phase I clinical trials reach the market. Average out-of-pocket spending is $1.4 billion to develop a new medicine, with an additional $470 million in direct, post-market research costs after a drug is approved.

Much of this money is spent meeting regulatory demands. In 2002 there were 494,000 data points collected to satisfy regulatory requirements in a typical, late-stage Phase III clinical trial. By 2012 researchers at the Tufts Center for the Study of Drug Development found that figure had grown to 929,000.

Government rules like the existing price controls in Medicaid prevent drug developers from experimenting with new ways to price their products according to the value they're delivering, like charging different prices based on the indication that a medicine is being used for. Or tying a drug's price to how well a patient is responding to the treatment. These are far better alternatives to price controls, but, ironically, the government's price interventions prevent these approaches.

Constructs like the Independent Payment Advisory Board are unpopular among liberals and conservatives because they target hospitals and providers as well as drugs. Yet conservatives in Congress have passed on chances to cut away IPAB and the Center for Medicare and Medicaid Innovation. They fear that excising the law's gangrenous decay makes the whole carcass harder to bury. But leaving these appendages in place weakens their hand. ObamaCare was designed to infect the normal political balance over health policy. The drug kerfuffle will demonstrate how much control Congress has already ceded.

Dr. Gottlieb is a physician and resident fellow at the American Enterprise Institute. He consults with and invests health-care companies.