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Lilly Sidelined Three Drugs Due To IRA, CEO Ricks Says

by Jessica Merrill

Eli Lilly & Co. CEO David Ricks highlighted how Medicare drug price negotiation policies are already impacting R&D investment during a J.P. Morgan investor call.

A new Medicare drug price negotiation program that is being implemented by the US Centers for Medicare & Medicaid Services (CMS) as required by the Inflation Reduction Act (IRA) is already having an impact on research and development investment decisions, *Eli Lilly and Company* CEO David Ricks said during an investor event sponsored by J.P. Morgan on 14 June to discuss the IRA and pharmaceutical industry policy priorities.

Lilly has deprioritized three drugs as a result of the new program that will allow CMS to negotiate drug prices for certain top-selling medicines beginning in 2026, Ricks said, although he didn't disclose which drugs or how advanced in development they were.

> ***"I can tell you, after nine months, there are three fewer Lilly drugs," Lilly CEO David Ricks said.***

The pharma industry has voiced outspoken opposition to the new Medicare program, which is in the early stage of development but moving forward quickly. The first 10 drugs to face negotiation are expected to be named by CMS in September.

One of the industry's biggest arguments against the legislation has been that it would dissuade investment in small molecule drugs, which are only granted nine years on the market before

potentially facing drug price negotiations, while biologic medicines get 13 years. (Also see "*Industry Looks At IRA Drawbacks And Silver Linings*" - Scrip, 20 Jan, 2023.)

Nonetheless, despite the rhetoric from industry leaders, few have come forward to say the legislation has stopped the development of specific programs.

"Already investors are making those decisions. We are making those decisions, which is de-emphasizing programs that would have been pursued as productive that are no longer productive," Ricks said.

A forecast from the Congressional Budget Office (CBO) that predicted the IRA would result in around 15 fewer drugs after 10 years under-appreciated the impact, he said.

"I can tell you, after nine months, there are three fewer Lilly drugs," he said. "We are 5% of the US market, so their estimate is off by orders of magnitude in terms of how much effort will go into small molecules."

No Jardiance For Heart Failure

There are other negative unintended consequences stemming from the IRA as well, Ricks said, highlighting real world examples. The expansion of Lilly's SGLT2 inhibitor Jardiance (empagliflozin), a drug first approved for diabetes in 2014, to a new indication for heart failure in 2022 probably wouldn't have happened under the IRA, he said.

"We did a whole Phase III program on that in the middle of the lifecycle; probably that ends up being more valuable than the original indication, but no one would have pursued that," he said. "What we would have done is gone back, found a new SGLT2 inhibitor that we haven't registered yet and have started all anew, and in the meantime, people would have been dying of congestive heart failure."

In other cases, drugs may simply not have been made available to Medicare patients, Ricks said, referencing drugs that are most widely used in younger patient populations, products like the new oral migraine drugs.

"These are incident populations that are spread more younger in the population, so you do raise the question of should I even try for government access for a new innovation if it is going to get caught up in a potential downstream negotiation, or should I focus on the 80% market," he said. "That, I think, is really sad for people who rely on government benefits but is a consequence that market actors will pursue."

Ricks raised another potential long-term issue that has not gotten much attention – the downstream effect on the availability of generic drugs if fewer small molecules are developed.

Small molecule generic drugs tend to be more quickly adopted, substantially lowering health care costs, than biosimilar versions of biologic drugs.

“Because we will have fewer small molecules, and the ones that do make it will be approved for fewer uses, we will have far less generic surplus value in the health care system forever,” he said.

Many of the issues raised by Ricks have been industry talking points against the Medicare negotiation program since the IRA was signed into law last year, but as the program moves forward into implementation some of the consequences of the legislation will become clearer.

Industry is still pushing for changes to some elements of the program, including perhaps most aggressively to end the steep penalty tax that will be levied on companies who don’t comply with a Medicare-negotiated price. *Merck & Co., Inc.* filed the first lawsuit against the IRA in early June, centering on that part of the legislation, and a second suit was also filed by the US Chamber of Commerce.