

## US drug prices face long-term risks

PaRR Strong evidence

- US Congress not expected to pass legislation soon
  - Average drug prices affected by discounts and rebates
  - HHS a wild card; antitrust agencies to avoid price regulation
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Although the current US Congress is unlikely to act on drug prices, there is growing anxiety in the pharmaceutical industry about presidential campaign politics and a potential role for the Department of Health and Human Services (HHS), industry sources said.

The US House Oversight Committee on 4 February will hold a hearing on drug pricing issues, with CEOs from **Turing Pharmaceuticals** and **Valeant Pharmaceuticals** (NYSE:VRX) having been asked to testify. But the expected political theater poses no real threat, industry sources said.

“Nothing happens on drug pricing in 2016 except political posturing in an election year designed to make drug pricing regulation a political wedge issue,” Evercore analyst Terry Haines wrote in a 21 January research note.

A DC-based pharma policy specialist agreed with that assessment. “Congress definitely isn’t going to do anything,” he said.

However, there is political risk outside of Congress, the specialist said. In particular, pharmaceutical companies are “frustrated and nervous” about ballot initiatives in California and Ohio to lower drug prices, as well as the “steady drumbeat” on the issue from 2016 presidential candidates.

Former Secretary of State Hillary Clinton, Sen. Bernie Sanders (D-VT) and Donald Trump have all said that Medicare should be able to negotiate drug prices. Also, Sen. Marco Rubio (R-FL) has criticized the industry for “pure profiteering”.

However, it is difficult to determine whether average drug prices are actually increasing substantially, since the ever-increasing size and power of ‘pharmacy benefits managers’ like **Express Scripts** and **UnitedHealthcare’s OptumRX** are forcing pharma manufacturers to lower prices. In addition, there are myriad government buyers who may be able to obtain different drug prices.

Industry data vendor IMS Health concluded that drug invoice prices increased 13.5% on average in 2014. But after discounts, rebates and other price concessions, the average price increase was just 5.5%, the lowest in five years.

### HHS and antitrust agencies

Lingering in the background of these policy debates is a Department of Justice (DoJ) investigation launched in 2014 that appears to focus on the generic drug industry. Companies including **Lannett** (NYSE: LCI), **Impax Laboratories** (NASDAQ: IPXL), **Par Pharmaceutical**, now owned by **Endo International** (NASDAQ: ENDP) and **Allergan** (NYSE: AGN) have disclosed the receipt of DoJ subpoenas.

A former DoJ attorney said the subpoenas are likely to ask for volumes of data including emails, travel records, invoices, and memos. There are often negotiations between the agency and the companies regarding the scope of the subpoena, and the DoJ also speaks with witnesses, such as former employees.

Although resolution can occur more quickly as a result of company cooperation, DoJ investigations typically last three to five years.

“These cases just take a long time – there are no shortcuts,” the former DoJ attorney said.

In terms of broader effects, a wild card for the industry is the Centers for Medicare and Medicaid Services (CMS) at the HHS, an agency which is involved in the DoJ investigation and already plays a role in reviewing health insurance rate increases.

“CMS could possibly play a role [on drug pricing], but I’m not sure what they can do at this point unilaterally other than changing formularies, which would upset a lot of people,” said the specialist.

The possibility of price regulation by CMS has arisen in the past, and it could reemerge, particularly under a new Democratic president. The current administration has given no indication of imminent action, Haines noted in his report.

In contrast to the HHS, the US antitrust agencies would likely resist a regulatory role on pricing issues.

Senator Amy Klobuchar (D-MN) and others have asked the Federal Trade Commission (FTC) to intervene on pricing, but former FTC lawyers said the agency has little appetite for active regulation of the market.

"I think they'd be very reluctant to step into a price regulator role, and they really would fight against that," said Joseph Miller, a partner at Crowell & Moring who previously worked at the DoJ and FTC.

The FTC does have authority under Section 5 to address unfair methods of competition. However, using Section 5 to prosecute high prices would be a "terrible, terrible precedent that I don't think they would want to set," Miller said.

by Ryan Lynch in New York

- Companies

- [Valeant Pharmaceuticals International, Inc.](#)
- [Endo International plc](#)
- [Allergan plc](#)
- [IMPAX Laboratories Inc](#)
- [Lannett Company, Inc.](#)
- [Turing Pharmaceuticals, LLC](#)

Agencies

- [US Department of Justice \(DoJ\)](#)
- [US Federal Trade Commission \(FTC\)](#)
- [US Department of Health and Human Services \(HHS\)](#)