

ML Strategies Health Care Update - DNA Sequencing Workshop and Drug Pricing Developments

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On Tuesday, ML Strategies (MLS) posted its weekly **Health Care Update**, which provides information from the previous week on a variety of important health-care-related topics.

In addition to covering a number of events related to the Affordable Care Act, telemedicine, and the nationwide opioid coverage crisis, this week's Update covered the workshops held by the Food and Drug Administration (FDA) for genome scientists on the technical aspects of integrating Next-Generation Sequencing (NGS), a DNA-sequencing method, into clinical practice. Joanne Hawana, Eli Greenspan and Erin Kathleen Morton also published an alert on these workshops last week.

While the FDA has not yet developed a new regulatory framework for NGS that is different from the process for more traditional diagnostic tests, its goal is to institute "appropriate oversight, in a way that is more suitable to the complexity and data-richness of this new technology." This focus on NGS is being driven by President Obama's Precision Medicine Initiative, bipartisan and bicameral interest on Capitol Hill, and the desire of patients and physicians to be able to choose the right treatment, at the right time, with hopefully minimal side effects. A number of federal agencies have taken steps to implement the Precision Medicine Initiative, including the National Institutes of Health which seeks to enroll one million volunteers in the next five years in a study that will evaluate the risk of developing a disease by looking at both genetic and environmental factors. The FDA workshop last week was also in step with the President's initiative.

This week's Update also highlights a number of developments related to prescription drugs:

1. President Obama reiterated his support for enabling the Department of Health and Human Services (HHS) to negotiate drug prices directly with manufacturer and is also looking at ways to prevent companies from raising prices of older drugs (which is a practice that has been the focus of criticism this year).
2. Last week, the Senate Special Committee on Aging, led by Senators Susan Collins (R-ME) and Claire McCaskill (D-MO), launched an investigation into price increases of certain drugs and sent letters requesting more information from Valeant Pharmaceuticals, Turing Pharmaceuticals, Retrophin, Inc., and Rodelis Therapeutics.
3. House Democrats announced an Affordable Drug Pricing Task Force designed to fight the rapidly increasing costs of pharmaceuticals. Members of this group are also urging House Oversight & Government Reform Chairman Jason Chaffetz (R-UT) to launch a formal investigation.
4. Today, HHS hosted an invite-only Drug Pricing Forum. The purpose of the forum is to address the impact of rising pharmaceutical costs and share information on how to address those rising costs while still encouraging innovation, strengthening incentives and promoting competition.

Mintz Levin and ML Strategies have been closely following the rising costs of prescription drugs and will continue to monitor related events in this blog and in future Updates, which can be accessed [here](#).

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