

Mintz/ML Strategies Pharmacy Summit White Paper Highlights Drug Development Process

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The pharmaceutical industry is facing the prospect of a rapidly evolving landscape, one that challenges its regulatory understanding and business model. States from [Vermont to California](#) are proposing transparency and price capping proposals through the state legislature while candidates for federal office – from the presidency down to congressional races – are proposing or endorsing policies which could drastically alter the status quo. With so much uncertainty in the political space as the 2016 election cycle heats up, Mintz and ML Strategies brought together stakeholders from across the industry last month to shed light on the debate over drug pricing and how regulatory initiatives and legislative proposals frame the issue moving forward.

A common theme among policymakers and consumer advocates is a need for transparency. However, understanding what transparency is from a policy perspective requires an in-depth look at how drugs are manufactured and brought to market. ML Strategies put together a White Paper to go along with the Pharmacy Summit titled, “[Issues to Consider from the Research Lab to the Consumer](#),” to understand and highlight the process manufacturers go through to bring a drug to market. We broke this process down by looking at the considerations that go into pricing before the drug leaves the manufacturer to the process between the manufacturer and the consumer.

While a drug manufacturer decides on the price of a drug, between the manufacturer and the consumer are a number of stakeholders who play a role and may add additional costs that are ultimately felt by the consumer. Many believe unpacking this process will help keep bad actors, and the industry as a whole, honest. However, that theory has yet to be fully tested.

It is up to policymakers to determine what level of transparency is needed to make the system operate fairly and effectively. For more detailed information on this process, you are encouraged to explore the ML Strategies [white paper](#) on this topic.

Authors