LIFE SCIENCES DEALMAKING SYMPOSIUM

AS THE DUST SETTLES: POST-ELECTION UPDATE AND IMPACT ON THE LIFE SCIENCES INDUSTRY

How will the election affect life sciences in 2021 and beyond? What's ahead for the regulatory and policy environment? In this session, our elite group of policy analysts reviewed the election results and the far-reaching effects for dealmakers, executives and investors.

Eric Zimmerman, global head of McDermott's Health Industry Advisory Practice Group, moderated this discussion that featured insights from Susan Van Meter, executive director at AdvaMedDx; Rodney Whitlock, PhD, vice president at McDermott+Consulting; and Brian Fortune, senior managing director at Farragut Square Group.

1. President-Elect Biden's legislative experience likely will help him reach across the aisle and engage with Republican congressional leadership to advance policy goals. "Biden spent his whole career on the Hill before he became vice president, so he really understands how his colleagues tick, and he particularly understands the process of how the Hill makes sausage," Mr. Fortune said. "That's something that you can't really say about either President Obama or President Trump. So, not surprisingly, you saw that when they had all the majorities lined up in their favor, they could move stuff, but when they didn't, it became a little harder."

2. With only a narrow projected majority in the US House of Representatives, Democrats will need to work together more effectively and reach across the aisle in order to pass legislation, including on issues such as drug pricing. "Partisanship is getting you nowhere in this next Congress," Mr. Whitlock said. Drug pricing, financing surrounding the Medicare program and COVID-19 relief packages are three significant legislative decisions that will take bipartisan cooperation to achieve, Mr. Zimmerman noted.

3. The COVID-19 pandemic has led to regulatory flexibilities from the FDA and other agencies to bring life-saving devices and treatments to market more quickly. Those flexibilities open up new avenues for innovation and improved care coordination should agencies decide to keep some of the waivers in place and prioritize modernization. One particular area of opportunity to bring regulatory change is in the diagnostics space, Van Meter said. "Diagnostics are currently regulated as medical devices. Modernizing the framework for diagnostics would mean having a diagnostics-specific regulatory framework that would apply to all diagnostics – both LDTs and IVDs - and reflect the types of evidence that are more suitable for bringing diagnostics through the agency, recognizing the diagnostics are relatively particular," Van Meter explained. "Also in the modernization facet, thinking about how can we ensure that the regulatory framework allows for innovations to be available to patients more quickly."

4. Life sciences industry stakeholders should watch to see who President-Elect Biden plans to appoint to various agency posts, Mr. Fortune said. Leaders at the US Food and Drug Administration and the US Centers for Medicare and Medicaid Services will play a key role in shaping the regulatory environment for life sciences.

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