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Foreword:

Throughout 2017, Congress has focused in large part on repealing and replacing the ACA, and that now-stalled process has dominated both news cycles and investor attention. With Congress back for the fall, however, the legislative agenda will likely focus on non-healthcare priorities for much of the time. Key items will include keeping the government funded, raising the debt ceiling, providing disaster relief funding, and tax reform. That said, the Children's Health Insurance Program (CHIP) must still be authorized, and we expect at least some effort toward ACA market stabilization in the early part of the fall.

The most interesting form the calendar can assume from a healthcare priorities perspective is a short-term extension of the CHIP reauthorization. If that is the case, along with a short-term government funding extension, there is ample opportunity for one or both to become a larger end-of-year legislative vehicle, which could help move other healthcare legislation that has support but lacks a clear vehicle.

Additionally, this fall will see the first health exchange open enrollment period of the Trump administration. The early suggestion has been that the administration will allow the program to wither on the vine, but the fact that states and insurers have worked to cover all previously open counties suggests that those entities may try to pick up some of the government's slack to try and drive higher enrollment.

The fall will also see the publication of several final CMS and HHS regulations from this initial round of rulemaking. For the most part, proposed rules have primarily included ideas and initiatives that were initially conceived toward the tail end of the Obama administration, though the changes to the Comprehensive Joint Replacement demonstration and the proposed change to 340B reimbursement do not fall under that category.

It will be important to watch how the administration reacts to comments and stakeholder concerns as it finalizes rules, as this will likely provide a key window into how it will treat these types of concerns in the future.

While President Trump continues to periodically add his commentary to the drug pricing debate, so far, the administration has been more bark than bite. There was some nervousness from the market when it became known that the President was planning to issue an executive order on drug pricing, but fears were assuaged following a leak of a document that appears to have been a draft. The draft did not seem to do anything that would be broadly negative for the pharmaceutical industry, and, in fact, it seemed pharma friendly. Given the personnel that the administration has in place, who tend to be business/pharma friendly, it is perhaps not too surprising that the draft executive order was benign. Executive orders do not enable any change of existing statute, so their power is inherently limited; essentially, they merely provide an additional emphasis to powers that an administration already possesses, although there may be some value in agency coordination. There is no visibility on when the executive order will be issued, if at all. We do caution that this administration, and particularly the President, is unpredictable, and some volatility could easily re-emerge around the issue.

The *Prescription Drug User Fee Act, Medical Device User Fee Act*, *Generic Drug User Fee Act*, and *Biosimilar User Fee Act* were all renewed with very little substantive change. Congress chose to take the path of least resistance to ensure strong bipartisan support. This meant that *de facto*, there was no chance of adding any amendments related to drug pricing. However, it is possible that the issue could surface during negotiations around CHIP reauthorization. For example, some members are pushing to use the CREATES Act as possible pay-for.

The pharmaceutical supply chain continues to be at risk of attracting attention in the drug pricing discussion. PBMs may be well positioned, ultimately, given their important role in moderating price and utilization. However, a lack of understanding regarding their role could be a handicap in Washington, at least in the early stages of the debate. While distributors are not likely to be a direct target, moderation in drug

price increases could have a negative impact, given that list prices dictate some of the economics of their business.

Medical devices could be set to benefit from the new administration. Reforms passed under the *21st Century Cures* legislation are helpful for the industry, but commentary from the administration on lowering regulatory barriers could be even more positive. We note that many new devices are currently approved for use in Europe before they achieve FDA clearance. In June 2017, newly appointed FDA Commissioner Scott Gottlieb announced the Digital Health Innovation Plan, which should simplify the approval of some forms of medical software, as well as the creation of a Medical Innovation Development Plan aimed at streamlining the development and review of drugs to treat costly rare diseases through improved adaptive trial designs and statistical tools.

We believe that the medical device tax suspension could be extended, and potentially permanently repealed, if the right legislative vehicle appears (for example, comprehensive tax reform).

The Clinical Lab Fee Schedule rebase, as described in PAMA, is set to begin in January 2018. The final rule made some concessions to the industry, and some hospital outreach labs may contribute some data. However, Marwood believes that independent laboratories are likely to dominate for many codes. The data reporting period for applicable labs began on January 1, 2017 and ended on May 30, 2017. We expect some clarity on the new fee schedule soon.

CMS's efforts to curtail third-party payments for dialysis patients on exchange plans were dealt a setback when a Texas judge granted a preliminary injunction to prevent implementation of an interim final rule that would have made sure that insurers were aware of and accepted third-party payments. The preliminary injunction will stay in place until overturned, and it relates to the fact that CMS did not go through its usual process of considering comments (the administrative procedures act). Rather than appealing the decision, CMS could simply collect comments and then issue a final rule, a process that would not be in violation of the administrative procedures act. It is unclear where the current administration stands on the issue, but it is likely to be a lower priority than it was for the Obama administration.

The pace for biosimilar approvals has picked up, and there are now 2 branded biologics that have 2 biosimilar competitors, Remicade and Humira. Hospira's and Merck's biosimilars have launched, setting up a competitive market. However, there have been some setbacks, including a Complete Response letter for Coherus's biosimilar Neulasta and Hospira's biosimilar version of Epogen (related to the manufacturing facility). An FDA panel recommended approval of biosimilars Avastin and Herceptin. The Supreme Court ruled that the 180-day notice of commercial marketing can be given prior to FDA approval, allowing somewhat faster product launches, but some biosimilar launches may be held up by ongoing patent litigation.

After a slowdown in new drug approvals in 2016, as of August 2017, FDA's Center for Drug Evaluation and Research had already approved 28 new molecular entities (8 BLAs and 20 NDAs). The trend toward approvals fitting the priority review, orphan drug, and breakthrough therapy designations continues to grow. Drugs targeting these niche markets are typically associated with significant price tags, which can add further fuel to the drug pricing debate.

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