

Viewpoints

ML Strategies Legislative & Regulatory Update

Looking Ahead to 2019 and the New 116th Congress

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ML STRATEGIES PLANNING SERIES OF UPDATES ON THE CONGRESSIONAL AGENDA

Following up on our recent [alert](#) on the remaining legislative agenda for the “lame duck” session of the current 115th Congress, ML Strategies will be releasing a series of updates over the coming weeks highlighting potential areas of legislative activity in 2019 as the new 116th Congress gets underway.

Today’s legislative outlook focuses on the Food and Drug Administration (FDA). There are a number of medical product issues that FDA and the 116th Congress will need to address or continue working on, and our forecast highlights the following hot topics: laboratory-developed tests (LDTs)/In Vitro Clinical Tests (IVCTs), digital health and software, cybersecurity, device servicing, OTC drug monographs, and opioids. While not an exhaustive list of FDA-related legislative topics, these issues are likely to be in the spotlight.

The full FDA update – Medical Products & FDA: What to Watch for in 2019 – can be found [HERE](#).

LEADERSHIP FOR THE 116th CONGRESS

Since the midterm elections, the House and Senate have selected their leadership for the 116th Congress.

Top leadership remains the same in the Senate with Majority Leader McConnell (R-KY) and Minority Leader Schumer (D-NY) remaining in their posts.

The Republican leadership team is rounded out by Sen. Thune (R-SD) as Majority Whip, Sen. Barrasso (R-WY) as Conference Chair, Sen. Blunt (R-MO) as Policy Committee Chair, and Sen. Young (R-IN) as Chairman of the National Republican Senate Committee.

The Democratic leadership team includes Sen. Durbin (D-IL) as Minority Whip, Sen. Murray (D-WA) as Assistant Democratic Leader, Sen. Stabenow (D-MI) as Policy Committee Chair, and Sen. Cortez Masto (D-NV) as Chair of the Democratic Senatorial Campaign Committee.

Democrats have nominated Minority Leader Nancy Pelosi (D-CA) to serve, again, as Speaker of the House, a position she previously held from 2007-2011. The former speaker has been busy, and successful so far, in pushing back against opposition to her retaking the speakership from a number of members in both the moderate and progressive wings of the caucus. To retake the speaker’s gavel, she will need to secure 218 votes from the full House in January. The remainder of the Democratic leadership team will consist of Rep. Hoyer (D-MD) as Majority Leader, Rep. Clyburn (D-SC) as Majority Whip, Rep. Lujan (D-NM) as Assistant Democratic Leader, Rep. Jeffries (D-NY) as Caucus Chair, and Rep. Clark (D-MA) as Caucus Vice Chair.

House Republicans have elected Rep. McCarthy (R-CA) to serve as Minority Leader, Rep. Scalise (R-LA) as Minority Whip, Rep. Cheney (R-WY) as GOP Conference Chair, Rep. Palmer (R-AL) as Policy Committee Chair, and Rep. Emmer (R-MN) as Chairman of the National Republican Campaign Committee.

POTENTIAL HOUSE RULES CHANGES FOR THE 116th CONGRESS

As Rep. Pelosi continues her push to secure enough Democratic votes to become Speaker of the House next year, an agreement was reached last week between Democratic leadership and Democratic members of the bipartisan House Problem Solvers Caucus on proposed changes to the Rules of the House of Representatives. Intended to foster greater bipartisanship and to allow less senior members of Congress a greater role in passing legislation, the proposed House rule changes are a part of the “Break the Gridlock” agenda of the caucus. The agenda is aimed at “encouraging and rewarding consensus-driven governing, fostering passage of member initiatives solving constituent priorities, increasing accountability and transparency, and electing a Speaker that is representative of the entire body.” Changes in the Rules of the House of Representatives are common at the start of a new Congress, and these and any other changes will be one of the first votes taken by the full House of Representatives in January. The agreement on reforms to the rules of the House includes:

- **Every Member Gets a Voice:** Once a bill reaches 290 cosponsors, a 25–legislative day clock will begin. If the primary committee of jurisdiction does not report the bill by the end of the 25 legislative days, the legislation will be placed on the new “Consensus Calendar” where it will remain until the bill is considered. For every in-session week, after February 28 of the First Session and before September 30 of the Second Session, majority leadership will be required to bring at least one bill on the “Consensus Calendar” to the full House for consideration.
- **Bipartisan Amendments:** Creation of a Rules Committee protocol that adds a preference to amendments that comply with the rules; have at least 20 members of each party as cosponsors.
- **Modernize the Discharge Petition:** Streamline the process for a discharge petition, which allows 218 members to bypass the leadership and bring a bill to a vote by the full House, by allowing the petition to be considered with three days’ notice and expanding the days upon which measures can be considered.
- **Increase Committee Transparency:** Require three–business days’ notice for committee markups, with certain exceptions.
- **Reform the Motion to Vacate the Chair:** Adopt a rule stating that a resolution causing a vacancy in the Office of the Speaker will be privileged (taking precedent over the regular order of business) if offered by the direction of a major party caucus or conference.
- **Legislative Committee Party Ratios:** Commit to a fairer party ratio for committees.
- **A More Inclusive Amendment Process:** Commit to a fairer and more inclusive legislative process where more ideas and amendments are debated.
- **Preserve “Majority Markups”:** Ensure that a majority of the members of a committee can request and schedule a markup of the committee they serve on.

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