



The Impact of the Mid-Term Elections on the Biotech Industry

The mid-term elections resulted in a dramatic shift in the political landscape of the 110th Congress. With the Democrats taking control of both chambers of Congress for the first time in 12 years, next year will bring a newly focused legislative agenda and greatly increased Congressional oversight.

New Landscape

Both Washington pundits and Wall Street analysts are predicting "grid lock" in the new Congress. Democrats can expect high hurdles to achieving any significant legislative reforms opposed by the Bush Administration given their narrow, one seat majority in the Senate. Additional hurdles include the President's veto power and the powerful role of the "Blue Dog" House Democrats coalition in the House. The "Blue Dogs" are the more conservative House Democrats who have in the past frequently aligned themselves with the Republicans to block adoption of policies that could adversely affect business interests, including the vaccine and biotechnology industry. In the 110th Congress the list of "Blue Dog" Democrats are: Joe Baca (CA), John Barrow (GA), Melissa Bean (IL), Marion Berry (AR), Sanford Bishop (GA), Dan Boren (OK), Leonard Boswell (IA), Allen Boyd (FL), Dennis Cardoza (CA), Ben Chandler (KY), Jim Cooper (TN), Jim Costa (CA), Bud Cramer (AL), Lincoln Davis (TN), Jane Harman (CA), Stephanie Herseth (SD), Tim Holden (PA), Steve Israel (NY), Jim Marshall (GA), Jim Matheson (UT), Mike McIntyre (NC), Charlie Melancon (LA), Mike Michaud (ME), Dennis Moore (KS), Collin Peterson (MN), Earl Pomeroy (ND), Mike Ross (AR), John Salazar (CO), Loretta Sanchez (CA), Adam Schiff (CA), David Scott (GA), Heath Shuler (NC), John Tanner (TN), Ellen Tauscher (CA), Gene Taylor (MS), Mike Thompson (CA). A large number of the newly elected freshman Democrats will likely join the "Blue Dog" caucus. Bi-partisan cooperation will be necessary to pass any legislation, particularly in the Senate, where 60 votes are often needed to pass legislation from the Chamber. Nonetheless, Democrats are skilled at extracting support, particularly given the depth of experience of the incoming chairman. History shows that some of the most radical reforms have occurred when both Houses of Congress were controlled by the Democrats while Republicans control the White House.¹ Congressional Democratic leaders should have ample opportunity to package their agenda in legislation that also responds to the White House agenda.

New Leadership

It will be very important for the biotechnology industry to engage in "educational" efforts with the new Democrat leaders -- and their staff-- who chair or serve on the key authorizing, appropriations and oversight Committees and Subcommittees to ensure they understand issues critical to the industry. Given that the election outcome will force the Administration and Congressional Republicans, with the support of "Blue Dog" Democrats, to push for greater fiscal restraint, a significant increase in spending is not expected. However, the priority of the spending will change and will likely be more favorable for financing vaccines against global occurring infectious disease threats, such as HIV/AIDS, TB and malaria, through advance market commitments and other funding mechanisms. The list of House and Senate Leadership positions are as follows:

House

Democrats

Speaker: Nancy Pelosi, (CA - 8)
Majority Leader: Steny Hoyer (MD- 5)

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Majority Whip: James Clyburn (SC - 6)
House Democratic Conference Chairman: Rahm Emanuel (IL - 5)
House Democratic Conference Vice Chairman: John Larson (CT - 1)
House Democratic Policy Committee: Rosa DeLauro (CT - 3), George Miller (CA - 7), Co-Chairs

Republicans

Minority Leader: John Boehner (OH - 8)
Minority Whip: Roy Blunt (MO - 7)
House Republican Conference Chairman: Adam Putnam (FL - 12)
House Republican Conference Vice Chairman: Kay Granger (TX - 12)
House Republican Policy Committee: Thaddeus McCotter (MI - 11)

Senate

Democrats

Majority Leader: Harry Reid, Nevada
Majority Whip: Richard Durbin, Illinois
Democratic Senatorial Campaign Committee: Charles Schumer, New York
Senate Democratic Conference Chairman: Patty Murray, Washington
Senate Democratic Conference Vice Chairman: Charles Schumer, New York

Republicans

Minority Leader: Mitch McConnell, Kentucky
Minority Whip: Trent Lott, Mississippi
National Republican Senatorial Committee: John Ensign, Nevada
Senate Republican Conference Chairman: Kay B. Hutchison, Texas

Incoming Chairmen John Dingell (MI - 15) and Henry Waxman (CA - 30) will shape healthcare policy during the 110th Congress. Rep. Dingell will chair the House Energy and Commerce Committee and is planning to focus on improving drug safety, lowering Medicare costs and easing the path for generics to be introduced into the market. Rep. Waxman, chairing the Government Reform Committee, will focus on creating a pathway for generic biologics. Both Chairmen will yield substantial oversight authority and have made clear their agenda will include numerous hearings on a variety of topics.

In the Senate, Chairman Edward Kennedy (D-MA) announced his top priorities for the HELP Committee to include providing greater access to health insurance coverage, expanding federal funding for embryonic stem-cell research, speeding up providers' adoption of health information technology, and improving Medicare's prescription drug benefit.

New Legislative Priorities

The incoming Congressional leadership has announced some of their goals for the 110th Congress, including:

1. Reducing Drug Prices and Medicare Costs: Expect legislation that will reduce drug prices and Medicare reimbursement rates (e.g., striking the noninterference clause of Medicare Part D, establishing follow-on biologics, and permitting drug reimportation.) Democrats will be looking for Medicare reforms that do not cut benefits but reduce reimbursement rates. Any savings will likely be used to offset their proposals to expand Medicare coverage (e.g., filling the donut-hole and expanded coverage of the uninsured). However, the increasing popularity of this benefit among seniors will present a significant political challenge in altering this program. Nonetheless, the Democrats have made this effort their top agenda item.

2. Passing Biodefense Legislation: The incoming House majority leader has called for the passage of the Biodefense/Bioterror legislation before the 109th Congress adjourns in **Sine die**. The legislation, among other things, would establish a new Authority (BARDA) to enter into contracts to support advanced research and development. The bill contains some procurement reforms, such as milestone payments, to bridge the "Valley of Death" and permit products to reach BioShield procurement eligibility. Ensuring the passage and conferencing of this legislation will be of specific importance to the biodefense industry. If this bill passes, the challenge for industry will be to garner continued commitment by Congress to support BioShield, NIAID biodefense R&D funding and the Strategic National Stockpile (SNS).

3. Eroding Countermeasure Liability and Compensation: Given the high probability that the new majority will focus on repealing liability protections afforded by the PREP Act, SAFETY Act and VICP, the biotech industry should prepare a defense to ensure their exposure to non-science based litigation is nominal. Democrats have tried to repeal the PREP Act on several occasions while they were in the minority. They have made repeal of this critical public health preparedness statute part of their 100 Hour Agenda.

4. Granting New Authorities to FDA to Ensure Drug Safety: Drug safety legislation as part of the Prescription Drug User Fee (PDUFA) Reauthorization is a political reality. The Biotech industry needs to be a force in shaping any drug safety legislation – if it is found that vaccines and certain biologics need to be a part of the reform -- to ensure safe drugs while not interfering with access to lifesaving vaccines and biologics.

5. Controlling Vaccine Pricing and Marketing: The vaccine industry needs to be vigilant in:

- Justifying to Congress -- and the private sector -- the significant increases in costs of new vaccines; and
- Ensuring that the government does not become the sole purchaser of vaccines.

Navigating the New Congress

The changes in the legislative agenda will not be immediate. They will unfold gradually over the next few months accelerating with the new session of Congress – particularly in the first 100 hours of the new Congress according to Speaker-Designate Pelosi. MLA is already ahead of the curve in our planning to ensure key stakeholders – Democrats, Republicans and the Administration -- in the 110th Congress receive sage counsel concerning the biotechnology industry's unique needs and priorities.

¹The [Social Security Amendments of 1983](#), and the [Tax Reform Act of 1986](#), are just two examples of this.

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