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## MORNING COLOR

January 12, 2022

### Today's Driving Events

- **Biden Administration Could Take Drug Pricing Reform into Its Own Hands:** With Build Back Better (BBB) stalled, so too has much of the broader Democratic push for prescription drug pricing reform. Some smaller regulations have been proposed by the Biden administration, but investors in pharma and biotech must wait in a holding pattern before finding out whether BBB implementation is the biggest story of 2022, or whether there is a last ditch effort to resurrect even more aggressive executive actions this summer to try to hammer pharma and deflect from BBB's failure.
- **Jumping on the (Broad)Bandwagon:** The Senate has confirmed Alan Davidson as director of the National Telecommunications and Information Administration, setting it up to begin administering broadband funding from the Infrastructure Investment and Jobs Act, but Gigi Sohn's nomination for the Federal Communications Committee remains pending in committee.
- **SAFE Banking's Leadership and Midterms Shake-up:** Action on cannabis has proved stagnant even with Democratic majorities in Congress and the incremental SAFE Banking Act is now losing its chief backer as it remains caught up in the broader political battle.

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**Why Pharma Might Prefer BBB to Pass:** The drug pricing reform agenda of congressional Democrats and the Biden administration has largely been put on hold since Senator Joe Manchin (D-WV) announced late last month that he could not support the current version of Build Back Better (BBB) legislation. That announcement resulted in a pause in the review of the bill by the Senate parliamentarian, including several key drug reform provisions such as extending inflation rebates and Medicare negotiated prices to private insurance plans. **If Democrats can get Manchin on board with BBB and it passes sometime this winter or spring, then the remainder of 2022 will be consumed with a multitude of rules that the Department of Health and Human Services (HHS) will have to write to implement BBB – particularly a redesigned Medicare Part D benefit and how negotiations would take place after the expiry of biologic and small molecule drug exclusivity periods.** While BBB is on hold, the Centers

for Medicare and Medicaid Services (CMS) has put forward its own rule that will impact drug spending, although it will perversely help manufacturers, as well as Medicare beneficiaries, while limiting revenues for pharmacy benefit managers (PBMs). This rule, [to lower beneficiary cost-sharing at the pharmacy counter](#), is a new version of what the Trump administration proposed to ensure that PBM-negotiated discounts are passed on to consumers, rather than pocketed by another actor in the pharmaceutical food chain. Manufacturers would benefit because reduced payments at the point of sale would slow the rate of beneficiaries moving into the catastrophic phase of Part D, which is heavily paid for by manufacturers. Besides PBMs, the other biggest loser will be the federal government, which will have to spend more money on Part D, although so long as voters pay less at the pharmacy, we do not expect that this will bother the Biden administration. If BBB does not pass, then the political need to act to distract from such a prominent policy failure could mean that the White House pressures CMS to put forward a unilateral policy reforming Part B and possibly even Part D, along the lines of the Trump administration's failed international reference pricing index (IPI) and most-favored nation (MFN) proposals. While this would take political courage and need to be drafted in a hurry, a great deal of the groundwork has already been done by career staff at CMS and it could be viewed by some Democratic political advisors as helpful for the 2022 midterm elections. **Interestingly, if PhRMA and BIO are successful in their efforts to defeat BBB (though it may be more President Senator Manchin) they could be setting themselves up for a more far-reaching regulatory action from the Biden administration in an effort to save face and have something to show on healthcare reforms before the November elections, as IPI and MFN are both far more aggressive than what is being considered in BBB.** Finally, yet another example of the Biden administration's commitment to paying less for prescription drugs is its decision to only cover Biogen's (BIB) Alzheimer's treatment, Aduhelm, if beneficiaries are enrolled in a clinical trial, threading the needle between refusing to pay for the exorbitantly expensive and not fully proven therapy and allowing anyone on Medicare to have access. Importantly, this trial-only rule will also apply to any other new Alzheimer's drug under Medicare Part B. HHS Secretary Xavier Becerra also asked CMS to reconsider its Medicare Part B premium hike for beneficiaries after Biogen halved the price of Aduhelm to \$28,000, which, coupled with the trial restrictions, should offset any potential monumental increases in Part B spending.

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**Davidson Confirmed by Senate to Lead NTIA but Sohn Still Pending:** The wait for an appointee to lead the Biden administration's broadband programs is over. **The Senate yesterday confirmed Alan Davidson to lead the National Telecommunications and Information Administration (NTIA), which is part of the Commerce Department.** Davidson, who's previously worked at the Mozilla Foundation, Google (GOOGL), and the Obama Commerce Department, was confirmed by a bipartisan vote of 60-31. Unlike President Biden's more polarizing Federal Communications Commission (FCC) nominee, Gigi Sohn, Davidson hasn't

attracted intense Republican opposition and netted 17 GOP votes. As director of the NTIA, Davidson will manage the allocation of about \$48 billion in new broadband funding under the Infrastructure Investment and Jobs Act (IIJA). This includes about \$42.5 billion in grants to states for broadband buildout, \$1 billion for middle mile infrastructure, and \$2.75 billion for digital equity programs. The NTIA took the first step towards implementing the IIJA's broadband programs last Friday by [opening a public comment period](#). The law directs the NTIA to release a notice of funding opportunity for the broadband buildout grants by this May. Disbursement of the funding will depend on the completion of the FCC's oft-criticized and delayed broadband maps, however, which are currently subject to contract bid protests under consideration by the Government Accountability Office (GAO). GAO's deadline to resolve the [most recent protest](#), filed by the losing competitor last week, is April 13th. No work can occur while the contract remains under protest. Once selected, the winning vendor will then have three months to develop the product and ISPs will have six months to submit information, so the earliest the map could be finished is late 2022. In a webinar organized by an industry media outlet last month, executives from the two companies competing for the FCC mapping contract [predicted](#) that the maps will likely not be finished until 2023. In addition to leading the Biden administration's execution of broadband expansion, Davidson will also play a key role in mediating the 5G spectrum dispute between the FCC and Federal Aviation Administration (FAA). The FCC seeks to make spectrum available for use by the telecommunications industry, while the FAA fears interference with airline safety. Davidson's confirmation leaves one major Biden telecom nomination pending: the selection of Sohn for the FCC's remaining open seat. In the face of opposition among many Republican senators, Sohn's confirmation will likely lie in the hands of moderate Democrats including Senator Kyrsten Sinema (D-AZ). Senate Commerce Committee Chair Maria Cantwell (D-WA) hasn't yet scheduled a committee vote for Sohn, but Politico reported yesterday that the committee currently plans to vote on nominees during the week of January 24th. Sohn's vote could come in that time frame. Our base case is currently that Sohn will be confirmed, but GOP opposition is dragging out the process. Until Sohn is confirmed, the FCC will remain split 2-2, and most of Biden's telecom agenda, such as net neutrality, will be unable to advance.

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**Cannabis Banking Losing its Champion:** The recent announcement of Rep. Ed Perlmutter's (D-CO) decision to not seek reelection this year is the latest shifting dynamic impacting the fate of cannabis banking and the bill that Perlmutter has championed, the Secure and Fair Enforcement (SAFE) Banking Act. Perlmutter has been one of the primary forces behind SAFE Banking, which would provide "protections for depository institutions that provide financial services to cannabis-related legitimate businesses and service providers for such businesses," and his efforts saw its passage on a standalone basis twice in the House and as part of must-pass bill three times, most recently as part of the FY22 National Defense

Authorization Act (NDAA). That latest effort failed after Democratic leadership nixed it from the NDAA. **While Democrats are not opposed to aiding the cannabis industry by extending financial and banking protections, the incremental action is ensnared in the larger Democratic cannabis agenda that includes decriminalization and criminal justice reforms and is overall too big and bold to pass with the current makeup of the Senate.** The cannabis lobby struck a more hopeful note in response to Perlmutter's retirement news, with the Minority Cannabis Business Association commenting that "As his leadership on this issue is unparalleled, this makes passing SAFE Banking this Congress a must do." The fate of SAFE Banking this year remains uncertain though as the dynamics have not changed and Democratic leadership remains focused on winning the war even if that means losing this battle in the short term. The only realistic hope for passage before year end is that Senate Majority Leader Chuck Schumer (D-NY) and other proponents of broader reform eventually recognize that their objective is too ambitious and are willing to accept a more incremental reform rather than the status quo before the midterm elections. However, **the changing makeup of Congress after the 2022 midterms has the potential to light up the Safe Banking effort.** In 2019, the SAFE Banking Act passed the House with the support of 106 Republicans and in 2021 with the support of 101 Republicans. This strong bipartisan showing means that if House Republicans take the majority in 2022 they could pass the bill again. Though a hurdle would likely again remain in the Senate, the midterms here also could change the political calculus for both parties. If Democrats maintain their Senate majority but lose the House, they may be more eager to accept a small win on cannabis. If Republicans take the Senate, the measure will lie in the hands of current Senate Minority Leader Mitch McConnell (R-KY) who has traditionally opposed cannabis reform and avoided bringing the SAFE Banking Act to the floor for a vote but could be swayed if doing so would prove politically beneficial enough or it is included as part of a broader must-pass measure. This is a possibility as Republican states and the American public proves more accepting of cannabis measures and as the business prospects for cannabis continue to develop.

## House

The House will reconvene at 12:00 p.m. and will consider a bill that would expand Post-9/11 GI Bill education benefits to the National Guard and Reserves by including mandated training as qualifying duty for the benefits and will consider a rule for consideration of the NASA Enhanced Use Leasing Extension Act.

## Senate

The Senate will reconvene at 12:30 p.m. and will resume consideration of the nomination of Amitabha Bose to be administrator of the Federal Railroad Administration. At 3:30 p.m., the chamber will hold a final confirmation vote on Bose's nomination.

## **White House**

At 10:20 a.m., President Biden will receive his daily intelligence briefing. At 12:45 p.m., the president and First Lady Dr. Jill Biden will attend the funeral of Gen. Raymond Odierno where he will deliver remarks.

## **Macroeconomic**

At 10:00 a.m., American University will hold a virtual media briefing titled "Biden's First Year: AU Experts Look Back - and Ahead." [More information here.](#)

At 1:00 p.m., the Peter G. Peterson Foundation will hold a virtual economic forum titled "America's Fiscal and Economic Outlook - Session II." [More information here.](#)

## **Defense**

At 10:00 a.m., the House Appropriations Committee Subcommittee on Defense will hold a hearing titled "Impact of Continuing Resolutions on the Department of Defense and Services."

At 2:00 p.m., the Senate Select Intelligence Committee will hold a hearing on the nomination of Kenneth Wainstein to be Homeland Security undersecretary for intelligence and analysis.

At 2:00 p.m., the Center for Strategic and International Studies will hold a discussion titled "Emerging Technologies & Long Range Strike." [More information here.](#)

## **Energy, Environment, and Natural Resources**

At 10:00 a.m., the House Transportation and Infrastructure Committee will hold a hearing titled "Proposals for a Water Resources Development Act of 2022: Administration Priorities."

At 10:00 a.m., the House Agriculture Committee will hold a hearing titled "Implications of Electric Vehicle Investments for Agriculture and Rural America." [More information here.](#)

At 11:00 a.m., the Environmental and Energy Study Institute will hold a virtual briefing titled "Innovation as Climate Action: Advances in Weather Forecasting - How Federal Agencies Partner with the Private Sector to Tackle Climate Challenges." [More information here.](#)

At 2:45 p.m., the Senate Environment and Public Works Committee will hold a markup to

vote on the nominations of David M. Uhlmann to be assistant administrator for enforcement and compliance assurance at the Environmental Protection Agency; Henry Christopher Frey to be assistant administrator for research and development of the Environmental Protection Agency; and Martha Williams to be director of the US Fish and Wildlife Service.

At 3:00 p.m., the Senate Environment and Public Works Committee will hold a hearing titled "Water Resources Development Act Oversight: USACE (U.S. Army Corps of Engineers) Implementation of Water Infrastructure Projects, Programs and Priorities."

## **Financial Services**

At 9:00 a.m., the Peterson Institute for International Economics will hold a virtual discussion titled "Are index funds harmful for global financial stability?" [More information here.](#)

## **Geopolitical**

At 9:00 a.m., the Senate Foreign Relations Committee will hold a markup to vote on the nominations of Amy Gutmann to be ambassador to Germany, Donald Blome to be ambassador to Pakistan, Christopher Hill to be ambassador to Serbia, Alice Albright to be CEO of the Millennium Challenge Corporation, Joseph Donnelly to be ambassador to the Holy See, Michele Taylor to be US representative to the UN Human Rights Council, and Enoch Ebong to be director of the Trade and Development Agency. Immediately following, the committee will hold a hearing on the nominations of Sarah Cleveland to be legal adviser of the State Department, James O'Brien to be head of the State Department Office of Sanctions Coordination, George Tsunis to be ambassador to Greece, and Beth Van Schaack to be ambassador at large for global criminal justice.

At 12:00 p.m., the Hudson Institute will hold a virtual discussion titled "China's Coercive Missile Strategy and the U.S. Response." [More information here.](#)

At 8:00 p.m., the Johns Hopkins University Paul H. Nitze School of Advanced International Studies will hold a virtual discussion titled "Global Economic Crisis and U.S.-Japan Cooperation 1971-2021." [More information here.](#)

## **Healthcare**

At 10:00 a.m., the Senate Health, Education, Labor, and Pensions Committee will hold a markup to vote on several nominations including Robert Califf to be

commissioner of the Food and Drug Administration and David Weil to be administrator of the Labor Department's Wage and Hour Division.

## Political

Today, Congress will hold events, including the formal arrival and departure ceremony, to honor former Senate Majority Leader Harry Reid (D-NV), who died on December 28th and whose body will lie in state in the US Capitol.

At 11:00 a.m., Washington Post Live will hold a virtual "Early 202" discussion with Rep. Kevin Brady (R-TX) on taxes, spending, free trade, and opposition to the Biden administration's "Build Back Better" plan. [More information here.](#)

## Tech-Media-Telecom

At 9:00 a.m., Punchbowl News will hold a discussion on the future of American innovation, the role of technology policy in shaping US leadership in science and research, and the global chip shortage. [More information here.](#) Expected participants include:

- Gina Raimondo, secretary, Department of Commerce

At 10:15 a.m., the Atlantic Council will hold a discussion with French Digital and Telecommunications Minister Cedric O titled "Europe's 2022 Digital Agenda." [More information here.](#)

At 2:30 p.m., the Senate Indian Affairs Committee will hold a hearing titled "Roundtable - Closing the Digital Divide in Native Communities through Infrastructure Investment."

## Transportation and Infrastructure

Today, the National Academy of Sciences, Engineering, and Medicine Transportation Research Board will continue its 101st annual meeting with the theme "Innovating an Equitable, Resilient, Sustainable and Safe Transportation System." [More information here.](#)

At 10:00 a.m., the House Agriculture Committee will hold a hearing titled "Implications of Electric Vehicle Investments for Agriculture and Rural America."

At 1:00 p.m., Micromobility Industries will hold its virtual Mobility World 2022 summit with the theme "how small vehicles can radically improve our world." [More information here.](#)



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