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SPOTLIGHT REPORT

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Biden's Updated Regulatory Agenda

What's Happening: Last week, the Office of Management and Budget's Office of Information and Regulatory Affairs released its semi-annual Unified Agenda of Regulatory and Deregulatory Actions (UA) outlining the Biden administration's regulatory agenda for the coming months.

Why It Matters: This particular agenda is especially important because of the expected defeat for Democrats in at least one, if not both, chambers of Congress. President Biden may have not originally expected to have a legislative majority, but with Senate victories in Georgia in January 2021, he found himself able to push through some of his legislative agenda. However, this window is now quickly coming to an end. **Without a legislative means for change, Biden will rely on his regulatory agencies to generate the reform that he hopes to achieve.** Although the president is not able to explicitly dictate policy to all executive agencies, we expect he will be active in using his bully pulpit to call for specific actions and provide political coverage for actors to pursue certain rulemakings, as he has done with his executive orders on cryptocurrency and competition policy. He has chosen several progressive candidates to lead key agencies like Securities and Exchange Commission Chair Gary Gensler, Federal Trade Commission Chair Lina Khan, and National Labor Relations Board General Counsel Jennifer Abruzzo who will be at the forefront of pushing through partisan policies.

What's Next: The immediate action item that has to be achieved to ensure that the maximum number of regulations can be promulgated is to confirm the remaining pending nominees. This is especially true for those in key positions like Gigi Sohn to be the third Democratic commissioner at the Federal Communications Commission and Michael Barr to be the vice chair for supervision at the Federal Reserve Board of Governors. **Senate Minority Leader Mitch McConnell (R-KY) has already made clear that he would be "picky" with any of Biden's nominees if Republicans regain control of the Senate as a result of this fall's midterm elections, which makes these outstanding nominations top items for Senate Majority Leader Chuck Schumer (D-NY) to get done.** We expect that most of Biden's candidates will get confirmed, but there are some that will likely be left behind, which may hamper the degree of reform some of his agencies are able to achieve.

Overview

The Spring 2022 Unified Agenda of Regulatory and Deregulatory Actions (UA) includes 2,673 rules under active consideration, comparable with past UAs from the Biden administration and the number of actions under consideration at the end of President Trump's term. But what reflects the scope of the reform that Biden's regulatory agencies are trying to achieve is the number of "economically significant" rules under consideration. These are regulations that the agencies estimate to have effects of at least $100 million. In this UA, there are 220 such rules under active consideration, up from the 205 in December. This number speaks not only to the breadth of reform that the agencies are trying to achieve, but also the meaningful impact that they are working to have.

One caveat that should come with reading the UA is that it more closely resembles a "Nice-To-Do" list rather than a "Must-Do" list. The items included are not ones that agencies have to act on nor do they have to follow the provided timelines. In most cases, regulatory bodies will take more time than what is listed in the UA. Thus, the best way to read the dates provided is as the earliest time when a given agency may take that action.

Below are selected regulations that we believe are worth watching in the coming months as they work their way through the rulemaking process.

Financial Regulation

Securities and Exchange Commission (SEC) Chair Gary Gensler has not hid the degree of reform that he hopes to bring to the financial markets while at the agency. This UA, as with the prior ones, backs that up with the SEC including over 60 rulemaking processes. The theme that seems to link all of these diverse rules is Gensler's push for transparency across the financial markets.

- Equity Market Structure Modernization: This is the SEC's rulemaking process that would address issues like payment for order flow, best execution, and pricing increments.
  - **Outlook:** Gensler seems intent to do something to address this area of the financial markets, but no official proposal has been made yet by the SEC. The agency does not expect to issue a notice of proposed rulemaking (NPRM) before this October. **What seems to be** Gensler's preferred approach **would be to route most individual investors' orders into auctions where trading firms would compete to execute them.** This has predictably been met with criticism from brokerages and trading firms. The other change to market structure Gensler is eyeing is shortening the settlement cycle from a T+2 to T+1 model. This is expected to be finalized as soon as October.

- Climate disclosure and ESG: The SEC plans to issue its final climate disclosure rule requiring climate disclosures from public companies in October. The agency is also planning for a NPRM on its environment, social, and governance (ESG) rule in

October that aims to achieve greater transparency in sustainability metrics in ESG funds, and, looking further out, the agency is considering an advanced notice of proposed rulemaking (ANPRM) in April 2023 to consider amendments to the payment from resource extraction rule that requires disclosures of certain types of payments made in the commercial development of oil, natural gas, or minerals from resource extraction issuers.

  - **Outlook:** The public comment period on the climate disclosure proposed rule closed last week, and it received pushback from a range of stakeholders including large corporations, small businesses, the agricultural sector, and even the Nasdaq. **The October date suggests that Gensler is holding firm to his authority to implement the rule despite hardening opposition and an imminent Supreme Court case that could challenge agencies' authorities to enact more innovative rules.** We do not expect the scope of the climate disclosure rule to widen and Gensler and his team will need to consider whether to include the required disclosure of Scope 3 emissions for companies that deem them material, the most controversial provision. The ESG rule is also in line with Gensler's priorities and recent actions to issue a first of its kind $1.5 million fine of **BNY Mellon (BK)** for misstating and omitting information on ESG factors in mutual funds, known as "greenwashing."

- Fund Disclosures: The SEC is considering increasing transparency of private equity and hedge funds fee structures as well as further reforms to Form PF, beyond the current expansion.
  - **Outlook:** No actions on the fee structure or further amendments to Form PF are expected before October at the earliest. Final action on the Form PF revisions that have already been proposed will not happen before April 2023. Gensler made clear last fall that he intends to bring more visibility into the business practices of private funds and this agenda suggests that he aims to move forward with that work. The SEC has also proposed new rules around the disclosure of short positions, which are not expected to be finalized before next April.

- Gamification: The SEC is considering rules to address digital engagement practices by investment advisers and broker-dealers.
  - **Outlook:** The use of behavioral prompts and notifications that, in the agency's view, aim to encourage retail investors to trade is an area about which Gensler has repeatedly expressed concern. **Seeing these rules included in the agenda is no surprise, but it is noteworthy as it has not been included before.** The SEC released a request for information to better inform the rulemaking process last fall, but has taken no action since. A NPRM is not expected for either before October.

- Modernization of Beneficial Ownership Reporting: In the wake of Archegos' collapse last year, the SEC felt a need to improve transparency around the use of swaps in an effort to avoid a similar incident in the future.

    - **Outlook:** The SEC has already proposed the above rule, which would accelerate the filing deadlines for beneficial ownership reports from 10 days to five and amendments would have to be filed within one business day. It would also clarify when and how certain derivatives count towards the five percent threshold and the circumstances under which two or more persons have formed a "group" that would be subject to the reporting requirements. Final action is not expected before next April. This is not the only Archegos-related rule in the agenda with the SEC also including a regulation that would require security-based swap execution facilities to register. The agency has previously proposed rules to require reporting of large security-based swap positions.
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- Crypto: In addition to rules affecting virtual wallets and AML/KYC rules from the Financial Crimes Enforcement Network (FinCEN), two rules from the SEC could have implications for digital assets too.
    - **Outlook:** The crypto industry has made their frustration with the potential implications of the SEC's rules for their business models well known. **Neither SEC rule is intended to directly regulate digital assets, but could have implications for crypto exchanges and decentralized finance.** No action is expected before October on either rule and Gensler has not given any indication as to whether he would consider revisions to mitigate these concerns or make more explicit the effect on crypto. The FinCEN rules were both initially proposed under the Trump administration but received significant industry pushback and are only beginning their process under the Biden administration now. Action is not expected before December with final action on the virtual wallets rule not coming before next March.

- SPACs: Following the explosion of special purpose acquisition companies (SPACs) in 2021, Gensler set about updating the rules for these vehicles.
    - **Outlook:** While the SPAC market has cooled off, Gensler seems intent to finalize the rules proposed earlier this year. The changes that these rules would bring include additional disclosures about the SPAC's sponsors, conflicts of interest, and sources of dilution. They would also address issues relating to projections made by SPACs and their target companies, including the safe harbor for forward-looking statements. The goal is to better align the standards for SPACs with those used for initial public offerings.

Consumer Finance

Continuing from the fall UA, the Consumer Financial Protection Bureau (CFPB) only has five rules on its docket, though **we expect that other regulatory agenda items will arise in the coming months, such as a rulemaking regarding buy-now, pay-later lending and redrafting of late fees under the CARD Act.** As always, CFPB Director Rohit Chopra will be looking at investigations and enforcement actions, including regulation via enforcement, as his regulatory division begins to issue and finalize what we expect to be a voluminous number of policy changes by 2024, well in advance of the period when a potential unified Republican government can use the Congressional Review Act (CRA) to nullify any recently finalized rules.

- Small Business Lending Data Under The Equal Credit Opportunity Act: The CFPB is drafting a rule to create a new mandate for lenders to collect racial and other data on borrowers and potential borrowers.
  - **Outlook:** It is what we expect the CFPB will do with the data that is most important, once the final rule is issued on or around March 2023. Once the CFPB has access to data about how lenders interact with those seeking loans, then it will be able to use it to determine whether any discrimination (intentional or not) has occurred. It will most likely use the disparate impact standard whereby a company is guilty of race or sex discrimination if it does not have sufficiently equal lending outcomes for various protected classes, even if it is not intentionally discriminating or it is solely using quantitative measurements to arrive at its underwriting results. The CFPB does not even shy away from this characterization, writing in the UA preamble, "Congress enacted section 1071 for the purpose of (1) facilitating enforcement of fair lending laws and (2) enabling communities, governmental entities, and creditors to identify business and community development needs and opportunities for women-owned, minority-owned, and small businesses." We expect that next spring's UA will only be more robust in setting the bureau up to use its enforcement powers in this regard.

- Consumer Access to Financial Records: Section 1033 of the Dodd-Frank Act provides that the bureau can promulgate rules that a regulated entity must provide to a consumer, upon request, access to their financial records and transaction data from any product or service that is used by the consumer. In November 2020, an Advanced Notice of Proposed Rulemaking (ANPRM) was issued and comments were accepted until February 2021. The next step is that the bureau will convene a Small Business Regulatory Enforcement Fairness Act hearing in November 2022, and then a final rule will be issued, likely sometime in 2023.
  - **Outlook:** We expect that this rule will proceed relatively smoothly and with less controversy than other bureau actions detailed above.

- Use of Prenotification Negative Option Marketing: In addition to stepping up enforcement of negative option marketing generally, the Federal Trade Commission (FTC) is considering amending the rule governing this practice, where consumers' silence is interpreted as acceptance of an offer or subscription.
  - **Outlook:** The agency is undetermined on what its next step will be, but had intended to do something this month. With the FTC set to miss this self-imposed deadline it is unclear when, or if, it will begin a rulemaking process to update the existing regulation which may involve an expansion of the covered practices. In the agency's policy statement announcing its intent to increase enforcement, it notes that the rule as it is just covering prenotification plans "does not reach most modern negative option marketing."

Energy & Environment

Rules relating to energy, environment, and climate issues are spread across a number of agencies due to their decentralized nature and in line with the Biden administration's much-touted whole-of-government approach. We have highlighted rules at the Environmental Protection Agency (EPA), Department of the Interior (DOI), and Council on Environmental Quality (CEQ), though there are others, including the Department of Energy's ongoing efforts to tighten energy efficiency requirements. **At the EPA, the environmental regulatory agenda faces a potential handicapping of its authority depending on the Supreme Court's ruling in *West Virginia v. EPA*, which is expected to be released tomorrow and could limit other agencies' powers as well.**

- Emissions at power plants: The EPA pushed back its plans to propose a new rule to regulate emissions at power plants that is intended as a broad replacement to the Obama administration's Clean Power Plan (CPP) and the Trump administration's Affordable Clean Energy Rule.
  - **Outlook:** The rule was at first slated to come out by the end of this year, but the new UA projects a March 2023 proposed rule. This rule could largely be shaped by the imminent Supreme Court decision on *West Virginia v. EPA*, which is centered on the CPP but could also more broadly hinder federal agencies' authorities. A top EPA official has said there are multiple versions of this rule in progress to account for the Supreme Court decision.

- PFAS: The EPA is planning for an ANPRM in October 2022 to designate PFAS as a hazardous substance under Superfund, which would trigger strict liability standards for requiring companies involved in producing, using, or transporting PFAS to pay for its cleanup. This is expected to generate considerable headline risk.
  - **Outlook:** The Biden EPA has taken a more active role in regulating PFAS than previous administrations and announced in its October 2021 PFAS Strategic Roadmap that it would pursue a hazardous substance designation with a NPRM in spring 2022. This makes the latest in the regulatory agenda a step back from that timeline for the EPA and downgrades the action from a NPRM to an ANPRM. While the EPA seems focused on PFAS as a whole, the enormity of what this would initiate in effort and cost – as well as current pushback – that would be required from the agency to handle litigation and clean ups could be delaying prompt action.

- Renewable Fuel Standard: The EPA will issue a NPRM on biofuel blending requirements for 2023 and beyond under the RFS in September and a final rule by April of next year.
  - **Outlook:** 2023 is the first year that Congress will not provide statutorily mandated blending volume requirements and the process is now turned over to the EPA. The new blending requirements are significant to oil refining and biofuel industries. Earlier this year the agency sought to ramp up the biofuel levels required for 2022 but later retroactively reduced the 2020 targets. A senior EPA official has said that the agency is constrained in using the

program to enact a low-carbon fuel standard due to the statutory obligations around blending requirements.

- National Environmental Policy Act (NEPA): The CEQ is looking to propose its "phase two" rule revising NEPA this August.
    - **Outlook:** CEQ already finalized its first NEPA revision in May, which largely sought to reverse the Trump era changes that relaxed some environmental restrictions in the name of speeding the permitting process for pipeline and other infrastructure projects. Phase two is expected to build on the restored NEPA status quo and include environmental justice and public participation provisions. Speeding the review process for infrastructure projects, though, has become increasingly popular in the wake of record energy inflation and efforts to slow that could put Biden again in the line of fire.

- Leasing Federal Land for Fossil Fuel Production: DOI is sticking to its plan to update the fees, rents, royalties, and bonding requirements related to oil and gas leasing, development, and production.
    - **Outlook**: These moves are in line with previous DOI reports to the Biden administration. Earlier this year, the agency briefly posted online plans to increase the royalty payments companies must pay for oil and gas produced on federal onshore properties to 18.75 percent, up from the current 12.5 percent, marking the first increase in these fees for onshore production in a century. The Biden administration faces a similar dilemma here to its NEPA reforms in that it does not want to appear to be raising gas prices, but this item would be a revenue raiser that appeals to Biden's climate constituency.

Privacy

The FTC has set a clear intent to get more involved in data privacy. Notably, FTC Chair Lina Khan indicated in a Protocol interview earlier this month that the FTC won't wait for congressional action. The Senate confirmation of privacy advocate Alvaro Bedoya last month restores a Democratic majority at the commission and unlocks Khan's ability to pursue partisan regulations.

- Trade Regulation Rule on Commercial Surveillance: The purpose of this rule is to "curb lax security practices, limit privacy abuses, and ensure that algorithmic decision-making does not result in unlawful discrimination."
    - **Outlook:** This rule first appeared in the Fall 2021 UA, which predicted that the FTC would release an ANPRM in February 2022. That target was now this month with a deadline for public comment on the ANPRM in August 2022, but with this month almost over, it raises the possibility that the timeline may be pushed back again. A delay should not be seen as the FTC not being committed to the rulemaking, but a reflection of the complexity of the task the agency is pursuing.

- [Children's Online Privacy Protection Rule:]() The FTC is continuing to review public comments submitted in 2019 regarding the agency's rule that implements the Children's Online Privacy Protection (COPPA) Act. The FTC [stated]() when it reopened consideration of the COPPA rule in 2019, several years ahead of schedule, that the speed of technological changes compelled an earlier re-evaluation.
    - **Outlook:** The timeline for this rule has slipped and the agency is now aiming to finish reviewing public comments this month. It's not yet clear when the FTC will finish evaluating public input on its COPPA rule, but the issue of children's privacy appears to be growing in stature at the agency. In May, FTC commissioners unanimously approved a new [policy statement]() on the agency's enforcement of COPPA relating to education technology. It delineates prohibitions on collecting children's personal information when using education tech services.

Healthcare

As always, the Department of Health and Human Services has an enormous number of rulemakings in various stages on its docket. While most investors with an interest in healthcare tend to focus on the annual payment rate notices for sub sectors like Medicare Advantage, home health, skilled nursing facilities, etc., we have chosen several rules that we expect to have an impact outside of those annual exercises: a new nebulous mandatory payment model for Medicare, Medicare Advantage and Medicare Part D drug reforms, Medicaid managed care, hearing aids, and the interchangeability of biologics and biosimilars.

- [Alternative Payment Model:]() This potential rule would create a new mandatory Medicare payment model under section 1115A of the Social Security Act. The purpose of the model is to save money for Medicare while "preserving or enhancing" quality of care for beneficiaries. If the model is deemed to be successful, then it can become a permanent and mandatory policy nationwide.
    - **Outlook:** It is unclear what the topic of the model will be, but there is a reasonable chance that it is focused on value-based care and that it could be the Biden administration's most important healthcare-focused action to date. This type of proposal would add an overlay of value-based care features on top of all Medicare beneficiary doctor/patient relationships and it would be mandatory for all participating doctors. If this is in fact the topic of the model, it will be incredibly controversial, but there is nothing to stop the Biden administration from pushing it through if they have the political stomach for any blowback.

- [Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy:]() This proposed rule is the Centers for Medicare and Medicaid Services (CMS) attempting to codify several Medicare Advantage and Part D payment policies that are outside the scope of the annual Advance Notice/Rate Announcement. The UA does not go into further detail about what those policies may be.

- **Outlook:** As with any CMS regulation, the only thing that stops a regulation from being implemented as proposed (aside from not adhering to the strict rules of the Administrative Procedures Act) is a lack of political will, so we expect that with an election ahead in 2024, the Biden administration will be doing all it can to finalize any drug pricing agenda items once this is released in December 2022.

- Medicaid Managed Care: This rule would propose changes to Medicaid managed care regulations, including additional parameters on states' use of In Lieu of Services or Settings (ILOS) and state directed payments under Medicaid managed care contracts. We expect that this rule could also include more value-based care policies as well as greater emphasis on equity and data collection to track outcomes.
    - **Outlook:** There has not been a wholesale change to Medicaid managed care in quite some time, as the focus has remained on Medicaid expansion in the wake of the Affordable Care Act. This new proposed rule, scheduled for February 2023, could have a large impact on the companies that participate in managed Medicaid and is almost certain to impose more costs onto them, though there is a chance that there could also be higher reimbursement rates if certain strict improved health equity outcomes are met.

- Over-the-Counter Hearing Aids Rule: The Food and Drug Administration (FDA) is finalizing a rule to allow products that help patient hearing be sold over the counter (OTC) in stores or online without a fitting or medical exam from an audiologist.
    - **Outlook:** This rule could benefit manufacturers by creating a new market that is more affordable and allow first-movers in this new sector to amass market share. Since hearing aids are currently not being considered for inclusion in any budget reconciliation proposal, the release of this final rule, scheduled for July in the UA, would spark a battle between new entrants making cheaper OTC hearing aids and legacy manufacturers making less sophisticated versions and competing in a more open market. The finalization of the rule would mean that companies would be able to begin to apply for clearance to sell their product, which is expected to take months, so there would likely not be a change in revenue until 2024 at the earliest.

- Biologics Regulation Modernization: The FDA is considering a rule that would create new interchangeability standards that clearly account for the existence of certain biosimilars and biologics in order to "support competition and enhance consumer choice by preventing efforts to delay or block competition from biosimilars and interchangeable products."
    - **Outlook:** While interchangeability has been controversial, it is not new to investors in drug and biologic manufacturers. The NPRM was previously listed as expected in August but it is now listed as March 2023. We expect that the rule will be finalized with the idea of being able to bring down prices without harming health firmly in mind, particularly as the original Democratic version of drug reforms has been so watered down during debate over budget

reconciliation and there remains a very real risk that nothing passes before Republicans take over at least one chamber of Congress. Going into the 2024 election, the Biden team is going to be looking for anything it can point to in terms of saving both Medicare and senior citizens money on their prescription drugs and further utilizing interchangeability is one very real area where savings can be felt.

Tobacco

Under the Biden administration, the FDA has launched a crackdown on tobacco. The agency has initiated several major rulemakings, including proposed bans on menthol cigarettes and characterizing flavors in cigars as well as a lower nicotine standard for all combustible cigarettes.

- Ban on Menthol Cigarettes: This proposed rule would block menthol-flavored cigarettes from the US market.
    - **Outlook:** The FDA is currently accepting public comments on this rulemaking with a deadline of July 5th. The agency will then evaluate the input received as it develops a final rule, the timing of which is still to be announced. Tobacco companies are expected to seek to delay or defeat the rule through lobbying and litigation. Big Tobacco mobilized against the proposed menthol ban before it was released this spring and targeted lobbying efforts at the White House Office of Management and Budget. The industry is expected to fight the final version of the menthol ban as well, and the rulemaking could potentially slip to near the end of Biden's term or beyond.

- Ban on Characterizing Flavors in Cigars: This proposed rule would block cigars with characterizing flavors other than tobacco (e.g., menthol, fruit, and cocoa) from the US market.
    - **Outlook:** As with the menthol cigarette ban, the flavored cigar ban is also currently undergoing a public comment period until July 5th and is likely to be subject to lobbying efforts and litigation from Big Tobacco once finalized.

- Lower Nicotine Tobacco Product Standard: This proposed rule would lower the nicotine content in cigarettes to minimally or nonaddictive levels.
    - **Outlook:** More than any other policy, a nicotine standard would upend the tobacco market. An FDA-funded study in 2018 showed that five million adult smokers would quit smoking within just one year of a nicotine standard, with the rate of adult smoking declining to 1.4 percent in 2100. FDA Commissioner Robert Califf has signaled support for the idea in the past, telling the Wall Street Journal in a 2017 interview that "If it works, it will save more lives than anything else the FDA could do." A rule of this magnitude will take time to develop and implement, however, and the tobacco industry is sure to fight it. Big Tobacco is likely to argue that a nicotine standard would not be a net benefit to public health, instead leading current smokers to increase their consumption to get their nicotine fix and boost the black market for cigarettes.

The rulemaking process could easily last beyond Biden's term in office, and a potential Republican administration coming into office in January 2025 is less likely to see the effort through.

Autonomous Vehicles

Transportation Secretary Pete Buttigieg has made clear that he aims to achieve "meaningful" development of autonomous vehicle (AV) policy in the coming years as the regulatory frameworks have not caught up with technological developments. The rules from the Federal Motor Carrier Safety Administration (FMCSA) and the National Highway Traffic Safety Administration (NHTSA) are first steps in this direction.

- Safe Integration of Automated Driving Systems-Equipped Commercial Motor Vehicles: This is the primary rulemaking the FMCSA is undertaking to create a regulatory framework for autonomous trucks.
  - **Outlook:** This rulemaking was started under the Trump administration and while it was included in the last UA, the agency has still not taken any action and is not expected to issue an NPRM until January 2023 at the earliest. This has been in part due to changes in leadership with the agency yet to have a confirmed administrator. Robin Hutcheson, who has been serving as the acting administrator since January, is nearing a confirmation vote on the Senate floor after advancing from the Senate Commerce, Science, and Transportation Committee by voice vote last week. Neither Hutcheson's background nor testimony in Congress has offered much insight into how she may handle the issue.

- Framework for Automated Driving Systems Safety: Similar to the FMCSA's rule, this is the primary regulation that the NHTSA will use to establish the parameters for the expansion of AVs in the US.
  - **Outlook:** The NHTSA has not experienced the same leadership challenges as the FMCSA, but has not made much more progress. The agency expects to be analyzing the comments it received through September and did not provide a timeline for when it may issue a NPRM. The NHTSA also included other rules related to AVs that would aim to ensure that the vehicles have appropriate safety standards with respect to signals and crash avoidance. No action is expected before September and December 2022 respectively. As soon as October, the agency may also issue a NPRM that would allow entities to request exemptions to operate nonconforming vehicles on public roads for research purposes.

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