Buchanan

M E M O R A N D U M

To: BioFlorida

From: Michael Strazzella and Sophia Estupinan

Date: July 8, 2025

Re: Monthly Federal Update

Executive Summary

On July 3rd, the United States Congress passed "The One Big, Beautiful Bill" (OBBB), a comprehensive tax reform initiative aimed at overhauling the U.S. tax code, which was subsequently signed into law by President Trump on July 4th. The legislation, resulting from extensive negotiations among Republican lawmakers, includes key provisions such as the permanent extension of the 2017 tax cuts, projected to cost approximately $4 trillion, alongside the repeal and modification of various existing measures and the introduction of new tax provisions. The Senate approved the bill with a narrow 51-50 vote, with Vice President Vance casting the tie-breaking vote, marking a significant achievement for the Republican agenda as the administration approaches the midterm elections. The OBBB encompasses reforms to Medicaid and SNAP, and removes the most-favored-nation policy for the pharmaceutical industry, which previously mandated that drug manufacturers align their prices with those in other affluent countries.

Additionally, the FDA has recently taken steps to enhance patient access to innovative therapies by removing Risk Evaluation and Mitigation Strategies (REMS) requirements for several CAR T cell therapies. This regulatory shift is designed to lower barriers to access for these potentially life-saving cancer treatments, allowing hospitals to administer therapies without the burden of special certifications. The FDA has also launched the Commissioner's National Priority Review Voucher (CNPV) program, which aims to expedite the drug review process for select companies addressing critical public health needs. By reducing review timelines from 10-12 months to as little as 1-2 months, the CNPV program reflects the FDA's commitment to fostering innovation and improving domestic drug manufacturing. However, concerns have been raised regarding the potential strain on the FDA's resources, as prioritizing certain drug reviews may inadvertently delay approvals for other essential medications.

The ongoing discussions surrounding the Congressional megabill and FDA initiatives highlight the complex interplay between drug pricing, access, and regulatory oversight. While the pharmaceutical industry has secured important victories, including exemptions for rare disease drugs and the removal of REMS requirements, challenges remain. The Senate's omission of provisions aimed at reforming pharmacy benefit managers (PBMs) and the call from the FDA to eliminate distinctions between interchangeable biosimilars and other biosimilars indicate that the conversation about healthcare costs will continue to evolve. Stakeholders, including patient advocacy groups and pharmaceutical companies, will need to navigate these changes carefully, as

the implications for drug pricing and access to medications will be critical areas of focus in the coming months.

Federal Update

One Big Beautiful Bill Becomes Law

On July 3rd, the United States Congress successfully passed The One Big, Beautiful Bill, a sweeping tax reform initiative aimed at overhauling the U.S. tax code. This landmark legislation, which reflects extensive deliberations and negotiations among Republican lawmakers over several months, encompasses a wide array of tax provisions. Key features include the permanent extension of the 2017 tax cuts, projected to cost approximately $4 trillion, as well as the repeal and modification of various existing measures and the introduction of new tax provisions.

On July 1st the Senate narrowly approved the bill with a 51-50 vote, with Vice President Vance casting the tie-breaking vote. This significant legislative achievement is expected to serve as a hallmark of the Republican agenda as the administration approaches the midterm elections. Following its passage by the U.S. House of Representatives on July 3rd, President Trump signed the OBBB into law the following day.

In addition to tax reforms, the OBBB includes various reforms to Medicaid and SNAP, and a notable change for the pharmaceutical industry was the removal of the most-favored-nation policy, which previously included required drug manufacturers to set their prices in alignment with those established in other affluent countries.

The absence of this policy is seen as a major victory for the pharmaceutical industry, as it would have imposed significant pricing pressures on drug manufacturers. Instead, the reconciliation package includes provisions that exempt more drugs, particularly those treating multiple rare diseases, from Medicare drug-price negotiations. Under the bill, companies developing drugs for rare diseases with multiple indications will not be subject to Medicare negotiations, addressing concerns that previous provisions disincentivized investment in treatments for smaller populations with high unmet needs. This change is expected to spur innovation in rare disease research and development, which is crucial for addressing unmet medical needs.

Despite these wins, the final bill did not address all of the pharmaceutical industry's priorities. Notably absent are provisions aimed at reforming PBMs, which have garnered bipartisan support in Congress for years. The Senate Finance Committee had previously scaled back some PBM provisions, including measures to prohibit spread pricing in Medicaid and limit the fees PBMs could collect to administrative costs. The omission of these provisions from the final version of the megabill has left some industry advocates disappointed, as they believe reforms are necessary to tackle practices that inflate drug costs for patients. Advocacy groups for affordable drugs are also pushing back against the decision to exempt drugs for rare diseases from Medicare price negotiations, arguing that it represents a significant cost to taxpayers and undermines the goal of providing affordable healthcare for all.

Following a marathon amendment "vote-a-rama," the Senate parliamentarian initially ruled several health provisions, including the Orphan Cures Act exemption, noncompliant with reconciliation

rules. However, a revised procedural decision allowed the Orphan Cures Act to be formally reinserted into the bill. With this reinstatement, drugs approved for multiple rare disease indications will remain exempt from Medicare price negotiation under the Inflation Reduction Act (IRA) even after January 1, 2028. The Congressional Budget Office estimates that this carve-out could cost the federal government nearly $5 billion over the next decade, a point heavily criticized by patient advocacy groups like Patients for Affordable Drugs Now. Proponents, including the Biotechnology Innovation Organization and key senators such as Sen. Martin Heinrich (D-NM), view the exemption as an essential incentive for continued investment in multisystem rare disease treatments.

Update on R&D Tax Credit Policy Developments

Significant federal and state developments are underway that could impact businesses relying on the Research & Development (R&D) Tax Credit. OBBB includes key provisions to restore immediate expensing for domestic R&D costs. This change would reverse the current requirement to amortize R&D expenses over five years, a policy in place since the 2017 Tax Cuts and Jobs Act. The proposed change would apply retroactively for small businesses dating back to 2022 and extend immediate expense through at least 2029, offering a significant incentive for companies investing in innovation, product development, and technological advancement.

In parallel, the IRS has finalized new reporting requirements for businesses claiming the R&D Tax Credit, set to take effect for tax year 2025. The updated Form 6765 will require more detailed documentation, including a breakdown of qualified research activities by business component and enhanced disclosures around wages, experimentation processes, and acquisitions. Companies with over $1.5 million in qualified research expenses will face heightened transparency thresholds. These changes are intended to increase accountability but may also add administrative burdens for businesses seeking to claim credit.

Finally, startups and small businesses continue to benefit from provisions allowing the federal R&D Tax Credit to offset payroll taxes, up to $500,000 annually. This provides critical cash flow relief for early-stage companies without current income tax liabilities.

FDA Regulatory Changes: Enhancing Access to CAR T-Therapies and Expediting Drug Reviews

The FDA has announced the removal of REMS requirements for six approved autologous CAR T cell therapies, marking a significant regulatory shift aimed at improving patient access to these potentially life-saving cancer treatments. This decision is part of a broader initiative under FDA Commissioner Makary's leadership, which also includes the launch of the CNPV program designed to expedite the drug review process for select companies addressing critical public health needs. The therapies affected include those targeting BCMA and CD19, used to treat various blood cancers such as multiple myeloma, leukemia, and lymphoma.

With the removal of REMS, hospitals will no longer require special certifications or on-site access to tocilizumab, a drug used to manage severe side effects associated with CAR T-therapies. Instead, the FDA will rely on existing product labeling to communicate risks, including boxed warnings. This regulatory change is expected to facilitate quicker access to CAR T-therapies,

which currently see only about 20% of eligible patients receiving treatment due to logistical hurdles associated with REMS. Industry experts and patient advocates have welcomed this decision, as it aims to lower barriers to access. Bristol Myers Squibb, whose therapies are impacted, plans to phase out REMS protocols at treatment centers and expand access to community cancer clinics across the U.S.

In conjunction with the REMS removal, the CNPV program aims to shorten the standard drug review timeline from approximately 10-12 months to as little as 1-2 months. This program has been praised for its potential to foster innovation and enhance domestic drug manufacturing. However, concerns have been raised regarding the strain it may place on the FDA's limited resources, as prioritizing certain drug reviews could inadvertently lead to delays for other essential medications, particularly given the agency's existing application backlogs. The CNPV program underscores the FDA's commitment to addressing urgent public health challenges, while also raising questions about the balance between expedited reviews and the thoroughness of regulatory oversight.

FDA Again Asks Congress to Remove Biosimilar-Interchangeable Distinction

The FDA is once again urging Congress to eliminate the distinction between interchangeable biosimilars and other biosimilars in its legislative requests for fiscal year 2026. The agency argues that this statutory distinction has led to confusion among patients and healthcare providers regarding the safety and effectiveness of biosimilars. The FDA’s request seeks to amend the Public Health Service Act to classify all biosimilars as interchangeable, which could align the U.S. biosimilar program with practices in other major regulatory jurisdictions like the European Union.

The FDA's proposal aims to increase the uptake of biosimilars, potentially enhancing competition and affordability in the pharmaceutical market. While the House Appropriations Committee's report acknowledged the need for streamlining the approval process for biosimilars, it stopped short of endorsing the complete removal of the interchangeable distinction. The FDA had previously eliminated labeling distinctions between biosimilars and interchangeable drugs in 2023, but experts continue to advocate for a unified classification to simplify the regulatory landscape.

Gillian Woollett, a biosimilars expert, emphasized the importance of removing the interchangeability designation to facilitate physician decision-making and encourage the adoption of biosimilars.

House Appropriations Ask FDA To Form Expert Panel on AI Drug Development

The House Appropriations Committee has requested that the FDA establish an expert panel to assist with AI-assisted drug development as part of its draft fiscal year 2026 funding bill. This initiative aims to address the growing intersection of artificial intelligence and pharmaceuticals, emphasizing the need for a dedicated team of experts in machine learning, data analysis, and predictive modeling to enhance the evaluation of AI models in drug development.

FDA Commissioner Makary has indicated plans to utilize AI in various aspects of drug development, including accelerating approvals and improving post-market surveillance. The establishment of an AI team aligns with the agency's broader goals of modernizing its review processes and leveraging technology to enhance efficiency without compromising safety and

efficacy standards. However, concerns have been raised about the potential strain on FDA resources, particularly as the agency grapples with existing application backlogs.

Industry stakeholders have expressed cautious optimism regarding the FDA's embrace of AI technology, noting that while it presents opportunities to streamline the review process, it is crucial to ensure the reliability and trustworthiness of AI models used in evaluating drug applications. The committee's request reflects a recognition of the transformative potential of AI in the pharmaceutical industry and the importance of regulatory frameworks that support innovation while safeguarding public health.