Life Science Wins In Omnibus

FDA Accel Approval, Cell Based Models, Robust NIH & ARPA-H Funds, R&D Tax Credit Reform Out for Now

Life science provisions largely reflect riders seen in the FDA user fees bills marked up and passed by the House this summer. We note that the omnibus contains helpful policies for the agency as provisions clarify and expand FDA authorities over drugs and devices. Provisions include ample ARPA-H and NIH funding, FDA accelerated approval reform, clinical trial diversity, medical device cybersecurity requirements, among others.

NEXT STEPS: The provisions are a plus for life sciences and drug approvals. The Senate is expected to file cloture for a vote at 2:30PM today. After the bill passes the Senate, it will take 1-2 days to pass in the House. We largely expect the legislation to wrap up by Friday with no additional amendments. For passage of life sciences provisions that did not make it, there is PAHPA (Pandemic & All-Hazards Preparedness Act) and Animal Drug User Fee Act slated for reauthorization in Oct 2023.

What's Out

- **R&D amortization is a negative for Life Sciences.** The R&D tax credit fix is not included in the omnibus. Healthcare and non-HC companies have asked lawmakers to repeal a change in the tax code that requires businesses to spread their R&D costs over five years rather than deduct them immediately. This will continue to negatively impact biotech and pharma as their R&D costs must be amortized over five years domestically and 15 years for international costs.
    - **What happened?** After a months-long staring contest between Dems, who said they would only include it if child tax credit expansion was included, and Republicans, who said they would not do it for CTC expansion (but would consider other bipartisan tax items like low income housing credit), neither side blinked and therefore no one got what they wanted.
    - **It's an uphill battle due to cost but we look to 2023 + for relief**. Note that this provision costs dollars/requires an offset. A 2-yr (retro 2022 and 2023) costs approx $3.5 B, a 4-yr (retro 2022 through 2023) costs about $7.5 B while a permanent fix costs $150 B

- **Some pharma unfriendly FDA provisions were pulled from the omni, which help industry**. Gone from the bill is a requirement that companies enroll clinical trials by the time of accelerated approvals. Senators also stripped a requirement that product labels disclose that medicines have been approved using the accelerated approval pathway.

- **PBM transparency in commercial markets was yanked but could see the light of day in 2023**. We expected to see increased PBM transparency, based on anticipated requirements for PBMs to provide group health plans, states, and federal regulators detailed data and reports on rebates, discounts, copayments every six months. The rule was a component of mental health bipartisan bill approved by the House in June 2022, Restoring Hope for Mental Health and Well-Being Act of 2022.

- **VALID Act would regulate diagnostic tests via FDA, which we saw as iffy at best at YE, and is not included here**. We noted previously that either PREVENT Pandemics or VALID Act was expected to be included as a nod to the retiring Senator Burr (R-NC). The in vitro clinical testing (IVCT) regulation is likely to be revisited in 2023. If passed, VALID sets up a risk-based system for FDA oversight of IVCTs starting in 2027 (may be delayed to 2028).

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What's Included

- **Basic science, public health and ARPA-H funding is robust**. $47.5 B for the National Institutes of Health (NIH), or a $2.5 B increase, $9.2 B for the Centers for Disease Control and Prevention, $1.5 B for ARPA-H (the President's initiative to fight cancer), and $950 M for the Biomedical Advanced Research and Development Authority.

- **Cancer moonshot support**. The budget aims to support Cancer Moonshot with increased funding for every CDC cancer program. These include programs for skin cancer, breast and cervical cancer, National Program of Cancer Registries, among others.

- **PREVENT Pandemics Act included.** We noted previously that this bill was a nod to retiring Senator Burr (R-NC), the current ranking member of the Senate HELP committee and had an above average chance of being included. The bill is a bipartisan, catch-all of roughly 37 different bills related to pandemic preparedness. It includes provisions to modernize FDA infrastructure, improve domestic biomanufacturing, establish a new office to oversee pandemic preparedness, improve public health data collection, and address healthcare workforce shortages.

- **Accelerated approval reform allows FDA to pull products from the market**. Accelerated approval reform gives FDA ability to withdraw approvals, request status reports. FDA would be authorized to require post-approval studies to be underway at the time of approval and allows the FDA to withdraw approvals where sponsors fail to conduct studies with due diligence (after a public meeting, dialogue with FDA commissioner). Within a year, the FDA will also have to create an intra-agency coordinating council (including CDER director Patrizia Cavazzoni, CBER director Peter Marks, OCE head Richard Pazdur and OND director Peter Stein) on accelerated approvals, and in some instances publicly explain "why a study is not appropriate or necessary."

- **Animal testing alternatives encouraged in FDA clinical trials**. Modernization of the FDA trials will allow for cell-based assays, organ chips and microphysiological systems, and sophisticated computer modeling. The new modalities move away from animal based pre-clinical models.

- **Clinical trial diversity required by FDA**. Manufacturers of drugs and some devices (particularly those applying for 510k) will be required to submit a diversity action plan that includes the goals for enrollment in the clinical trial, rationale for such goals, and an explanation for how the sponsor intends to meet such goals. Diversity plans will be required for Phase 3 trials that start enrollment 6 months after enactment. However, the FDA may waive diversity requirements if the prevalence or disease conditions make it "impractical" or if the research is necessary to protect public health during a PHE. FDA will also be required to update guidance on the enactment of diversity plans, the use of decentralized clinical trials, and on the use of digital health in clinical trials.

- **Therapeutic equivalence for 505(b)(2) makes for speedier approvals**. FDA will be required to make timely therapeutic equivalence evaluations for follow-on drugs approved through the 505(b)(2) pathway that have similar formulations as other approved products.

- **Qualified Infectious Disease Product (QIDP) changes**. The bill allows biological products to qualify as Qualified Infectious Disease Product (QIDP) and allows for priority review of innovative biological antifungal such products if such products require clinical data to demonstrate safety or effectiveness. The policy does not extend QIDP exclusivity to biological products, however.

- **New FDA programs & initiatives are listed below.**

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- **Rare disease endpoint advancement pilot program**. The pilot program will provide increased interaction with sponsors of rare disease drug development programs to advance the development of efficacy endpoints for drugs intended to treat rare diseases. It will last 4 years, sunsetting in 2027.

- **Advanced manufacturing program establishment**. Within a year, the FDA will be required to establish an advanced manufacturing program through which drug manufacturers can obtain a designation. Advanced manufacturing is defined as a method of manufacturing, or a combination of manufacturing methods that incorporate a novel technology or uses an established technique or technology in a novel way, that substantially improves the manufacturing process while maintaining drug quality. The program will last 10 years.

- **Biosimilar exclusivity clarification**. The bill clarifies FDA's ability to tentatively approve a subsequent interchangeable biosimilar biological product while a first interchangeable product's period of exclusivity is pending. Multiple interchangeable biosimilar biological products will be able to share a period of first interchangeable exclusivity if they are approved on the same day and otherwise qualify for exclusivity.

- **Extension of FDA hiring flexibility.** FDA's 21st Century Cures Act hiring authorities are extended,. The FDA has previously used flexibilities to streamline hiring and offer higher salaries to key staff. As hiring improves, FDA review times and capacity going forward are also expected to improve.

- **Addressing dual submission for certain devices**. A device authorized under an EUA with a laboratory procedure that has a minimal risk of errors may submit a single submission that includes information on the laboratory procedure when applying for a De Novo classification.

- **Medical device cybersecurity requirements**. Starting 90 days after enactment, device manufacturers will be required to submit cybersecurity information including a plan to monitor, identify, and post-market cybersecurity vulnerabilities. Within the next 2 years, FDA will be required to update the guidance on how to submit cybersecurity management plans in premarketing applications for medical devices. FDA will also be required to publish resources for cybersecurity within 6 months.

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