Biocom California FY 2023
Omnibus Summary

In December 2022, Congress passed a $1.7 trillion FY2023 Omnibus Appropriations bill that includes funding for federal agencies, emergency funding for disaster relief and Ukraine, as well as new policies that were discussed as part of the Preparing for and Responding to Existing Viruses, Emerging New Threats (PREVENT) Pandemics Act and the Food and Drug Omnibus Reform Act (FDORA). This summary focuses on the Health and Human Services (Division FF) policies, many of which impact the life science industry.

Division FF, Title II—Health and Human Services
Preparing for and Responding to Existing Viruses, Emerging New Threats (PREVENT), and Pandemics Act

This bill includes the PREVENT Pandemics Act (sections 2101-2515), which:

- Creates a White House Office of Pandemic Preparedness and Response Policy
- Modernizes biosurveillance capabilities and infectious disease data collection
- Strengthens the supply chain for vital medical products
- Advances genomic sequencing, analytics, and public health surveillance of pathogens
- Supports epidemic forecasting and outbreak analytics
- Improves countermeasure research coordination
- Improves transparency and predictability of processes of the SNS
- Creates grants for state stockpiles
- Increases EUA transparency
- Mitigates Shortages
- Accelerates countermeasure development and review
- Advances qualified infectious disease product innovation
- Supports laboratory capacity and international collaboration to address antimicrobial resistance
- Requires HHS to make public policies and procedures related to public and private entities accessing specimens of pathogens to support research and development of medical countermeasures
- Protects America's biomedical research enterprise
- Creates a Platform Technology Designation program at FDA to support the development and review of new treatments and countermeasures that use cutting-edge, adaptable platform technologies that can be used in more than one drug or biological product
- Does NOT include new shortage reporting for devices and no risk management plans

ARPA-H – Sec. 2331

- Creates the Advanced Research Projects Agency–Health (ARPA-H) by establishing ARPA–H within NIH to accelerate innovation by investing in novel, broadly applicable, high-risk, high-reward research projects
  - The President will appoint the Director of ARPA–H, who shall report to the Secretary of HHS
  - ARPA-H cannot be located on NIH grounds and have no less than 3 facilities around the country

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The omnibus includes provisions on drugs, biologics, and devices. Many of these provisions were discussed over the course of 2022 as part of the user fee reauthorization process but were included in the end of year package.

Division FF, Title III—Food and Drug Administration
Key Provisions Related to Biocom California's 2022 User Fee Advocacy

Accelerated Approval (AA) - Sec. 3210

- Authorizes FDA to require post-approval studies to be underway at the time of approval or within a specified time period after approval
- Requires FDA to specify aspects of required post-approval studies for AA drugs by approval
- Clarifies existing authority to withdraw drugs if sponsors fail to conduct studies in a timely way and streamlines the procedures for withdrawal of approval
- Requires frequent reports on post-approval study progress (every 180 days)
- Requires FDA to report to Congress on the use of real-world evidence to support post-approval studies and issue guidance on novel surrogate endpoints and clinical trial designs
- Requires the Secretary to establish an intra-agency coordinating council within FDA to ensure the consistent and appropriate use of the AA pathway
- Does NOT change the labeling of AA products

Rare Diseases – Sections. 3208 and 3202

- Rare Disease Endpoint Advancement Pilot Program (RDEA):
  - Establishes the Rare Disease Endpoint Advancement Pilot Program (RDEA) pilot program to provide increased interaction with sponsors of rare disease drug development programs to advance the development of efficacy endpoints for orphan drugs

- Improving the Treatment of Rare Diseases and Conditions:
  - Requires FDA to submit a report summarizing its activities relating to designating, approving, and licensing drugs to treat rare diseases
  - Requires FDA to finalize the draft guidance "Rare Diseases: Common Issues in Drug Development"
  - Requires the Secretary to enter into a contract with the National Academies of Sciences, Engineering, and Medicine to study processes for evaluating the safety and efficacy of drugs for rare diseases in the US and the EU
  - Requires FDA to convene one or more public meetings regarding approaches to improving engagement with rare disease patients, patient groups, and experts\
  - Adds the science of small population studies as a topic for consultation with external experts on issues related to the review of orphan drugs
  - Requires the GAO to conduct a study on FDA's activities regarding the review of orphan drugs

Clinical Trial Diversity - Sections. 3601-3607

- Requires Diversity Action Plans for Phase 3 Clinical Studies
- Instructs FDA to publish guidance on Diversity Action Plans for Clinical Studies
- Instructs FDA to hold public workshops to enhance clinical study diversity
- Requires an annual summary reporting on progress to increase diversity in clinical studies
- Requires a public meeting on clinical study flexibilities initiated in response to COVID–19
- Requires guidance on enrollment considerations and aspects of decentralized clinical studies
- Instructs FDA to issue guidance on modernizing clinical trials to include digital health technology, decentralized and other types of innovative clinical trial design

Predetermined Change Control Plans – Sec. 3308

- Establishes Predetermined Change Control Plans for devices, which allows the Secretary to approve a predetermined change control plan submitted in an application or supplement that describes planned changes that may be made to the device if the device remains safe and effective

Cybersecurity of Devices - Sec. 3305

- Requires manufacturers of cyber devices to:
  - Develop processes to ensure their devices are secure
  - Have plans to identify and address cybersecurity vulnerabilities
  - Provide a software bill of materials in their labeling, and submit this information to FDA in premarket submissions
  - This provision does NOT impact already marketed devices

Provisions NOT Included in the Omnibus

- Allowing for the personal importation of drugs (opposed by Biocom California)
- The inclusion of RACE 2.0/Give Kids a Chance Act (opposed by Biocom California)
- The inclusion of the generic drug disclosure provision, known as Q1/Q2 (opposed by Biocom California)
- Overly burdensome device reporting requirements (opposed by Biocom California)
- A retrospective cybersecurity provision that would have applied to legacy devices (opposed by Biocom California)
- A fix to the Clinical Trial Diversity and Modernization section (Division FF, Title III, Subtitle F) that includes a timeline overlap for the guidance and public meetings (supported by Biocom California)
- A timeframe for a response from the Secretary about a sponsor's Diversity Action Plan in Section 3601 (supported by Biocom California)
- A change to the orphan drug definition to align exclusivity with the FDA-approved indication, also known as the Catalyst issue. However, FDA has issued guidance on this topic, saying they will continue with their current policy for designating orphan drugs (supported by Biocom California)
- R&D amortization fix (supported by Biocom California)
- The VALID Act, or FDA regulation of lab-developed tests

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Division FF, Title III—Food and Drug Administration (cont.)

Additional Provisions

Drugs and Biologics Provisions – Subtitle B

- Requires prompt reports of marketing status by holders of approved biological products
- Creates an Emerging Technology Program to support innovative approaches to drug design and manufacturing
- Requires a public workshop on cell therapies
- Clarifies exclusivity for first interchangeable biosimilar products
- Requires a GAO Report on nonprofit pharmaceutical organizations
- Allows for animal testing alternatives to evaluate the safety and effectiveness of human drugs
- Clarifies therapeutic equivalence evaluation for 505(b)(2) to allow for pharmacy substitution
- Requires a public docket on proposed changes to third-party vendors for REMS
- Allows market access for a generic if the reference product label is changed within 90 days of the generic launch

AMR/Infectious Diseases

- Requires FDA Guidance on Antifungal Research and Development for Valley Fever
- Supports advancing Qualified Infectious Disease Product (QIDP) Innovation by making biologic QIDP products eligible for fast track

Manufacturing

- Allows FDA designation of institutions as National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing
- Establishes an Advanced Manufacturing Technologies Designation Program:
  - Requires FDA to initiate a program for designating methods of manufacturing as advanced manufacturing technologies
  - Designates technologies that qualify for expedited application development and review
  - Requires FDA to hold a public meeting, issue guidance, and report to Congress regarding this program

Devices Provisions - Subtitle C

- Establishes a small business (less than $1 Million) MDUFA fee waiver for medical devices
- Supports dual FDA-CLIA Submission for De Novo diagnostic tests approved under the EUA for full approval
- Requires Medical Devices Advisory Committee Meetings on pandemic preparedness and response
- Commissions a GAO Report on 510(k) third-party review
- Supports data transparency to evaluate third-party research on medical devices that are used for regulatory decision-making
- Supports certificates to foreign governments for importation of approved medical devices that are manufactured outside of the U.S.
- Allows FDA to issue bans of a use of a device for one or more approved uses

Cross-Cutting Provisions - Subtitle F

This bill includes cross-cutting drug, biologics, and devices provisions, which:

- Facilitates the use of real-world evidence (RWE) via guidance on the use of real-world data and RWE to support regulatory decision making, including RWE from EUA products
- Facilitates the exchange of product information prior to approval by providing no drug or device shall be considered misbranded by sharing information regarding investigational products or uses to payors, formulary committees, or other similar entities under specified conditions
- Deems all contrast agents, radioactive drugs, and over-the-counter monograph drugs to be drugs and not medical devices
- Requires the FDA Office of Women's Health to update the Women's Health Research Roadmap within 2 years of enactment

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Division FF, Title III—Food and Drug Administration (cont.)

Further Provisions

Program Reauthorizations - Subtitle A, Sections 3101-3109

- The Critical Path Public-Private Partnership through FY 2027
- The Best Pharmaceuticals for Children Program through FY 2027
- The Humanitarian Device Exemption Incentive for Rare Diseases through October 1, 2027
- The Pediatric Device Consortia Program through FY 2027
- A provision pertaining to drugs containing single enantiomers through October 1, 2027
- Certain device inspections for the third-party accreditation program through October 1, 2027
- Orphan drug grants through FY 2027

Inspections Provisions - Subtitle F, Chapter 2

- Expands the scope of device inspections
- Clarifies FDA authority to inspect bioresearch monitoring sites
- Improves FDA pre-approval or risk-based surveillance inspections
- Provides that FDA work with foreign governments to recognize inspections of foreign establishments to streamline pre-approval inspections
- Commissions a GAO report on inspections of foreign establishments manufacturing drugs
- Establishes an Unannounced Foreign Facility Inspections pilot program
- Enhances coordination and transparency on inspections by advancing intra-agency coordination between staff at FDA
- Harmonizes the timing of the FDA reporting requirement on inspections in FDARA to align with requirements related to PDUFA
- Enhances transparency of drug facility inspection timelines for certain generic drugs, drugs subject to discontinuance reporting, and drugs on the shortage list

FDA Modernization - Subtitle F, Chapter 3

- Increases user fee program transparency and accountability by strengthening the reporting requirements for the user fee programs regarding FDA's commitments and UFA negotiations/meeting minutes
- Requires a Strategic Workforce Plan update every 4 years
- Enhances FDA Hiring Authority for scientific, technical, and professional personnel
- Allows for facilities management by utilizing user fees
- Improves Information Technology systems at FDA
- Requires reports on the mailroom and the Office of the FDA Executive Secretariat to Congress
- Requires reports related to pending generic drug applications and priority review applications through October 1, 2027
- Authorizes a third-party accreditation program for the review and classification of certain medical devices through October 1, 2027.

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The omnibus includes several provisions that impact pricing and reimbursement.

Division FF, Title IV, V—Medicare & Medicaid Provisions

Section 4101-5141

- Extends Medicare telehealth flexibilities through December 31, 2024
- Supports adjusting to Medicare payment changes for 2023 and increases by 2.5 percent otherwise applicable Medicare Physician Fee Schedule payments
  - Services in 2024 will have a 1.25 percent payment increase
- Extends increased Inpatient Hospital Payment Adjustment for Certain Low-Volume Hospitals for 2 years
- Extends Medicare-Dependent Hospital Program for 2 years
- Extends incentive payments for participation in eligible Alternative Payment Models under Medicare and CHIP through 2025
  - Eligible clinicians qualify for a 5 percent Medicare Part B incentive payment in payment years 2019 through 2024 and a 3.5 percent Medicare Part B incentive payment for services covered in 2025
- Delays for 1 year the phase-in of Medicare Clinical Laboratory Test Payment Changes under PAMA
- Temporarily includes EUA Oral Antiviral Drugs as Covered Part D Drugs through 2024
- Restores CBO Access to Certain Part D Payment Data, including rebate and direct and indirect remuneration (DIR) data, under Medicare Part D
- Allows for Medicare Coverage of Certain Lymphedema Compression Treatment Garments starting in 2024
- Allows for permanent in-home benefit for Intravenous Immune Globulin Services (IVIG) in 2024
- Allows access to non-opioid treatments for pain relief from 2025 through 2027 for non-opioid treatments that are currently packaged into the payment for surgeries under Medicare's OPPS
- Adjusts Medicare payment for disposable negative pressure wound therapy devices by using the supply price to determine the relative value for the service
- Extends payment rates for Durable Medical Equipment under Medicare through December 31, 2023
- Extends Acute Hospital Care at Home waivers and flexibilities through December 31, 2024
- Extends Pass-Through Status under the Medicare Program for certain devices impacted by COVID-19 that would have expired on January 1, 2022, through December 31, 2023
- Extends through Calendar Year 2024 safe harbor for absence of deductible for telehealth services from the deductible in HDHPs
- Transitions from Medicaid FMAP increase requirements by providing funding and requirements for state Medicaid programs to support the transition from the enhanced Medicaid funding and continuous coverage requirements of the FFCRA.
  - FFCRA's continuous coverage requirement as of April 1, 2023 will sunset and allow for states to begin the process of initiating redeterminations of eligibility over a period of at least twelve months.
- Increases the Medicaid Improvement Fund to $7,000,000,000

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Omnibus Summary

The FY23 Omnibus includes several provisions related to Intellectual Property.

Intellectual Property

Unleashing American Innovators Act - Division W

- Requires the U.S. Patent and Trademark Office (USPTO) satellite offices to include outreach activities targeting economically and geographically underrepresented groups
- Establishes more USPTO satellite offices and community outreach offices
- Establishes a southeast regional office of the USPTO, directs a study for additional satellite offices, and establishes at least four community outreach offices
- Mandates a report to Congress on patent pro bono programs
- Establishes a pre-prosecution program
- Provides reduced fees for certain small and micro entities

Protecting America's Biomedical Research Enterprise

Included as part of PREVENT Pandemics Act - Division FF, Title II, Section 2324, which:

- Requires the HHS Secretary to consult with the National Security Advisor, the Director of National Intelligence, the Director of the FBI, and other relevant agencies, research institutions and advocacy groups to:
  - Identify ways to improve the protection of IP and other types of sensitive information in biomedical research
  - Develop strategies to address national security threats in biomedical research, including through foreign talent programs
  - Make recommendations to protect proprietary information from potential misuse that may pose national security risks
  - Develop a framework to identify areas of federally supported biomedical research that are emerging areas of interest for adversaries and may pose national security risks, if subjected to foreign influence
- Requires the HHS Secretary to regularly review policies made under this section and provide updates as appropriate, as well as submit a report to the President and relevant congressional committees that addresses the findings and recommendations of this section

Since its founding in 1995, Biocom California has emerged as the most respected association voice for the state's life science industry in regional government, the State Capitol, and Washington, D.C.

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