MEMORANDUM

TO: Clients

FROM: Jeffrey J. Kimbell & Associates

DATE: December 20, 2022

RE: Summary of FY 2023 Omnibus Package

On Tuesday, December 20, House and Senate lawmakers released the legislative text of a bipartisan, bicameral omnibus fiscal year (FY) 2023 appropriations bill. The $1.7 trillion package, negotiated by Senate Appropriations Chair Patrick Leahy (D-VT), Ranking Member Richard Shelby (R-AL), and House Appropriations Chair Rosa DeLauro (D-CT), totals $858 billion for national defense, a $76 billion increase over current levels. The omnibus totals $772.5 billion for non-defense discretionary programs, a $42.5 billion increase over current levels. The Senate is expected to consider the measure before Thursday, December 22. The House will need to pass the package before the end of Friday, December 23, to avoid a government shutdown. If passed, the omnibus will be the last legislative item of the 117th Congress. The House and Senate will convene on Tuesday, January 3, to begin the 118th Congress.

A summary of the healthcare items and other provisions of note is below. Read the bill HERE and read the summaries and explanatory statements HERE.

FDA

The bill provides $3.53 billion in discretionary funding for the Food and Drug Administration (FDA), $226 million over the FY22 enacted level. The increases for FDA include $26 million for medical product safety, $41 million for food safety activities, $121 million for cross-cutting initiatives supporting both medical and food safety, and $21 million for infrastructure investments. Included in the cross-cutting initiatives are increases to support FDA's core functions, including additional funding for inspections, information technology, laboratory safety, and other essential services. The bill also provides $50 million as authorized in the 21st Century Cures Act.

FDA User Fee Riders

Cosmetics

The bill contains updates to cosmetics regulations, requiring cosmetic manufacturers to register each of their facilities within one year. Companies also would need to provide FDA with information that includes a list of ingredients in their products, including fragrances, and update that annually, among other items.

Rare Diseases

The bill reauthorizes grants for the development of drugs for rare diseases or conditions. It also allows grants to be used for the development of regulatory science pertaining to chemistry, manufacturing, and controls of individualized medical products to treat rare diseases or conditions.

It also requires FDA to submit a report summarizing its activities relating to designating, approving, and licensing drugs used to treat rare diseases no later than September 30, 2026. It requires FDA to finalize the draft guidance document entitled "Rare Diseases: Common Issues in Drug Development" and make

other improvements regarding engagement with rare disease condition patients, patient groups, and experts.

The legislation establishes a rare disease endpoint advancement pilot program to implement procedures to provide increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints for drugs intended to treat rare diseases.

Pediatric Populations
The package reauthorizes programs that require the NIH to identify the drugs of highest priority for study in pediatric populations, publish a list of drugs/needs in pediatric therapeutics, and fund studies in the prioritized areas.

Cell-based Products
The bill requires FDA to convene a public workshop on best practices for generating scientific data necessary to further facilitate the development of certain human cell-, tissue-, and cellular-based medical products, and the latest scientific information about such products.

Drug Design
It authorizes the Emerging Technology Program at FDA, a collaborative program wherein industry representatives, academics, and others can meet with FDA officials to support the adoption and improve the development of innovative approaches to drug design and manufacturing.

Interchangeable Biosimilars
The legislation clarifies FDA's authority to tentatively approve a subsequent interchangeable biosimilar biological product while a first interchangeable product's period of exclusivity is pending. It clarifies that multiple interchangeable biosimilar biological products can share a period of first interchangeable exclusivity if they are approved on the same day and otherwise qualify for exclusivity.

Nonprofit Pharmaceutical Organizations
The bill requires GAO, not later than two years after the enactment, to submit a report on what is known about nonprofit pharmaceutical organizations, including the impact of such organizations on the development, availability, and cost of prescription drugs, and any challenges to manufacturing or other operations.

Animal Testing
The legislation clarifies that drug application sponsors can use alternative testing methods to animal testing in evaluating the safety and effectiveness of human drugs. It clarifies that sponsors of biosimilar applications can demonstrate biosimilarity to a reference product using alternative testing methods to animal studies.

Accelerated Approval
The bill requires FDA to specify conditions for required post-approval studies for drugs approved under accelerated approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the drug is approved. It grants the authority to withdraw approvals where sponsors fail to conduct studies with due diligence applies with respect to the approval conditions and streamlines the procedures for withdrawal of approval. It also requires FDA to issue a 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. The legislation also would require establishment of a coordinating council within the FDA to ensure consistent use of the accelerated approval pathway agency-wide

Advanced Manufacturing
The bill requires FDA to initiate a program for designating methods of manufacturing as advanced manufacturing technologies.
Follow-on Products
The legislation requires FDA 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. It also facilitates the availability of lower-cost drugs available for automatic substitution at the pharmacy.

REMS
It requires FDA to provide a public comment period regarding patient access and provider administration when a proposed modification to an approved risk evaluation and mitigation strategy (REMS) related to a change in third-party vendor is reviewed.

Generic Drugs
The legislation provides that a generic drug is eligible for approval notwithstanding differences between its proposed labeling and that of the listed drug due to revisions made to the labeling of the listed drug approved by FDA within 90 days of when the generic application is otherwise eligible for approval.

510(k)
The bill requires GAO to report on the program for accredited third-party review of 510(k) premarket notifications for medical devices.

CFG
The bill clarifies that FDA can issue Certificates to Foreign Governments (CFG) for medical devices that are manufactured by a device establishment located outside of the United States, if the establishment is registered, the medical device is listed, the device is lawfully marketed and imported or offered for import into the United States.

Cybersecurity
The legislation 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 any premarket submissions.

Waiver of Fees for Small Manufacturers
The bill allows certain small businesses, defined as those that reported $1 million or less of gross receipts in its most recent federal income tax return for a taxable year, to qualify for a waiver of the Medical Device User Fee Amendments (MDUFA) annual establishment registration fees, if the Secretary finds that paying such fee represents a financial hardship

Clinical Trial Diversity
The bill requires sponsors of phase 3 and other pivotal studies of new drugs and sponsors of studies of devices to develop and implement a diversity action plan, subject to certain exceptions. Such plan must include the sponsor's goals for enrollment in the clinical studies, the sponsor's rationale for such goals, and an explanation for how the sponsor intends to meet such goals. It also requires FDA to issue three guidances to modernize and improve clinical trials, including on the use of: (1) Digital health technologies in clinical trials to help improve recruitment, participation, and data collection; (2) Decentralized clinical trials to improve trial participant engagement and advance the use of flexible and novel clinical trial designs; and (3) Seamless, concurrent, and other innovative clinical trial designs to support the expedited

development and review of drugs and biological products.

Foreign Inspections
The legislation requires FDA to conduct a pilot program in which FDA increases the conduct of unannounced surveillance inspections of foreign drug establishments, evaluates the differences between such inspections of domestic and foreign establishments, including the impact of announcing inspections, and post a report of its findings and recommendations on the FDA website.

Definition of Radiologic Contrast Agents
The bill deems all contrast agents, radioactive drugs, and over-the-counter monograph drugs to be drugs and not medical devices. It waives application fees for products that are currently medical devices that would be deemed to be drugs.

Real-World Evidence
The bill requires FDA to issue or revise guidance on the use of real-world data and real-world evidence to support regulatory decision making, including with respect to real-world data and real-world evidence from products authorized for emergency use.

Medicare Extenders
The legislation extends the Medicare low-volume hospital payment adjustment for two years through September 30, 2024; extends the Medicare-Dependent Hospital (MDH) program for two years through September 30, 2024; and extends a number of add-on payments for ground ambulance services under the Medicare fee schedule through December 31, 2024.

Medicare and Physician Payment Cuts
The bill waives the statutory Pay-As-You-Go (PAYGO) 4% Medicare sequester for two years. The bill also reduces the 4.42% cut to the Medicare Physician Fee Schedule (PFS) conversion factor to 2.5% in 2023 and 1.25% in 2024. The bonus for physicians participating in value-based care programs would be reduced from 5% to 3.5% and continued for one additional year.

Telehealth
The bill would extend Medicare telehealth flexibilities for two years through 2024. These flexibilities were set to expire 151 days after the end of the public health emergency (PHE). Telehealth flexibilities for high-deductible health plans coupled with Health Savings Accounts would also be extended.

NIH
The bill provides $47.5 billion to the National Institutes of Health (NIH), an increase of $2.5 billion from FY 2022 enacted levels. This includes $3.74 billion for Alzheimer's disease and related dementias research, $7.32 billion for the National Cancer Institute, and $75 million for the Accelerating Access to Critical Therapies for ALS (ACT for ALS).

Opioid Epidemic
The bill allocates $4.9 billion to combat the opioid epidemic. This includes funding for treatment and prevention efforts; finding alternative pain medications; workforce needs, research; and treating behavioral health. The bill gives states flexibility to use opioid response funds on stimulants across multiple government programs.

Buprenorphine

The bill also includes the Mainstreaming Addiction Treatment (MAT) Act, which would remove a requirement that healthcare providers get a special waiver from the Drug Enforcement Agency (DEA) before being able to prescribe buprenorphine, a treatment for opioid addiction.

Non-Opioid Treatments

The bill provides a separate Medicare payment, from 2025 through 2027, for non-opioid treatments that are currently packaged into the payment for surgeries under Medicare's Outpatient Prospective Payment System (OPPS). The bill also caps the separate payment at 18 percent of the estimated average OPPS payment amount for the surgeries and other services for which the non-opioid is used in conjunction with.

Mental Health

The bill includes $5.27 billion for mental health research, treatment, and prevention. This includes, $385 million for Certified Community Behavioral Health Clinics; $512 million for the Substance Abuse and Mental Health Services Administration's (SAMHSA) suicide prevention activities, including the recently launched 9-8-8 Suicide Lifeline; $1.01 billion for the Mental Health Block Grant; $2.34 billion for the National Institute of Mental Health; and $111 million for school-based mental health grants at the Department of Education.

CDC

The bill includes $9.2 billion for the Centers for Disease Control and Prevention (CDC). The increases in funding would be spread across core programs like the Public Health Infrastructure and Capacity Program, the Infectious Disease Rapid Response Reserve Fund, Global Public Health Protection, the Forecasting and Outbreak Analytics Center, Public Health Workforce, and Data Modernization program.

ASPR

The bill allocates $3.3 billion to the Assistant Secretary for Preparedness and Response (ASPR) to accelerate advanced research and the development of medical countermeasures for pandemic threats, and fortify the nation's stockpiles and supply chains for drugs, masks, and other lifesaving medical supplies.

Project BioShield

The bill also contains $965 million for Project BioShield. These funds may be used for advanced research, clinical development, manufacturing and procurement of medical countermeasures. Products may be purchased under Project BioShield if they are licensed, approved or cleared by FDA, or if they may be made available under an Emergency Use Authorization (EUA) during a public health emergency.

Pandemic Preparedness

The package includes $950 million to support advanced research and development of medical countermeasures at the Biomedical Advanced Research and Development Authority (BARDA); $965 million for the Strategic National Stockpile (SNS); and $335 million for pandemic influenza preparedness.

The bill also includes many provisions in the Senate Health, Education, Labor, and Pensions (HELP) Committees PREVENT Pandemics Act.

CDC Director

The bill requires Senate confirmation of the Director of the CDC beginning on January 20, 2025, and establishes specific functions of the Director. It also requires an agency-wide strategic plan to be developed every four years that describes CDC's priorities and objectives, the capabilities that need to be

developed to achieve these objectives, and how CDC will leverage strategic communications, external partnerships, and coordination with other agencies.

Advisory Committee
It also requires the CDC Director to maintain an advisory committee shall consist of up to 15 non-federal members in relevant fields of expertise, of which 12 shall be appointed by the Director from relevant health disciplines, and three shall be appointed by the Secretary from the general public, such as individuals with expertise in public policy, public relations, or economics. It would also establish an Office of Pandemic Preparedness and Response Policy within the Executive Office of the President, led by a Director appointed by the President, to advise on pandemic preparedness and response policy and to support coordination and communication within the federal government related to preparedness and response.

Medical Countermeasures
It also requires the NIH Director to consult with ASPR, BARDA, CDC, and the heads of other federal agencies and offices regarding research needs to advance medical countermeasures for any virus agent or toxin that may cause a public health emergency, or other research needs related to emerging public health threats. Furthermore, the bill improves coordination and communication between private sector partners, BARDA, and the Food and Drug Administration (FDA) to ensure that this manufacturing capacity and capabilities are appropriately maintained, follow good manufacturing practices, and any related challenges are identified and addressed for the Strategic National Stockpile (SNS).

Drug and Device Shortage Reporting
The bill clarifies that all foreign drug and medical device establishments that manufacture or process drugs or medical devices intended to be marketed in the United States must register with FDA, including products manufactured at an establishment that are not directly imported into the United States. It allows for the voluntary reporting of certain medical device shortages outside of a public health emergency.

ARPA-H
The bill includes $1.5 billion for the second year of the Advanced Research Projects Agency for Health (ARPA-H). Under the bill, the ARPA-H Director would be appointed by the President and report directly to the Department of Health and Human Services (HHS) Secretary.

VA
The bill authorizes $118.7 billion for VA medical care in fiscal year 2023 to provide essential health services for more than 7.3 million veterans, including deferred care due to the COVID-19 pandemic. Also included is $5 billion for the Cost of War Toxic Exposures Fund, which provides additional funding to implement the landmark PACT Act that expands eligibility for health care services and benefits to veterans with conditions related to toxic exposure during their service.

The bill aims to improve veterans' healthcare by expanding access to care for World War II veterans and improve the research and treatment of prostate cancer. It also addresses oversight of health care providers and strengthens accountability for substandard care. Additionally, the bill improves veteran access to care outside VA and improves accountability for non-VA providers. It increases oversight of rural care and telehealth, studies effectiveness of VA's Foreign Medical Program, and makes improvements to VA research efforts, including for mental health treatments. The bill directs the HHS Secretary to develop and report to Congress within one year a strategy for long-term care for aging veterans, including the feasibility of implementing a veteran-focused independent provider model for non-institutional care.

IHS
The bill includes $6.93 billion for the Indian Health Service (HIS) to reduce wait times, build hospitals in areas that currently have insufficient access to healthcare, better equip health facilities with medical equipment such as mammography machines, and modernize health records.

Semiconductors
The bill includes $1.8 billion in new funding to implement the bipartisan CHIPS and Science Act of 2022.

HIV/AIDS
The package includes $613 million for the fourth year of the domestic HIV/AIDS elimination initiative and $6.725 billion to combat HIV/AIDS abroad.

Hospital at Home
The bill includes a two-year extension for the hospital at home program, which enables some patients who need acute-level care to receive care in their homes rather than in a hospital.

Home Health Providers
The package extends, for one year through December 31, 2023, the 1 percent add-on payment provided to certain home health agencies that furnish services in counties with a low population density.

U.S. Territories
The bill extends Puerto Rico's higher federal Medicaid match of 76 percent through fiscal year 2027 and permanently extends a higher federal Medicaid match of 83 percent for American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands.

CHIP
The bill extends funding for the Children's Health Insurance Program (CHIP) for two additional years through fiscal year 2029. It would also require states to provide justice-involved youth who are eligible for Medicaid or CHIP with screening, diagnostic, and case management services in the 30-day period prior to their release from incarceration in a post-adjudication setting.

Transitioning From Medicaid FMAP Increase Requirements
The legislation provides funding and requirements for state Medicaid programs to support the transition from the enhanced Medicaid funding and continuous coverage requirements of the Families First Coronavirus Response Act (FFCRA). This Section would sunset FFCRA's continuous coverage requirement as of April 1, 2023 and allow for states to begin the process of initiating redeterminations of eligibility over a period of at least twelve months. States would be able to receive enhanced Medicaid funding from April 1 through December 31, 2023, subject to meeting certain conditions.

Lab Payment Cuts
The bill revises the phase-in of lab pay cuts tied to the Protecting Access to Medicare Act by delaying the reporting period and the payment cuts until 2024.

Retirement Savings Plans
The package includes provisions in the SECURE 2.0 Act, which increases participation in retirement plans by expanding automatic enrollment features in retirement plans, decreases costs for employers that seek to offer retirement plans for their employees, encourages small businesses to offer retirement plans, and simplifies various rules relating to 401(k), 403(b), and other retirement plans. Also encourages

workers to save more and allows retirees to save longer. Finally, the bill provides flexibility for workers who have unexpected emergency expenses.

Tax Provisions

Notably, the bill does not include a tax title with R&D and corporate tax credits that was discussed as a potential component of the package. It does contain a limitation on the use of syndicated conservation easements.

Offsets

To offset the cost of some of the health items in the legislation, the bill reduces the amount in the Medicare Improvement Fund from $7,278,000,000 to $180,000,000. It also extends, by one year, the change to the annual updates to the hospice aggregate cap made in the Improving Medicare Post-Acute Care Transformation Act (IMPACT Act) of 2014 and applies the hospice payment update percentage rather than the Consumer Price Index for Urban Consumers (CPI–U) to the hospice aggregate cap through 2032. Furthermore, it extends the mandatory Medicare payment reductions under sequestration for the first six months of fiscal year 2032, while revising Medicare sequestration percentages to 2 percent for fiscal year 2030 and fiscal year 2031.