



What is included in this newsletter:

- Congressional State of Play
- FY2023 Appropriations Wins
- Telehealth Update
- Immigration Policy Update
- In The News

Congressional State of Play

After 15 votes over the course of 4 days, the House of Representatives finally has a Speaker of the House. Ultimately, Rep. Kevin McCarthy (R-CA) was elected along party lines after reaching a deal with the remaining House Freedom Caucus members on a Rules Package that would dictate how business in the House is conducted. Now that the Speaker has been elected and the Rules Package likely to pass on the evening of January 9, 2023, Congress can begin its regular scheduled and necessary work. Committee assignments will be released over the next week, we expect hearings to commence soon after. As discussed in previous newsletters, we expect the Republican House to focus on oversight of the Biden administration through hearings on topics such as the Inflation Reduction Act, border security and immigration, and the business deal of Hunter Biden.

The Democrat controlled Senate is expected to resume normal work in the coming weeks with committee assignments being released the week of January 9, 2023. Once committee assignments are made, the Senate will begin conducting hearings and taking other legislative action on the floor. Due to the split Congress, we can expect the Senate to largely focus on confirming Biden administration nominations and judicial appointments.

However, there are a number of issues that will need to be addressed despite the split. Congress will have to find some way to increase the debt ceiling as well as fund the government for Fiscal Year 2024. This will likely prove to be no small task as many Republicans have committed to fighting spending increases and opposition to increasing the debt ceiling.

Fiscal Year 2023 Appropriations Wins

Below please find the key cancer related provisions in the FY23 Omnibus. Potential provisions such as the VALID Act, Childhood Cancer STAR Act Reauthorization, and Gabriella Miller Kids First Reauthorization were not included in the final package. Additional analysis is linked at the bottom of the page.

of each section where available. However, the Childhood Cancer STAR Act was reauthorized by unanimous consent before the end of the year in both the House and Senate.

[FY23 Omnibus Bill Text](#)

[LHHS Explanatory Statement](#)

[LHHS Summary](#)

[Defense Explanatory Statement](#)

[Defense Summary](#)

Peer-Reviewed Cancer Research Program

The agreement provides \$130,000,000 for the peer-reviewed cancer research program for research on cancers not addressed in the breast, pancreatic, prostate, ovarian, kidney, lung, melanoma, and rare cancer research programs.

The funds provided in the peer-reviewed cancer research program are directed to be used to conduct research in the following areas: bladder cancer; blood cancers; brain cancer; colorectal cancer; endometrial cancer; esophageal cancer; germ cell cancers; head and neck cancer; leukemia; lymphoma; mesothelioma; metastatic cancers; myeloma; neuroblastoma; pediatric brain tumors; pediatric, adolescent, and young adult cancers; sarcoma; stomach cancer; thyroid cancer; and Von Hippel-Lindau syndrome malignancies (excluding cancers of the kidney and pancreas).

The peer-reviewed cancer research program shall be used only for the purposes listed above. The inclusion of the individual rare cancer research program shall not prohibit the peer-reviewed cancer research program from funding the above-mentioned cancers or cancer subtypes that may be rare by definition. The report directed under this heading in House Report 117-88 is required to be provided not later than 12 months after the enactment of this Act.

Glioblastoma

Glioblastoma (GBM).--Glioblastoma is a cancer with less than a five percent five-year relative survival rate, and the average survival time from diagnosis has improved by only six months over the last 30 years. To date, there have only been five drugs and one medical device approved by the FDA for the treatment of GBM. With prior Congressional investment in NCI programs, glioblastomas have been molecularly characterized, resulting in a new and promising understanding of these tumors, including the identification of potential clinical strategies, drug agents, trial designs, and imaging and pathology technologies.

The Committee commends NCI for its establishment and initial implementation of the Glioblastoma Therapeutics Network (GTN). The GTN's cross-cutting teams' capabilities to conduct pre-clinical studies and early-phase clinical trials enables the careful evaluation of potential treatments including small molecule drugs, immunotherapies, radiation, and devices. The overall goal of GTN is advancing progress towards future cures and improved quality of life for GBM patients.

Given this initial progress, the Committee urges NCI to continue to enhance and accelerate implementation of the GTN and continue to fund to the full extent necessary so that this program can rapidly launch clinical trials that speed access to promising qualified treatments to patients consistent with NCI's Glioblastoma Working Group recommendations in 2019.

Advanced Research Projects Agency – Health

The agreement includes \$1,500,000,000 for ARPA-H. The agreement strongly encourages HH collaborate with the Defense Advanced Research Projects Agency (DARPA) to develop foundational policies, procedures, and staff training for ARPA-H employees. The agreement believes ARPA-H will require a very different culture and mission than NIH's other 27 Institutes and Centers. To foster the development of an entrepreneurial culture, the agreement expects ARPA-H to be physically located away from the main NIH campus. The agreement directs NIH to brief the Committees no later than 30 days prior to conducting the location search on its criteria and the Committees should be notified of the decision no less than 5 days prior to a location being announced publicly. While the NIH workforce is composed of dedicated, talented, and frequently brilliant scientists, recruitment from the existing NIH workforce should be avoided. Instead, the agreement recommends that ARPA-H consider recruiting from industry, academia, and think tanks, as well as from proven advanced research project organizations. The agreement directs ARPA-H to provide quarterly briefings to the Committees on its establishment process, hiring, scientific priorities and progress. These briefings should specifically address how its activities will advance biomedical research and development and the mission to create breakthrough health technologies, as well as how to balance long-term scientific challenges with short-term research goals.

See Politico Pro Analysis [HERE](#).

National Institutes of Health and National Cancer Institute

The agreement provides \$47,459,000,000 for NIH, including \$1,085,000,000 from the 21st Century Cures Act (P.L. 114-255, Cures Act), an increase of \$2,500,000,000, or 5.6 percent, above the fiscal year 2022 enacted level. The agreement provides a funding increase of no less than 5 percent above the fiscal year 2022 enacted level to every Institute and Center (IC). Per the Cures Act, \$216,000,000 is transferred to the National Cancer Institute (NCI) for cancer research; \$225,000,000 to the National Institute of Neurological Disorders and Stroke (NINDS); \$225,000,000 to the National Institute on Mental Health (NIMH) for the BRAIN Initiative; and \$419,000,000 to the Office of the Director (OD) for the All of Us precision medicine initiative.

The agreement directs NIH to include updates on the following research, projects, and programs in the fiscal year 2024 Congressional Justification: metastatic breast cancer; NCI's plans to update the Surveillance, Epidemiology, and End Results Registry; pulmonary fibrosis; cellular immunology and opportunities to enhance childhood cancer research efforts, including coordinating efforts already underway through the Trans-NIH Pediatric Research Consortium.

Clinical Trial Diversity

Clinical Trial Diversity.--The Committee recognizes NIH's efforts to increase meaningful participation across the lifespan of ethnic and racial minority populations and underrepresented communities in clinical trials. The Committee encourages NIH to continue improving clinical research diversity, equity, inclusion, and accessibility by engaging in proactive outreach efforts with people including women and racial and ethnic minority groups, underrepresented communities, and health care organizations serving these populations, to improve awareness of clinical

research, including trials, and understanding of how people can participate. The Committee requests an update on these activities in the fiscal year 2024 Congressional Justification.

Cancer Moonshot

Cancer Moonshot.- The agreement directs NCI to provide a report to the Committees within 90 days of enactment of this Act describing the steps it will take to advance efforts to develop a robust pipeline of new treatments for recalcitrant cancers, defined in the Recalcitrant Cancer Research Act of 2012 (P.L. 112-239) as those with a five-year survival rate below 50 percent.

Childhood Cancer Data Initiative

Childhood Cancer Data Initiative (CCDI).- The agreement includes no less than \$50,000,000 for the CCDI, including no less than \$750,000 to continue to support enhancement of the Childhood Cancer Molecular Characterization Initiative.

Childhood Cancer STAR Act

Childhood Cancer STAR Act.-The agreement includes no less than \$30,000,000 for continued implementation of sections of the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act (P.L. 115-180). The agreement directs NIH to provide an update in the fiscal year 2024 Congressional Justification on opportunities to enhance childhood cancer research efforts and the actions NCI has taken to ensure pediatric cancer expertise is included on all panels as appropriate.

Gabriella Miller Kids First Research Act

\$12,600,000 is appropriated to the Common Fund from the 10-year Pediatric Research Initiative Fund described in section 9008 of the Internal Revenue Code of 1986 (26 U.S.C. 9008), for the purpose of carrying out section 402(b)(7)(B)(ii) of the PHS Act (relating to pediatric research) authorized in the Gabriella Miller Kids First Research Act.

Telehealth

Telehealth Centers of Excellence (COE).- The agreement includes \$8,500,000 for the Telehealth Centers of Excellence awarded sites.

Provider Bridge.- The agreement includes \$500,000 to continue the development of the Provider Bridge as part of the Licensure Portability Grant Program.

The omnibus continues Medicare's expanded access to telehealth by extending COVID-19 telehealth flexibilities for an additional two years, through December 31, 2024.

Accelerated Approval

The bill would allow the FDA to set parameters — such as enrollment goals, milestones and target completion date — for post-approval studies and institute an expedited process to request an accelerated approval while giving the drug sponsor an opportunity to appeal.

It would specify that the FDA may require post-approval studies before approval or within a certain time frame after approval and would require the agency to explain instances in which it doesn't mandate such a study.

The measure would require manufacturers to submit progress reports on their post-approval studies every six months until they're completed and would make failure to file them or to conduct any mandated post-approval studies enforceable offenses.

The legislation also would require establishment of a coordinating council within the FDA to ensure consistent use of the accelerated approval pathway agency wide.

See Politico analysis [HERE](#).

Deadliest Cancers

Deadliest Cancers.-The agreement directs NIH to identify the greatest obstacles and most promising research opportunities to advance progress against each of the deadliest cancer types in the fiscal year 2024 Congressional Justification.

Cancer

Cancer.- The agreement supports the Cancer Moonshot by providing an increase for every Cancer Program. In addition to skin cancer discussed separately under this account, the agreement includes an increase for Breast and Cervical Cancer for the activities included in House Report 117-403, as well as increases for Breast Cancer Awareness for Young Women, the National Program of Cancer Registries, colorectal cancer, the National Comprehensive Cancer Control Program, Johanna's Law, ovarian cancer, prostate cancer, and the Cancer Survivorship Resource Center.

Breast and Cervical Cancer.....	235,500,000
Breast Cancer Awareness for Young Women.	6,960,000
Cancer Registries.....	53,440,000
Colorectal Cancer.....	44,294,000
Comprehensive Cancer.....	22,425,000
Johanna's Law.....	11,500,000
Ovarian Cancer.....	14,500,000
Prostate Cancer.....	15,205,000
Skin Cancer.....	5,000,000
Cancer Survivorship Resource Center.....	725,000

Telehealth Update

As is detailed above, the FY23 Omnibus package included a two-year extension of telehealth flexibilities originally enacted during the COVID-19 pandemic. The emergency provisions were to expire five months after the COVID-19 public health emergency ends. However, the provisions in the Omnibus ensures that the flexibilities will be available for two additional years with

goal of this being enough time for the Biden administration to determine which of the pandemic flexibilities should be made permanent.

Immigration Policy Update

On January 5, 2023, the Biden administration released a new [immigration plan](#) that would allow 30,000 migrants a month from Cuba, Haiti, and Nicaragua. The plan is modeled on a similar program that was designed and implemented for Venezuelans and Ukrainians, that “combines safe, orderly, and lawful pathways to the United States, including authorization to work, with significant consequences for those who fail to use those pathways.” The program will be implemented using the Title 42 authority to turn away migrants at the U.S.-Mexico border who do not qualify. Further, migrants who cross into Panama or Mexico illegally, will be ineligible for the program. This is an attempt by the Biden administration to discourage migrants from taking the dangerous illegal journey.

In The News

[Politico](#) (1/6/2023): **FDA EXPECTED TO PUBLISH 38 RULES IN 2023** — This week, the Office of Information and Regulatory Affairs released the Fall 2022 Unified Agenda containing rules that give agencies government-wide hope to finalize this spring.

[Axios](#) (1/6/2023): **A banner year for drugs brings cost concerns** - A series of pricey breakthrough prescription drugs are poised to shake up the market this year — including an Alzheimer's treatment that could be approved today by the FDA, Axios' Caitlin Owens writes.

[Washington Post](#) (1/6/2023): **Top lawmakers to watch on health care this Congress** - The House's Cathy McMorris Rodgers (R-Wash.): In 2021, McMorris Rodgers stepped into the top GOP slot on the Energy and Commerce Committee. She's now poised to lead the panel for the first time and has laid out an agenda that includes probing the Biden administration's covid policies and the rate of deaths from fentanyl. She's also planning oversight into how the federal health department decides to implement Democrats' new drug-pricing policies and transparency on how much hospitals charge, the latter of which has been bipartisan.

[Bloomberg](#) (1/6/2023): **FDA Readies Action on Clinical Diagnostics** - The FDA will likely rekindle its efforts to oversee laboratories' diagnostic tests after lawmakers failed to act on legislation requiring the agency to regulate them, former Food and Drug Administration officials and public health analysts say.

[Politico](#) (1/6/2023): **PATIENT PORTAL DISPARITY** — White patients are more likely to know about and use online patient portals than are Black and Hispanic patients, POLITICO's Ben Leor reports.

[Bloomberg](#) (1/5/2023): **New Biden Rules Agenda Released With Health Measures**: The Biden administration released its next regulatory to-do list on Wednesday, with several health-related

highlights. HHS is ramping up efforts to stop discrimination against disabled people by way of a proposed rule scheduled to drop in March. Also on deck is a proposed HHS rule that would cut disincentives aimed at health-care providers who interfere with the exchange or sharing of electronic health records.

[Bloomberg](#) (1/5/2023): **Hardliners Angle for Plum Posts as Price of McCarthy Support:** demands from House Republicans who back someone other than Kevin McCarthy (Calif.) to keep the speaker continue to grow. Rep. Matt Gaetz (Fla.), who questions if Covid-19 originated from a Chinese lab, wants to lead a House Armed Services subcommittee, and Rep. Andy Harris (Md.), an ardent opponent of abortion, wants to lead the Appropriations HHS panel. Billy House has m

[Bloomberg](#) (1/4/2023): **Drugmaker Pricing Data Lacks Medicare Scrutiny, Watchdog Says:** C in Medicare oversight on the average sale price of certain cancer drugs and others administered in outpatient settings has led to millions in lost savings to beneficiaries, the HHS Inspector General's office said. Two reports released Tuesday identified issues at the Centers for Medicare & Medicaid Services that the watchdog office said helped allow inaccurate data to impact Medicare Part B payments.

[Axios](#) (1/4/2023): **Medicare Part B oversight gaps costs millions** - Medicare and its enrollees were unable to realize millions in savings because of gaps in CMS' oversight of the Part B program, according to a federal watchdog report released Tuesday.

[Politico](#) (1/3/2023): **THE BERNIE EFFECT** — Lobbyists across the health care sector are steeling themselves for when Sen. Bernie Sanders becomes chair of the Senate's Health, Education, Labor and Pensions Committee, POLITICO's Megan R. Wilson reports.

[Politico](#) (1/3/2023): **DEMS BANK ON DRUG PRICING LAW** — Democrats are hoping last year's passage of the Inflation Reduction Act will pave the way for more government action in the coming years, writes POLITICO's Alice Miranda Ollstein.

[Modern Healthcare](#) (1/3/2023): **What's ahead for healthcare in 2023?** - Modern Healthcare spoke with industry stakeholders about their 2023 forecasts, and how leaders can best prepare for the next 12 months.

[Bloomberg](#) (1/3/2023): **Drug Prices in Crosshairs for New Congress** - Overseeing Medicare's authority to negotiate prices of the country's highest-spending drugs is among the top priorities for lawmakers as Congress returns to Washington.

[The Hill](#) (1/3/2023): **Medicare lost millions in savings due to spotty oversight: federal watchdog** - A federal watchdog has found that Medicare lost out on millions of potential savings due to spotty oversight of the average sales price of medications, impacting how much Medicare Part B beneficiaries pay for coverage.

[Politico](#) (12/16/2022): **DURBIN: DIETARY SUPPLEMENT BILL NOT IN OMNIBUS** — A last-ditch effort to include legislation to overhaul the FDA's regulatory authority over dietary supplements in an end-of-year omnibus bill has fallen short, according to Senate Majority Whip Dick Durbin (Ill.). "We sure did try and couldn't get it done, I don't think it's in there," Durbin, the bill's sponsor, told POLITICO. **BUT NEARLY EVERYTHING ELSE IS FLUID** — As for other health-related good ideas being bandied about for possible inclusion in the omnibus, most appear to be live possibilities.

members and staff rush to wrap up negotiations by Dec. 23, when the one-week continuing resolution approved by the Senate last night expires.

[Bloomberg](#) (12/16/2022): **Senate Passes Stopgap Carrying Health Provisions:** The Senate cleared by a 71-19 vote stopgap funding legislation to keep the federal government running until Dec. 23. The measure would extend through next week several provisions relating to Department of Health and Human Services programs.

[Bloomberg](#) (12/15/2022): **NCI Director Announces Early Stage Cancer Diagnosis:** National Cancer Institute Director Monica M. Bertagnolli was diagnosed with early stage breast cancer, but her prognosis is favorable, the NCI said. Bertagnolli has been in the post for two months as the first woman to lead the largest institute at the National Institutes of Health.

[Axios](#) (12/15/2022): **Just 14% of cancers found through screening** - Only 1 in 7 cancers in the United States are diagnosed after the patient had a recommended screening test, while most cases are discovered when symptoms arise or through other medical care, according to new research from the NORC at the University of Chicago.

[STAT](#) (12/15/2022): **Fixing price instability can improve access to affordable prescription drugs** - The high cost of prescription drugs is a very real problem in the United States. The average American spends approximately \$1,300 per year on prescription drugs, more than residents of any other country in the world. And for some new medications, it seems the sky's the limit when it comes to cost.

[Politico](#) (12/15/2022): **HEALTH ON THE HILL** — After appropriators clinched a deal Tuesday night on an omnibus package — albeit thin on details — there was optimism on the Hill that health care provisions would be included, Ben reports.

[Politico](#) (12/14/2022): **FIRST IN PULSE (II)** — Dozens of patient, consumer and employer organizations are calling on the federal government to stand firm following a series of efforts to undermine the No Surprises Act.

[Bloomberg](#) (12/14/2022): **Matsui Joins Rare Disease Caucus Leadership:** Rep. Doris Matsui (Calif.) will co-chair the Rare Disease Congressional Caucus in the 118th Congress, according to a statement. The caucus “provides a platform to engage on policy issues impacting the rare disease community,” it says. She’ll succeed the retiring Rep. G.K. Butterfield (D-N.C.) and join current chairs Rep. Gus Bilirakis (R-Fla.) and Sens. Roger Wicker (R-Miss.) and Amy Klobuchar (D-Minn.).

[Politico](#) (12/13/2022): **CONGRESS INCHES TOWARD OMNIBUS DEAL** — Congressional spending leaders are nearing agreement on a massive government funding deal, but one powerful skeptic remains: Rosa DeLauro (D-Conn.), the House Appropriations Committee chair, POLITICO’s California Editor Emma, Sarah Ferris and Burgess Everett report.

[Politico](#) (12/13/2022): **ARPA-H TO CHOOSE ITS HEADQUARTERS WITHOUT REQUEST FOR PROPOSALS** — The Advanced Research Projects Agency for Health doesn’t plan to release a request for proposal for its highly sought-after headquarters location, an agency spokesperson told POLITICO’s Ben Leonard. Jared Adams, ARPA-H’s chief of engagement and communications, says the agency is in the final stages of selecting a location.

declined to provide a timeline on the decision but gave some insight into the process, saying the agency is taking a number of factors into consideration and wants to allow “open competition”

[Axios](#) (12/13/2022): **Biden's drug pricing decisions aren't over** - The Biden administration faces a host of high-stakes decisions on prescription drug costs over the next several months, Axios' Caitlin Owens writes.

[STAT](#) (12/11/2022): **Novartis develops CAR-T therapy that can be made in a fraction of standard time** - NEW ORLEANS — For some patients suffering with certain blood cancers, CAR-T therapy can offer the tantalizing chance to end their disease with a single treatment.

[Politico](#) (12/9/2022): **FDA RIDER WATCH** — Senate HELP Committee Ranking Member Richard Burr told reporters on Wednesday that if Congress moves forward with a longer-term continuing resolution, the likelihood of health care legislation hitching a ride will significantly diminish.

[Bloomberg](#) (12/9/2022): **Lawmakers Want Biomedical Innovation Bill in Omnibus**: Lawmakers behind a sweeping biomedical innovation law are pushing to incorporate pieces of their follow-up legislation into the end-of-the-year spending package. Rep. Fred Upton (R-Mich.), said he is working with Rep. Diana DeGette (D-Colo.) to push forward on Cures 2.0 (H.R. 6000). But the clock is ticking, with just days left in the current session of Congress and Upton set to retire. Jeannie Baumann has more.

[Bloomberg](#) (12/9/2022): **Patent Office Will Launch Expedited ‘Cancer Moonshot’ Program**: The US Patent and Trademark Office will launch a new Cancer Moonshot Expedited Examination Program on Feb. 1, according to the office Thursday. Read more.

[Politico](#) (12/8/2022): **THE COST OF TELEHEALTH** — Efforts to expand telehealth access for people on high-deductible health plans have hit a snag, POLITICO's Ben Leonard reports.

[Bloomberg](#) (12/8/2022): **Califf Calls for Greater Focus on Trial Diversity**: Clinical trial diversity should be a more prominent priority among health research administrators, FDA Commissioner Robert Califf said yesterday as the agency prepares updated guidance on the topic. The Food and Drug Administration is preparing a manuscript of the agency's thinking on how to bolster diversity in clinical trials, he said. Read more from Celine Castronuovo and Jeannie Baumann.

[Bloomberg](#) (12/8/2022): **ARPA-H, Research Bills Lead Eshoo's Agenda**: Bills to establish an independent ARPA-H (H.R. 5585) and to improve diversity in clinical trials remain Rep. Anna Eshoo's (D-Calif.) top agenda items, but the head of the Energy and Commerce Committee health panel said she'll continue to pursue those measures in the next Congress if it doesn't pass up in a year-end spending package before lawmakers convene for the 118th session.

[Bloomberg](#) (12/8/2022): **Democrats Plan to Release Funding Package as Deadline Nears**: Congressional Democrats will publish a government funding package on Dec. 12, a Senate Democratic aide said, as the Dec. 16 deadline to avert a shutdown approaches with no bipartisan agreement on funding levels. The appropriations package, to be released the Monday before the Friday night deadline, is an offer Democrats think could pass both chambers, the aide said. Read more from Jack Fitzpatrick.

[Bloomberg](#) (12/8/2022): **Cancer Institute Prepares for New Screening Network:** The National Cancer Institute is looking to roll out a new cancer screening network to increase access to early detection programs while advancing research to screen for multiple cancers at the same time. The network is still in the planning phases, NCI Director Monica Bertagnolli said. Jeannie Baum has more.

[Politico](#) (12/7/2022): **ASTRAZENECA EXEC SAYS DRUG PRICING COULD GO FURTHER** — AstraZeneca executive praised the Inflation Reduction Act's drug-pricing negotiation provisions and suggested they should go further, Ben reports from the Milken Future of Health Summit Tuesday.

[Bloomberg](#) (12/7/2022): **Medicare Drug Price Changes Become a Top Focus of Biden's Health Administration** — Implementing changes to Medicare's Part D drug program is a top priority for the Biden administration, a health-care adviser to the president said Wednesday.

[Bloomberg](#) (12/7/2022): **Progressives Push Patent Office on High Drug Prices:** Progressive lawmakers are pressing the Patent and Trademark Office on its efforts to combat high drug prices and what the lawmakers describe as anti-competitive business practices by pharmaceutical companies. In a letter to PTO Director Kathi Vidal, Sen. Elizabeth Warren (D-Mass.) and Rep. Pramila Jayapal (D-Wash.) say that the PTO's lack of urgency raises questions on whether it's "not cognizant" of the problem. Read more from Riddhi Setty.

[Politico](#) (12/6/2022): **HEALTH GROUPS PUSH TO STOP MEDICARE CUTS** — Efforts to persuade Congress to dial back Medicare payment cuts to doctors intensified this week with more than 100 health care groups coordinating an all-out push, Daniel reports.

[Politico](#) (12/6/2022): **FDA TO HOLD MEETING ON DRUG SUPPLY CHAIN SECURITY ACT** — Tomorrow and Thursday, the agency will host a public meeting on the final implementation of the Drug Supply Chain Security Act — a law passed 10 years ago intended to create interoperable electronic tracing of certain prescription drugs. Over the next two days, stakeholders will discuss the final actions they need to take by Nov. 2023, when the law requires prescription drugs to be traceable from manufacturers to those who distribute drugs to patients.



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