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**State of Infrastructure and Reconciliation Negotiations**

Democratic leadership has started making progress on legislative pieces that may come together to form the basis for a partisan reconciliation package to be passed before the looming midterm campaign season and the September 30 procedural deadline. On July 6, Senate Democrats sent an agreement on drug pricing to the parliamentarian for review, an important step forward in talks. Energy and climate provisions remain in flux, as Senator Joe Manchin (D-WV) has reiterated his opposition to direct payment of tax credits. A reconciliation deal will still take significant compromise, legislative text drafting, and vetting through the Byrd bath process, but optimistic notes from both Sen. Manchin and Majority Leader Chuck Schumer (D-NY) may provide the spark needed to push ahead on a clean energy and healthcare focused bill before the August recess.

**Appropriations Update**

On June 22, 2022, the House Appropriations Committee approved the Fiscal Year 2023 Defense funding bill on a 32-26 vote. The funding bill included two of SNO's appropriations priorities for Fiscal Year 2023. The Peer-Reviewed Cancer Research Program received \$130 million in funding and "pediatric brain tumors" and "brain cancer" remained eligible funding categories. The inclusion of these provisions is the direct result of advocacy from the SNO Public Policy Committee.

Additionally, on June 30, 2022, the House Appropriations Committee also approved the Fiscal Year 2023 Labor, Health and Human Services, Education, and Related Agencies funding bill on a 32 to 24 vote. The legislation includes:

**Department of Health and Human Services (HHS)** – The bill provides a total of \$124.2 billion for HHS, an increase of \$15.6 billion above the FY 2022 enacted level and \$298 million below the President's budget request. Of this amount, the bill includes:

- **National Institutes of Health (NIH)** – The bill provides a total of \$47.5 billion for NIH, an increase of \$2.5 billion above the FY 2022 enacted level. The total includes:
  - \$7.4 billion, an increase of \$466 million above the FY 2022 enacted level, for the **National Cancer Institute**, including \$216 million for the **Cancer Moonshot**;
  - \$3.7 billion, an increase of \$200 million above the FY 2022 enacted level for **Alzheimer’s disease and related dementias research**;
  - \$25 million, an increase of \$12.5 million above the FY 2022 enacted level, for **firearm injury and mortality prevention research**;
  - \$75 million, an increase of \$50 million above the FY 2022 enacted level, to support research and expanded access to promising treatments authorized in the **ACT for ALS Act**;
  - \$3.4 billion, an increase of \$200 million above the FY 2022 enacted level, for **HIV/AIDS research**;
  - An increase of \$100 million for research related to **opioids, stimulants, and pain/pain management**;
  - An increase of \$100 million for **health disparities research**;
  - \$260 million, an increase of \$15 million above the FY 2022 enacted level, for **Universal Flu Vaccine Research**;
  - \$90 million, an increase of \$15 million above the FY 2022 enacted level, for the **INCLUDE initiative** related to research for Down syndrome;
  - \$64 million, an increase of \$5 million above the FY 2022 enacted level, for the **Office of Research on Women’s Health**; and
  - An across-the-board increase of 3.2 percent for **NIH Institutes and Centers to support the biomedical research workforce** and expand promising research.
  - Creates a new 10 percent set-aside within the MHBG to support **prevention and early intervention services**.
- **Centers for Medicare & Medicaid Services (CMS)** – The bill provides \$4.3 billion for CMS administrative expenses, an increase of \$322 million above the FY 2022 enacted level and equal to the President’s budget request. This funding level includes an increase of \$96.9 million above the FY 2022 enacted level for State Survey and Certification activities to strengthen improvement efforts, increase health and safety inspections of nursing home facilities, and ensure that long-term care and other facilities have proper infection controls in place.
- **Office of the Secretary—Public Health and Social Services Emergency Fund (PHSSEF)** – The bill provides \$3.7 billion for PHSSEF, an increase of \$500 million above the FY 2022 level and \$115 million below the President’s budget request. The bill provides funding to improve the nation’s preparedness for public health emergencies, including:
  - \$382 million, an increase of \$82 million above the FY 2022 enacted level, for **pandemic influenza**.
  - \$845 million, an increase of \$100 million above the FY 2022 enacted level, for the **Biomedical Advanced Research and Development Authority (BARDA)**.
  - \$800 million, an increase of \$20 million above the FY 2022 enacted level, for **Project BioShield**.
  - \$855 million, an increase of \$10 million above the FY 2022 enacted level, for the **Strategic National Stockpile**.
  - \$262 million, an increase of \$30 million above the FY 2022 enacted level, for **Hospital Preparedness Program** cooperative agreements.

- **Advanced Research Projects Agency for Health (ARPA-H)**—The bill includes \$2.75 billion, an increase of \$1.75 billion, to accelerate the pace of scientific breakthroughs for diseases such as ALS, Alzheimer’s disease, diabetes, and cancer.

## **Cancer Moonshot Update**

### **The White House**

#### **White House Cancer Moonshot Update**

July 11, 2022

### **Participants**

#### **Danielle Carnival**

White House

Cancer Moonshot Coordinator

### **Summary**

On July 11, 2022, the White House held a brief webinar providing an update on the White House’s Cancer Moonshot initiative. Danielle Carnival, the White House Cancer Moonshot Coordinator, delivered remarks on current progress and briefly mentioned actions that her group intends to take in the coming weeks.

After summarizing the goals of the Cancer Moonshot, which was revived in February 2022, Carnival outlined the seven pillars of focus for the initiative: improve cancer screening; enhance prevention; address inequities; target effective treatments to patients; develop approaches for deadly and rare cancers, including childhood cancers; support patients, survivors, and caregivers; and learn more from people with cancer. She called special attention to expanded screening tools, research connecting toxic exposure to cancer diagnoses, and cutting-edge research from the private sector to assist patients.

She also mentioned the efforts of the Cancer Cabinet to advance the goals of the Moonshot. The group, consisting of leadership from a variety of federal agencies, will add new members later this week. She said that the group will further flesh out the seven identified priority areas, with more specifics to be announced in the coming weeks.

## **Telehealth Update**

The telehealth industry has seen a great expansion since the start of the pandemic due to several policies enacted by the government to encourage its use. [These include](#) reimbursing providers for telehealth visits, allowing controlled substances to be prescribed remotely, allowing pre-deductible telehealth coverage, and most importantly of all, allowing doctors to perform telehealth visits with patients in any state, not just ones where they are licensed to practice medicine. However, with the threat of COVID-19 fading, these benefits may soon disappear. With the midterms approaching, lawmakers want to convince the public that COVID has been defeated and may not be willing to further extend pandemic-era benefits. Several of these benefits will be lost the moment the federal state of emergency ends in October, assuming it is not extended

again. Already, there are signs of backsliding in the telehealth industry. The Department of Justice is [ramping up](#) investigations into telehealth startups that prescribe controlled substances, indicating that the government may return to a ban on remote prescriptions of controlled substances. Additionally, a number of states which passed waivers to allow patients to have telehealth visits with doctors in other states have [allowed those waivers to lapse](#).

Another big source of uncertainty for telehealth providers is the abortion debate. As states scramble to set in place their rules on abortion, every aspect of the medical industry is being scrutinized for any possible role it might play in abortions, and telehealth is no exception. The primary concern is over the ability for doctors to remotely prescribe abortion pills. In states where patients are still allowed to have telehealth visits with out-of-state doctors, this could serve as a way to circumvent abortion bans. Thus, the telehealth industry could be a savior for those seeking abortions—but this is a role the industry [has no interest in playing](#). Telehealth lobbyists have been able to take advantage of a broad bipartisan coalition thus far, and the divisiveness of the abortion issue could destroy that coalition. Any action by the industry to protect or limit abortion rights would burn bridges, potentially accelerating the rollback of pandemic-era telehealth expansion. But with headlines like “[What does Utah’s trigger law say about abortion pills by mail or telehealth?](#)” running around the country, it’s clear that the telehealth industry has no power to downplay this debate or keep itself out of the greater conversation on abortion laws.

## **House Energy and Commerce Committee Markup**

### **House Committee on Appropriations**

#### **[FY 2023 Transportation, and Housing and Urban Development, and Related Agencies; Labor, Health and Human Services, Education, and Related Agencies Appropriations Bills and Revised Report on the Subcommittee Allocations](#)**

6/30/22

#### **Summary**

In her opening statement, Chair Rosa DeLauro (D-CT) explained an overview of the [FY 2023 Labor – HHS – Education Appropriations Bill](#). She stated that the bill would prioritize the lives of working- and middle-class families. Many people’s incomes are not keeping up with inflation, and women are having trouble entering the workforce because of the lack of childcare and this bill gives people the lifeline they are seeking. She illustrated how it provides \$242.1 billion in investments that support early childhood education and childcare, it funds greater education opportunity, strengthens federal support for public education and high poverty schools; and supports babies, young adults, and children living with disabilities with special education programs. These education improvements include commitments to historically underserved students. Chair DeLauro stated that the bill enhances the workforce, as \$11.8 billion has been allocated for employment and training, community college training grants, and increased funding for registered apprenticeships. \$139 million dollars are allocated for The International Labor Affairs Bureau to protect against abusive labor practices abroad. As for public health, the bill provides funding for CDC to help build public health infrastructure, modernize data, and strengthen the public workforce initiative. Additionally, the bill expands contraceptive care, maternal and child

healthcare, school-based health centers, and behavioral health workforce training. It strengthens the commitment to biomedical research, funding NIH, the cancer moonshot initiative, and flu vaccine development. Regarding mental health, it increases funding for substance abuse and mental health services. The bill strengthens support for women's rights and women's health, especially for more vulnerable women. It also advances equal treatment for women even as the Supreme Court tries to take control of women's healthcare decisions.

Ranking Member Tom Cole (R-OK) began his opening statement by agreeing with Chair DeLauro on the need for investment in biomedical research, public health infrastructure, and the importance of funding early education and special education. However, he opposed the bill by stating that Americans are experiencing the highest inflation rates and consumer prices that have been seen in 4 decades. He cited a report that said that inflation will stay well into 2023. A severe worker shortage still exists, and Americans are struggling to feed their families and pay their rent. Cole argued that the Biden Administration and democrats have ignored this crisis and fueled inflation by proposing more wasteful and out of control spending. He then asserted that the bill exacerbates American economic problems by pouring additional spending to programs that cannot absorb it. Ranking member Cole also stated that the bill removes longstanding bipartisan amendments, and that these protections must be reinstated to move forward. He closed by expressing that the bill funds many good projects, but that the price tag is too high, there is too much funding for unauthorized programs, and that the bill ultimately bows to a liberal agenda that is not in line with the American people. However, he was confident that a consensus would be made.

Representative Kay Granger (R-TX), in her opening statement, opposed the bill. She stated that although it funds many important programs, it is based on a funding level that has passed the House without any Republican support. She additionally opposed some of the controversial policies in the bill. She said that it drops bipartisan language that prevents federal tax dollars used to pay for abortions and removes language that protects American doctors and nurses from being forced to participate in abortions. Lastly, she argued that the bill promotes excessive spending on new unauthorized programs.

Representative Lucille Roybal-Allard (D-CA) was in support of the bill, saying that it provides funding for many of her priorities. She was grateful the bill includes the wage and hour division to reduce work related injuries and deaths for children working in agriculture. She highlighted the aspects of the bill that strengthen public health infrastructure and invest in climate change and health disparities.

Representative David Valadao (R-CA), in his opening remarks, stressed the importance of human trafficking prevention. He provided the fact that many victims are just children when they fall prey to coercion of traffickers, and that hybrid learning has put children at high risk of encountering predators. With respect to the bill, he stated that educating our youth to avoid exploitation is a critical trafficking prevention strategy.

Representative Sanford Bishop (D-GA) talked about the Job Corps program, and how it is important that the bill promotes sustainable, long-term investments in the public health system. He additionally mentioned how the CDC has an important role in the state of Georgia, especially in terms of employment. Lastly, he highlighted the importance of non-emergency medical transportation.

Representative Barbara Lee (D-CA) opened by commenting that given current threats to reproductive rights, it is crucial that contraceptive care is accessible and affordable for all women. She stated that the bill addresses systemic racism and health equity and provides 10 million dollars for the development of patient advocacy programs. The bill also addresses gaps in our country as it relates to black and brown children and addresses the school to prison pipeline.

In her opening remarks, Representative Debbie Wasserman Shultz (D-FL) focused on how the bill sets provisions to improve access to breast cancer screening and more advanced screening techniques. It provides 10 million dollars to services that help Holocaust survivors with psychological harm. She highlighted how the bill protects youth populations by combatting the e-cigarette epidemic and reinforcing the FDA ban on Juul products. The bill also reinforces oversight to access to ORR facilities for migrant children and supports initiatives on school climate and safety.

Representative Cheri Bustos (D-IL) centered on the social determinants of health, specifically the factors in everyday lives that impact health outcomes. She mentioned how the community under the congressional district she serves in has one of the most distressed zip codes in America. These families live in food deserts, and people lack adequate transportation needs. The neighborhoods also lack basic amenities like sidewalks. She then stated that this bill allocates 92 million in grants for social determinants of health so that communities can have the tools to develop tailored programs to uplift their vulnerable populations.

Representative Katherine Clark (D-MA) mentioned how the bill provides funding for improving early childcare learning programs. She said how childcare providers are currently facing severe labor shortage, which has ended up closing classrooms and adding to long waitlists. She acknowledged the importance finding solutions to improve these conditions.

Representative Bonnie Watson Coleman (D-NJ) stated how this bill invests in children, education health equity, and workforce programs. It prioritizes supporting programs that provide social and emotional support for COVID breed children. Additionally, it expands diversity at NIH and the disparities in its workforce. Lastly, Representative Watson Coleman discussed how the bill prioritizes suicide and mental health.

Representative Lois Frankel (D-FL) talked about the physical and psychological effects on the elderly relating to falls. She mentioned the importance of preventative action – bill works to support and scale up fall prevention programs. She stated that the bill invests in student veteran centers designed to help veterans coming out of the military with mentoring and financial counseling.

Representative Adriano Espaillat (D-NY) addressed the importance in funding essential systems to support the nation's depleted nursing workforce and make sure vulnerable population have access to Medicare. He talked about the funding for the Department of Education, where the bill invests in programs like the teacher quality program.

Ranking Member Cole proposed the addition of the Hyde Amendment to the bill. He highlighted the important in protecting life and preventing federal tax funded abortions. He provided the statistic that the Hyde Amendment has saved more than 2 million lives in the past. He expressed

his view on supporting and protecting the lives of unborn children. He acknowledged that many people have differing opinions on the issue of abortion but stated that even those who are pro-choice don't believe that tax dollars should be used on abortion. Representative Granger supported Ranking Member Cole with respect to the amendment and stated that the removal of the provision from the bill is deeply troubling. Representative Herrera Beutler (R-WA) also supported the amendment, asserting that we should not be taking other people's money to end life in the womb. She added that the Hyde Amendment has exceptions to save the life of the mother and claimed that supporting it is not a radical position because it remains consistent with protecting life.

Both Chair DeLauro and Representative Lee opposed the amendment. DeLauro argued that the amendment is discriminatory, and that it is crucial to empower all women to make personal life decisions without the interference of politicians. She mentioned that when Medicaid covers abortion, it means an individual can make a choice based on their personal circumstances. Representative Lee said that the amendment would prohibit abortion coverage for people insured through Medicaid. She claimed that Republicans are trying to control people's lives without regard to the control that women have over their bodies. She added that the amendment is a discriminatory and dangerous policy whose impact falls the hardest on women of color and low-income women, denying them the full spectrum of reproductive healthcare.

Ultimately, the amendment was ultimately ruled against in a vote of 26 to 31.

Representative Barbara Lee offered an Amendment that would urge the Department of Health and Human Services to ensure that medication abortion care is accessible, affordable, and covered for patients including through access to Telehealth. Chair DeLauro, Representative Watson Coleman, and Representative Lauren Underwood (D-IL) supported this amendment. Representative Cole rose in opposition of this amendment. The amendment was ultimately adopted.

## **Up to Date List of Drug Related Legislation for the 117<sup>th</sup> Congress**

- [H.R. 8299](#)

This bill, introduced on July 7, 2022, by Rep. Gus Bilirakis (R-FL), amends the Federal Food, Drug, and Cosmetic Act to allow for devices with a predetermined change control plan to be marketed without submitting a supplemental application or premarket notification if the changes to such devices are consistent with such plan.

- [H.R. 8289](#)

This bill, introduced on July 5, 2022, by Rep. Abigail Spanberger (D-VA), requires the Secretary of Health and Human Services to promulgate a past due final rule with respect to direct-to-consumer prescription drug advertisements, and for other purposes.

- [H.R. 8270](#)

This bill, introduced on July 1, 2022, by Rep. Lucy McBath (D-GA), amends the Employee Retirement Income Security Act of 1974, title XXVII of the Public Health Service Act, and the Internal Revenue Code of 1986 to require group health plans and health insurance issuers offering group or individual health insurance coverage to provide notices relating

to prescription drug refills to individuals covered under such plans or coverage who reside in emergency areas during emergency periods.

- [S. 4446](#)

This bill, introduced on June 22, 2022, by Sen. Susan Collins (R-ME), modernizes the process of accelerated approval of a drug for a serious or life-threatening disease or condition.

- [H.R. 8078](#)

This bill, introduced on June 15, 2022, by Rep. Mark Green (R-TN), ensures that prior authorization medical decisions under Medicare are determined by physicians.

- [H.R.7997](#)

This bill, introduced on June 9, 2022, by Resident Commissioner Jenniffer González-Colón (R-PR) amends title XVIII of the Social Security Act to establish a floor in Medicare Advantage benchmark rates for regions with low Medicare fee-for-service penetration and to make the Medicare Savings Program available in all jurisdictions.

- [S.4349](#)

This bill, introduced on June 6, 2022, by Sen. Roger Marshall (R-KS), amends the Federal Food, Drug, and Cosmetic Act with respect to notifications of emerging signals concerning devices.

- [S. 4338](#)

This bill, introduced on May 26, 2022, by Sen. Margaret Wood Hassan (D-NH), amends the Federal Food, Drug, and Cosmetic Act by providing for increased transparency in generic drug applications.

- [H.R.7208](#) – Price Relief, Innovation, and Competition for Essential Drugs Act

This bill, introduced on May 18, 2022 by Rep. Janice D. Schakowsky (D-IL), amends the Public Health Service Act to shorten the exclusivity period for brand name biological products from 12 to 5 years.

- [H.R. 7669](#)

This bill, introduced on 5/6/2022 by Rep. Doris Matsui (D), requires guidance on extending expiration dates for certain drugs, and for other purposes.

- [H.R.7472 - Discounted Drugs for Clinical Trials Act](#)

This bill, introduced by Rep. Carolyn Maloney (D-NY) on April 7, 2022, amends amend the Federal Food, Drug, and Cosmetic Act to grant eligible researchers access to eligible products at a discounted price for qualified research, and for other purposes.

- [H.R. 7640](#)

This bill, introduced by Rep. Gus Bilirakis (R-FL) on 5/3/2022, amends the Orphan Drug Act to reauthorize a program of grants and contracts for the development of drugs for rare diseases and conditions (commonly referred to as "orphan drugs").

- [H.R.7473](#)  
This bill, introduced on 04/07/2022 by Rep. Carolyn B. Maloney (D-NY-12), works to prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, and for other purposes.
- [S.3991](#)  
This bill, introduced 04/05/2022 by Sen. Tina Smith (D-MN), works to direct the Secretary of Health and Human Services to conduct a demonstration program to test providing preferential treatment under the Medicare, Medicaid, and CHIP programs for certain drugs and biologicals manufactured in the United States.
- [H.R.7032](#)  
The Bill, introduced 03/09/22 by Rep. Ann M. Kuster is increases Transparency in Generic Drug Applications Act of 2022, amending section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) with respect to a process to inform persons submitting an abbreviated application for a new drug whether the new drug is qualitatively or quantitatively the same as a listed drug, and for other purposes.
- [H.R.7474](#)  
Introduced 04/07/2022 by Rep. Carolyn B. Maloney, the bill amends the Public Health Service Act to increase the transparency of pharmaceutical research costs, and for other purposes.
- [S.4037](#)  
Introduced 04/07/2022 by Sen. Debbie Stabenow (D-MI). The bill amends the Public Health Service Act to increase the transparency of pharmaceutical research costs, and for other purposes.
- [H.R.7400](#) - American Made Pharmaceuticals Act of 2022  
The bill, introduced 04/05/2022 by Rep. Angie Craig (D-MN-2), created to direct the Secretary of Health and Human Services to conduct a demonstration program to test providing preferential treatment under the Medicare, Medicaid, and CHIP programs for certain drugs and biologicals manufactured in the United States.
- [H.R.7121](#) - Protecting our Pharmaceutical Supply Chain from China Act of 2022  
Introduced 03/17/2022 by Rep. Mike Gallagher (R-WI-8). A bill to require the Secretary of Health and Human Services to maintain a list of the country of origin of all drugs marketed in the United States, to ban the use of Federal funds for the purchase of drugs manufactured in the People’s Republic of China, and for other purposes.
- [H.R. 6875 – Right Drug Dose Now Act](#)  
This bill introduced on 02/28/2022 by Rep. Eric Swalwell [D-CA-15], is to update the National Action Plan for Adverse Drug Event Prevention to provide educational information on adverse drug events and pharmacogenomic testing, to improve electronic health records for pharmacogenomic information, and for other purposes.

- [H.R. 6834 – Recall Unsafe Drugs Act of 2022](#)  
The bill, introduced on 02/25/2022 by Rep. Rosa L. DeLauro [D-CT-3], will provide the mandatory recall of drugs regulated by the Food and Drug Administration.
- [H.R. 6833 – Affordable Insulin Now Act](#) and [S.3700](#)  
The bill, introduced in the Senate on 02/17/2022 by Sen. Raphael G. Warnock [D-GA] and in the House on 02/25/2022 by Rep. Angie Craig [D-MN-2], will amend title XXVII of the Public Health Service Act, the Internal Revenue Code of 1986, and the Employee Retirement Security Act of 1974 to establish requirements with respect to cost-sharing for certain insulin products.
- [H.R. 6757 – Insulin Savings for Patients Act](#)  
The bill, introduced on 02/18/2022 by Rep. Michael C. Burgess [R-TX-26] will amend title XVIII of the Social Security Act to establish under the Medicare prescription drug program a minimum amount of price concessions for insulin to be passed through to beneficiaries at the point-of-sale.
- [H.R. 6710](#)  
Introduced by Rep. Yvette Herrell [R-NM-2] on 02/11/2022, the bill will direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to submit to Congress a report on barriers, including regulatory inefficiencies, to domestic manufacturing of active pharmaceutical ingredients, finished drug products, and devices.
- [S. 3615 – Cutting Medicare Prescription Drug Prices in Half Act](#)  
The bill, introduced by Sen. Bernard Sanders [I-VT] on 02/09/2022, will establish a cap on costs for covered prescription drugs under Medicare parts B and D.
- [S. 3493 - Drug Shortages Shelf Life Extension Act](#)  
This bill, introduced by Sen. Ben Cardin (D-MD) on January 12, 2022, requires guidance on extending expiration dates for certain drugs, and for other purposes.
- [H.R. 6483 - Improved Transparency of Foreign Drug Manufacturing Act of 2022](#)  
This bill, introduced by Rep. Anna Eshoo (D-CA) on January 25, 2022, amends the Federal Food, Drug, and Cosmetic Act to clarify reporting requirements for establishments within a foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of an active pharmaceutical ingredient, and for other purposes.
- [S. 3576](#)  
This bill, introduced by Sen. Mike Braun (R-IN) on February 3, 2022, allows sponsors of certain new drug applications to rely upon investigations conducted in certain foreign countries, and for other purposes.
- [H.R. 6584](#)  
This bill, introduced by Rep. Anna Eshoo (D-CA) on February 3, 2022, directs the Commissioner of Food and Drugs to amend certain regulations to increase clinical trial diversity, and for other purposes.

- [S. 3449](#)  
This bill, introduced by Sen. Gary Peters (D-MI) on January 10, 2022, requires foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device to register with the Food and Drug Administration regardless of whether the drug or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported into the United States.
- [S. 3401 – ABC Safe Drug Act](#)  
This bill, introduced by Sen. Tom Cotton (R-AR) on December 15, 2021, requires the Secretary of Health and Human Services to maintain a list of the country of origin of all drugs marketed in the United States, to ban the use of Federal funds for the purchase of drugs manufactured in the People's Republic of China, and for other purposes.
- [S.3339 - Capping Prescription Costs Act of 2021](#)  
This bill, introduced by Sen. Raphael Warnock (D-GA) on December 8, 2021, limits cost sharing for prescription drugs, and for other purposes.
- [H.R.6101 - Drug Price Transparency in Medicaid Act of 2021](#)  
This bill, introduced by Rep. Buddy Carter on December 1, 2021, amends title XIX of the Social Security Act to improve transparency and prevent the use of abusive spread pricing and related practices in the Medicaid program.
- [H.R.5872](#)  
This bill, introduced by Rep. Sean Patrick Maloney (D-NY) on November 4<sup>th</sup>, 2021, amends the Federal Food, Drug and Cosmetic Act to treat as misbranded cosmetics with packaging or labeling using the term “natural” unless the cosmetic meets certain standards , and for other purposes.
- [S.3080](#)  
This bill, introduced by Senator Tina Smith (D-MN) on October 27, 2021, amends the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide for cost-sharing for oral anticancer drugs on terms no less favorable than the cost-sharing provided for anticancer medications administered by a health care provider.
- [H.R.5632](#)  
This bill, introduced by Rep. Kurt Schrader (D-OR) on October 19, 2021, establishes a statutory definition for long-term care pharmacy under the Medicare prescription drug benefit.
- [H.R.5576](#)  
This bill, introduced by Rep. Susan Wild (D-PA) on October 12, 2021, allows states to apply the requirements of the Medicaid Drug Rebate Program to covered outpatient drugs under the Children's Health Insurance Program (CHIP).
- [H.R.5463](#)

This bill, introduced by Rep. Matthew Rosendale (R-MT) on September 30, 2021, increases reporting requirements and transparency requirements in the 340B Drug Pricing Program, and for other purposes.

- [H.R.5237](#)  
This bill, introduced by Rep. Scott Peters (D-CA) on September 10, 2021, amends titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes.
- [S. 2595](#) - Drug Shortages Prevention and Quality Improvement Act  
This bill, introduced by Senator Ben Cardin (D-MD) on August 4, 2021, address prescription drug shortages and improve the quality of prescription drugs, and for other purposes.
- [H.R. 4991](#) - Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2021  
This bill, introduced by Rep. Peter DeFazio (D-OR) on August 10, 2021, requires persons who undertake federally funded research and development of a biomedical product or service to enter into reasonable pricing agreements with the Secretary of Health and Human Services, and for other purposes.
- [H.R. 5099](#) - Lowering Medicare Premiums and Prescription Drug Costs Act  
This bill, introduced by Rep. Bradley Schneider (D-IL) on August 24, 2021, amends title XVIII of the Social Security Act to move Medicare cost-sharing benefits from Medicaid to Medicare, and for other purposes.
- [H.R. 3662](#)  
This bill, introduced by Rep. Morgan Griffith (R-VA) on June 1, 2021, amends the Federal Food, Drug, and Cosmetic Act to ensure patients have access to certain urgent-use compounded medications, and for other purposes.
- [H.R. 3761](#)  
This bill, introduced by Rep. Mike Gallagher (R-WI) on June 8, 2021, amends the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes.
- [H.R. 3927](#) and [S. 2082](#)  
This bill, introduced by Rep. Buddy Carter (R-GA) and Sen. Tim Scott (R-SC) on June 16, 2021, mitigates drug shortages and provide incentives for maintaining, expanding, and relocating the manufacturing of active pharmaceutical ingredients, excipients, medical diagnostic devices, pharmaceuticals, and personal protective equipment in the United States, and for other purposes.
- [S. 2257](#)  
This bill, introduced by Sen. Jacky Rosen (D-NV) on June 24, 2021, provides Federal support for nonprofit generic and essential medicine and device manufacturers to

increase the availability of drugs and devices in order to reduce drug or device shortages and drug and device costs.

- [S. 2304](#)  
This bill, introduced by Sen. Dick Durbin (D-IL) on June 24, 2021, amends title XI of the Social Security Act to require that direct-to-consumer advertisements for prescription drugs and biological products include an appropriate disclosure of pricing information.
- [H.R. 4121](#)  
This bill, introduced by Rep. Jody Arrington (R-TX) on June 24, 2021, codifies a final rule issued by the Secretary of Health and Human Services relating to fraud and abuse and the removal of safe harbor protection for certain drug rebates, and for other purposes.
- [H.R. 4158](#)  
This bill, introduced by Rep. Bobby Rush (D-IL) on June 24, 2021, amends titles XVIII and XIX of the Social Security Act to eliminate cost sharing with respect to coverage of insulin as a covered part D drug under the Medicare program or as a covered outpatient drug under the Medicaid program.
- [H.R. 4287](#)  
This bill, introduced by Rep. Greg Murphy (R-NC) on June 30, 2021, directs the Comptroller General of the United States to conduct a study on how direct-to-consumer pharmaceutical advertising negatively impacts drug costs to consumers, and for other purposes.
- [S. 1644](#)  
This bill, introduced by Sen. Mike Braun (R-IN) on May 13, 2021, amends the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes.
- [S. 1645](#)  
This bill, introduced by Sen. Mike Braun (R-IN) on May 13, 2021, provides for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries.
- [H.R. 3203](#)  
This bill, introduced by Rep. Doris Matsui (D-CA) on May 13, 2021, enables certain hospitals that were participating in or applied for the drug discount program under section 340B of the Public Health Service Act prior to the COVID-19 public health emergency to temporarily maintain eligibility for such program, and for other purposes.
- [S. 1773](#)  
This bill, introduced by Sen. Bob Casey (D-PA) on May 20, 2021, amends title XI of the Social Security Act to establish internet website-based dashboards to allow the public to review information on spending for, and utilization of, prescription drugs and biologicals covered under the Medicare and Medicaid programs.

- [H.R. 3437](#)  
This bill, introduced by Rep. Bobby Rush (D-IL) on May 20, 2021, requires the Secretary of Health and Human Services to guarantee BioBonds in order to provide funding for loans to eligible biomedical companies and universities to carry out clinical trials approved by the Food and Drug Administration, and for other purposes.
- [H.R. 2344](#)  
This bill, introduced by Rep. Tim Ryan (D-OH) on April 1, 2021, requires the use of prescription drug monitoring programs.
- [H.R. 2484](#)  
This bill, introduced by Rep. Katie Porter (D-CA) on April 13, 2021, amends title XXVII of the Public Health Service Act and title XVIII of the Social Security Act to require pharmacies to disclose any differential between the cost of a prescription drug based on whether certain individuals use prescription drug coverage to acquire such drug, and for other purposes.
- [S. 1124](#)  
This bill, introduced by Sen. Marsha Blackburn on April 14, 2021, preserves non-interference under the Medicare part D Prescription Drug Benefit program.
- [H.R. 2608](#)  
This bill, introduced by Rep. Peter Welch (D-VT) on April 15, 2021, amends title XVIII of the Social Security Act to ensure equal access of Medicare beneficiaries to community pharmacies in underserved areas as network pharmacies under Medicare prescription drug coverage, and for other purposes.
- [H.R. 2623](#)  
This bill, introduced by Rep. Josh Gottheimer (D-NJ) on April 16, 2021, amends the Internal Revenue Code of 1986 to restore the amount of the orphan drug tax credit, and for other purposes.
- [H.R. 2706](#)  
This bill, introduced by Rep. Katie Porter (D-CA) on April 20, 2021, amends title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part B rebate for certain drugs if the price of such drugs increases faster than inflation.
- [H.R. 2829 and S. 1323](#)  
This bill, introduced by Rep. Peter Welch (D-VT) and Sen. Jeff Merkley (D-OR) on April 22, 2021, requires the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of Federal health programs, and for other purposes.
- [S. 1366](#)  
This bill, introduced by Sen. Elizabeth Warren (D-MA) on April 26, 2021, secures the supply of drugs in the United States, and for other purposes.
- [H.R. 2846](#)

This bill, introduced by Rep. David McKinley (R-WV) on April 27, 2021, amends title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

- [H.R. 2853](#)  
This bill, introduced by Rep. Kurt Schrader (D-OR) on April 27, 2021, amends the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, and for other purposes.
- [S. 1425](#)  
This bill, introduced by Sen. Amy Klobuchar (D-MN) on April 28, 2021, enables the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition, and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.
- [S. 1428](#)  
This bill, introduced by Sen. Amy Klobuchar (D-MN) on April 28, 2021, prohibits brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.
- [H.R. 2868](#)  
This bill, introduced by Rep. G.K. Butterfield (D-NC) on April 28, 2021, amends title XIX of the Social Security Act to prohibit additional rebates under the Medicaid program for certain noninnovator multiple source drugs.
- [H.R. 2870](#)  
This bill, introduced by Rep. Buddy Carter (R-GA) on April 28, 2021, amends the Public Health Service Act to provide for stockpiles to ensure that all Americans have access to generic drugs at risk of shortage, and for other purposes.
- [H.R. 2883](#)  
This bill, introduced by Rep. Hakeem Jeffries (D-NY) on April 28, 2021, enables the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.
- [H.R. 2891](#)  
This bill, introduced by Rep. Jerry Nadler (D-NY) on April 28, 2021, prohibits prescription drug companies from compensating other prescription drug companies to delay the entry

of a generic drug, biosimilar biological product, or interchangeable biological product into the market.

- [S. 1462](#)  
This bill, introduced by Sen. Bill Cassidy on April 29, 2021, amends the Federal Food, Drug, and Cosmetic Act to simplify the generic drug application process.
- [S. 1463](#)  
This bill, introduced by Sen. Bill Cassidy on April 29, 2021, amends the Federal Food, Drug, and Cosmetic Act to modernize therapeutic equivalence rating determinations.
- [S. 1508](#)  
This bill, introduced by Sen. Roger Marshall (R-KS) on April 29, 2021, provides for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes.
- [S. 1523](#)  
This bill, introduced by Sen. Mike Braun (R-IN) on April 29, 2021, amends title XI of the Social Security Act and title XXVII of the Public Health Service Act to establish requirements with respect to prescription drug benefits.
- [H.R. 2148](#)  
This bill, introduced by Rep. Ro Khanna (D-CA) on March 23, 2021, aims to significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.
- [S. 909](#)  
This bill, introduced by Sen. Bernie Sanders (I-VT) on March 23, 2021, aims to significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.
- [S. 898](#)  
This bill, introduced by Sen. Tammy Baldwin (D-WI) on March 23, 2021, requires reporting regarding certain drug price increases, and for other purposes.
- [S. 833](#)  
This bill, introduced by Sen. Amy Klobuchar (D-MN) on March 18, 2021, amends XVII of the Social Security Act to allow the Secretary of Health and Human Services to negotiate fair prescription drug prices under part D of the Medicare program.
- [H.R. 597](#)  
This bill, introduced by Rep. Jan Schakowsky (D-IL) on January 28, 2021, requires any COVID-19 drug developed in whole or in part with Federal support to be affordable and accessible by prohibiting monopolies and price gouging, and for other purposes.

- [S. 141](#)  
This bill, introduced by Sen. Jeanne Shaheen (D-NH) on January 28, 2021, amends the Internal Revenue Code of 1986 to deny the deduction for advertising and promotional expenses for prescription drugs.
- [H.R. 153](#)  
This bill, introduced by Rep. Bobby Rush (D-IL) on January 4, 2021, prohibits brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes.

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## In The News

[Politico](#) (7/8/2022): **'BYRD BATH' REDUX** — Democrats sent the drug pricing piece of their still-under-negotiation reconciliation package to the Senate parliamentarian this week to ensure the provisions can pass with fewer than 60 votes. They also want to get this particular procedural step — in which the parliamentarian reviews the proposed text to determine if it complies with the Byrd rule — out of the way while talks continue on the thornier tax, climate and Obamacare subsidy pieces, Hill sources told Alice and Megan.

[Bloomberg](#) (7/8/2022): **Democrats Propose Medicare Solvency Plan** - Senate Democrats have reached a deal to extend the solvency of Medicare by closing a tax loophole frequently used by law firms and other partnerships, adding another leg to President Joe Biden's revised economic agenda.

[Politico](#) (7/7/2022): **DEMS ATTEMPT TO REVIVE DRUG PRICING** — Much to the chagrin of the pharmaceutical industry, Senate Democratic leadership released legislative text on Wednesday detailing their updated drug pricing plans in an attempt to revive the sweeping Build Back Better reconciliation bill that fell apart last year.

[Modern Healthcare](#) (7/7/2022): **Oncologists turn to telehealth for an extra layer of patient care** - Even as physicians in other sectors return to in-person visits, some health systems plan to expand remote monitoring technology and digital platforms for cancer care.

[Axios](#) (7/7/2022): **Dems revisit drug price negotiations** - Democrats are trying again to enact government price negotiations for prescription drugs, with a revised plan that would be wrapped into a broader reconciliation bill, Axios' Adriel Bettelheim writes.

[Bloomberg](#) (7/7/2022): **Agencies Join Democrats' Drug Price War** - Biden administration officials are committing to curbing patent practices that lead to high drug costs as Senate Democrats push ahead with a plan to lower pharmaceutical prices.

[STAT](#) (7/7/2022): **Here's what Democrats changed in their latest drug pricing bill - WASHINGTON** — Senate Democrats have put final tweaks on their drug pricing proposal, as they race to achieve one of their signature domestic policy promises ahead of the midterm elections.

[Bloomberg](#) (7/6/2022): **Senate Democrats Finalize Prescription Drug Pricing Bill** - Democrats finalize a prescription drug plan in a step to initiate the Senate parliamentary review process, according to a copy obtained by Bloomberg News.

[Axios](#) (7/6/2022): **A national bidding war for ARPA-H** - An interstate bidding war has broken out for the chance to house the headquarters of a multibillion-dollar new science agency aimed at curing major diseases — before the agency's structure has even been finalized by Congress, Axios' Emma Hurt writes.

[Modern Healthcare](#) (7/6/2022): **The future of telehealth reimbursement** - Many providers are advocating for CMS to permanently lift its restrictions on billing Medicare for telehealth care.

[Vox](#) (7/6/2022): **Democrats' latest attempt at resurrecting Build Back Better, explained** - This month, Democrats are, once again, trying to resurrect parts of the Build Back Better Act after the broader package imploded last year.

[Punchbowl News](#) (7/6/2022): **Schumer moves on reconciliation** - Senate Majority Leader Chuck Schumer is getting the ball rolling on a potential Democratic reconciliation package.

[Politico](#) (7/1/2022): **USER FEE REAUTHORIZATION TIMELINE SLIPPING** — Congress will likely miss its self-imposed goal of sending a bill to reauthorize the FDA user fee programs to President Joe Biden's desk before August, raising the specter that reduction-in-force notices will have to be sent to thousands of agency employees, people familiar with ongoing negotiations told Prescription Pulse.

[Axios](#) (7/1/2022): **Consumers will soon get access to huge amounts of health care price data** - Patients will soon have a clearer picture of what insurers and employers pay for health care thanks to a federal rule that kicks in today — if a collection of health tech companies can make the trove of data understandable.

[Bloomberg](#) (7/1/2022): **McConnell Threatens China Bill Over Biden Drug, Climate Plan**: Senate Minority Leader Mitch McConnell (R-Ky.) said he will block bipartisan legislation (H.R. 4521) to boost US competition with China as long as Democrats pursue a go-it-alone economic package. McConnell's threat comes as Majority Leader Chuck Schumer (D-N.Y.) and holdout Sen. Joe Manchin (D-W.Va.) are close to a framework agreement on a \$1 trillion bill that includes prescription drug price cuts, Erik Wasson and Laura Davison report.

[Politico](#) (7/1/2022): **HOUSE APPROPRIATORS ADVANCE HHS BILL AFTER ABORTION FIGHT** — The House Appropriations Committee approved \$242 billion legislation Thursday on a party-line vote that would fund the Department of Health and Human Services for fiscal 2023 — but without longstanding language banning the use of federal funds to cover abortions. Debate over the so-called Hyde amendment dominated the first two hours of the markup, with Republicans arguing that the provision would eventually need to be added to the bill to win enough Senate votes for HHS funding to be appropriated.

[The Hill](#) (6/30/2022): **Senate Democrats push revised drug pricing plan as they prep larger Biden economic package** - Senate Democrats plan to submit a revised proposal to lower prescription drug prices for a key procedural review in the coming days as they press forward with preparations for a vote on President Biden's economic package.

[Axios](#) (6/30/2022): **Lawmakers eye health spending bill** - House appropriators today are due to mark up a fiscal 2023 spending bill covering HHS that would allocate \$242.1 billion to beef up public health infrastructure, Axios' Adriel Bettelheim writes.

[Bloomberg](#) (6/30/2022): **Key Republican Calls for More NIH Scrutiny**: The NIH could face more scrutiny from the House Energy and Commerce ranking member after Cathy McMorris Rodgers (R-Wash.) called for more oversight in a hearing Wednesday. House Republicans have repeatedly complained the office has been uncooperative about investigations over the origins of Covid-19.

[Stat](#) (6/30/2022): **Democrats tweak their drug pricing plan in last-ditch effort to pass reforms** - WASHINGTON — Senate Democrats are vetting a new, tweaked version of a drug pricing package as they hurtle toward a September deadline to pass any major reforms.

[Washington Post](#) (6/29/2022): **Democrats forge ahead on drug pricing, eyeing wider deal with Manchin** - Democratic leaders have finalized a revised proposal to lower prescription drug prices for seniors, part of a broader scramble to satisfy Sen. Joe Manchin (D-W.Va.) and resurrect a long-stalled economic package that they hope to advance as soon as this summer.

[Bloomberg](#) (6/29/2022): **Diversity Push for Clinical Trials Prompts House Panel Look** - Clinical trial diversity is garnering more attention from lawmakers as they seek to resolve a longstanding deficiency amid a larger national focus on health equity.

[Politico](#) (6/28/2022): **FDA FLOATS NEW NONPRESCRIPTION DRUG PATH** — Drugmakers might eventually be able to add new requirements on nonprescription drugs — such as having consumers, as a condition of purchase, fill out and pass a test to ensure they understand how to use a drug appropriately — which would make more drugs accessible without a prescription.

[Politico](#) (6/28/2022): **CMS INTRODUCES NEW ONCOLOGY MODEL** — Oncology practices may participate in a new voluntary model unveiled by the Centers for Medicare and Medicaid Services on Monday that builds on the Center for Medicare and Medicaid Innovation's Oncology Care Model that was operational from July 2016 to June 2022.

[Politico](#) (6/24/2022): **HOUSE APPROPRIATIONS ADVANCES FDA SPENDING BILL** — The House Appropriations Committee advanced its fiscal 2023 spending bill that funds the Food and Drug Administration by a 31-26 vote on Thursday, setting up the package for floor consideration this summer.

[Axios](#) (6/24/2022): **Public option gets new life — with a twist** - Colorado is reviving an old progressive health care goal with a new twist, creating a public health insurance option that could be a model for other states trying to expand affordable coverage as they move past the pandemic, Axios' Arielle Dreher writes.

[Politico](#) (6/24/2022): **SENATE PANEL ADVANCES PBM BILL** — On Wednesday, the Senate Commerce Committee approved a bill, S. 4293 (117), to forbid pharmacy benefit managers from setting “spread pricing” and arbitrarily clawing back payments made to pharmacies. The panel advanced the bill in a 19-9 vote.

[Politico](#) (6/24/2022): **THE PLOT TO SAVE BIDEN’S ACA SUBSIDIES** — Democrats have a plan to preserve Obamacare’s enhanced subsidies and avert a politically damaging spike in premiums later this year.

[Politico](#) (6/24/2022): **LAWMAKERS DEMAND DRUG PRICING ACTION FROM BIDEN** — The Biden administration needs to wield compulsory licensing and march-in rights to compel lower drug costs, wrote 96 lawmakers, led by Sen. Elizabeth Warren (D-Mass.) and Rep. Lloyd Doggett (D-Tex.), in a letter to Health and Human Services Secretary Xavier Becerra.

[Bloomberg](#) (6/23/2022): **House Passes Bill to Create Biden’s Biomedical Agency**: House passage of legislation to shepherd biomedical breakthroughs through a new agency marks a key step in shaping how the entity will use billions in health spending, Jeannie Baumann reports. The bill (H.R. 5585), which the House passed by a 336-85 vote, would establish the Advanced Research Projects Agency for Health.

[Bloomberg](#) (6/23/2022): **Generic Makers Score Big in Rare Federal Circuit Reversal**: An unusual Federal Circuit decision has given generic drugmakers a new way to successfully challenge pharmaceutical patents with certain types of claims. Novartis’ patent on the dosage regimen for the blockbuster multiple sclerosis drug Gilenya didn’t have an adequate description, which the Patent Act requires for a valid patent, a US Appeals Court for the Federal Circuit panel ruled in a new opinion this week.

[Politico](#) (6/23/2022): **WHERE SHOULD ARPA-H LIVE?** No, this isn’t the usual discussion about whether President Joe Biden’s vision for a Pentagon-like approach to health challenges, the Advanced Research Projects Agency for Health, should be housed inside the National Institutes of Health.

[Politico](#) (6/22/2022): **SENATE, HOUSE PRECONFERENCING USER FEE PACKAGE** — The four corners of the Senate HELP Committee and the House Energy and Commerce Committee are currently preconfereing the FDA user fee reauthorization package ahead of Senate floor action, three sources familiar with discussions told POLITICO.

[Axios](#) (6/22/2022): **Some vitamins don't prevent cancer, heart disease** - The U.S. Preventative Services Task Force recommended against taking beta carotene and vitamin E supplements to prevent cancer or heart disease, saying there's not enough evidence to prove either supplement has preemptive effects, Arielle writes.

[Axios](#) (6/21/2022): **How much Medicare could have saved** - Medicare could have saved up to \$3.6 billion in a single year if it were purchasing generic drugs as billionaire businessman Mark Cuban's online pharmacy does, says a research report published in the Annals of Internal Medicine.



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