Documents for the Record – 3/12/2024

Majority:

- March 12, 2024 - Article submitted by Rep. Harshbarger
- March 12, 2024 - Statement from the US Oncology Network
- March 11, 2024 - Document submitted by Rep. Carter
- March 11, 2024 - Statement from the American Society of Health-System Pharmacists
- March 11, 2024 - Statement from the Global Down Syndrome Foundation (GLOBAL)

Minority:

- March 12, 2024 - Article submitted by Rep. Pallone
- March 12, 2024 – Document submitted by Rep. Kelly

STAT Reporting from the frontiers of health and medicine

FIRST OPINION

New federal guidance is hurting cancer patients, especially those in rural areas

By Samyukta Mullangi
March 1, 2024

I recently started a patient with metastatic triple-positive breast cancer patient on a targeted therapy regimen consisting of capecitabine and neratinib, both oral chemotherapy pills that are dosed on a 21-day cycle. Given that her cancer also thrives on estrogen, I chose to continue her monthly fulvestrant injections (which targets estrogen) in my clinic in Dickson, Tennessee, a small town 40 minutes outside Nashville.

Until last year, my patient would have been able to make the hour-long drive to my clinic every four weeks for the injection and have our medically integrated specialty pharmacy send her the oral chemotherapeutics every three weeks by courier to her home.

However, as of spring 2023, that is no longer possible. That's when the Centers for Medicare and Medicaid Services began to enforce guidance that was issued in 2021 (but temporarily suspended in the course of the pandemic) that specialty pharmacies embedded into independent physician practices would be in violation of the Physician Self-Referral Law—commonly known as the Stark Law — if they were to dispense oral medications to a patient's home by mail or courier, or even if they were to dispense the drugs to a patient surrogate such as a family member.

The Physician Self-Referral Law, originally issued in 1989, is intended to prevent fraud and abuse by prohibiting physicians from referring Medicare or Medicaid patients to a

health care entity in which the doctor might have a financial interest. In its guidance, CMS seems to indicate that the actual existence of a medically integrated specialty pharmacy isn't in violation of Stark. Rather, it's the shipping or mailing of drugs to patients — in other words, patient-centric activities that, if anything, typically cost the pharmacy in extra postage, and which have no impact on physician prescribing behavior.

This befuddling rule change has led to serious disruptions in the world of community oncology, where the vast majority of Americans receive their cancer care. The new interpretation of Stark reveals a somewhat limited understanding of the evolution in medical therapy and practice over the past decade (today, nearly half of my patients receive oral anti-cancer drugs) and has a disproportionate effect on rural patients.

For example, Tennessee Oncology, where I practice, is the largest provider of rural cancer care in the state. The practice maintains a centralized dispensing pharmacy in Nashville, with a large staff of more than 35 team members who peruse the electronic health records to gain context on patients' treatment plans, comorbidities, and medication lists, and advise physicians on dosing, drug-drug interactions, or expected toxicities through an integrated electronic health record and text-based messaging system. Such a close working relationship with our pharmacists allows oncologists to share the load of educating and monitoring patients on these drugs, many of which carry toxicities and side effects that are as severe as their infusion counterparts. No longer able to mail or courier drugs directly to their homes, our patients are stuck with one of two choices: switch to a pharmacy-benefit manager-owned mail-order pharmacy, which would not integrate with or communicate with their oncology provider, or rely on picking up their cancer meds in person for every refill. In fact, many states have passed anti-steerage bills in recent years that prohibit PBMs from requiring physicians to route prescriptions to corporate specialty pharmacies, recognizing that such steerage is explicitly profit-, not patient-centric. However, given the scope of state law, these anti-steerage laws typically only apply to fully insured or self-funded non-ERISA plans.

Currently, Tennessee Oncology's pharmacy has devised a complicated work-around to comply with the Stark regulation by sending daily shipments of drug to the 36 various clinic sites around the state. We attempt to time delivery to sync with patient visits to clinic to minimize disruption as much as possible and allow patients to pick up their medication refills when they visit their physicians. This work-around is operationally complex and not totally foolproof. After all, not every refill aligns with a planned visit to a doctor's clinic. My patient with metastatic breast cancer flatly refused to travel in twice a month — once to pick up her oral refills, and once to receive her fulvestrant injections — and given the long commute, I don't blame her. We had to adjust her oral regimen out to a monthly schedule. This is not how the regimen was studied on

trial or approved by the FDA, and I have no data to quantify the degree of loss in efficacy with an extra off-week between cycles.

My colleagues across the state and country have reported similar troubling tales. A physician practicing in Chattanooga told me about "a very pleasant 74-year-old that I have been treating for chronic lymphocytic leukemia (CLL) almost 20 years." Now, instead of having her prescription mailed to her house, "her granddaughter who works the third shift has to drive [her] an hour each way once a month. ... This terrible legislation is impacting whole families not just the patient."

Again and again, my colleagues and I note that the patients most affected by the CMS guidance are older, live in rural areas far from their nearest clinic, and are often dependent on family members for transportation. An analysis performed at Texas Oncology (part of the U.S. Oncology Network) found that nearly a third of all patients lived more than 20 miles from their nearest clinic, and two-thirds of patients living that far ranked highly on an Area Deprivation Index scale, which correlates with socioeconomic disadvantage. CMS's guidance feels very much at odds with the Biden's administration's goal to reduce disparities in health care access and outcomes, particularly in cancer care.

This new interpretation isn't just hurting patients; it's also exacerbating waste, driving up health care costs. If a drug shipped out to a satellite clinic isn't picked up — because of disease progression leading to a regimen change, toxicity leading to a treatment pause, hospitalization, patient death — it is ineligible to be restocked and must be discarded. This is despite the fact that the medication never left custody of the practice, and is unopened, unused, and unexpired. That wouldn't have happened under the old workflows. The pharmacy team at Tennessee Oncology has calculated that this has led to millions of dollars of drug wastage. As the nation collectively emerges from a year marked by very publicly catastrophic chemo drug shortages, this senseless wastage of perfectly viable, reusable cancer medication is deeply upsetting.

I've tried to understand why this change was made, but I simply cannot find the benefit to patients. Yet, despite mounting evidence of negative repercussions, CMS remains insensate to the pleas of community oncologists, leading to lawsuits and proposed legislative amendments. Though 2024 is an election year, which can divert attention to more headline-grabbing issues, my hope is the optimal care of cancer patients remains one that can garner grassroots enthusiasm and bipartisan support.

Samyukta Mullangi, M.D., M.B.A., is a medical oncologist at Tennessee Oncology and is the medical director of oncology for Thyme Care, a cancer population health company.

Good Morning,

On behalf of The US Oncology Network (The Network) we write to share our strong support of H.R. 5526, the Seniors' Access to Critical Medication Act, to protect cancer patients' access to oral chemotherapy prescriptions.

Many community cancer practices offer a range of services all under one roof, including chemotherapy, radiation therapy, support services like nutrition or financial counseling, and medically-integrated dispensing (MID). MID platforms allow cancer patients to access their oral chemotherapy prescriptions at the point-of-care and are a critical component of integrated cancer care. Practices with medically integrated pharmacy services have been shown to significantly improve patient adherence, reduce time to treatment, and improve outcomes at a lower cost. The ability to mail or deliver patient medications to their home is an extension of this service.

Unfortunately, an FAQ published by CMS has created significant uncertainty for practices who offer MID services and deliver prescriptions to their patients' homes constituting a violation of the physician self-referral law. The CMS FAQ states the agency's view that the physician self-referral law's in-office ancillary services exception requires Medicare patients to pick up their prescription from the physician's office in-person. This is especially problematic for Medicare beneficiaries undergoing cancer treatment as they may be too sick to travel regularly to their oncologists' office or have treatment regimens that require frequent dose changes or close monitoring. It also impacts health equity as many patients may not drive at all, may lack access to transportation, or may rely on family or caregivers for transportation to our clinics.

The Seniors' Access to Critical Medications Act of 2023 would clarify that delivering medicines by mail, courier, or other methods, or allowing a family member or caregiver to pick up medicines on behalf of a patient would not violate the physician self-referral law and would fall under the in-office ancillary services exception. Importantly, mail/ delivery services carry very low risk of program abuse. In the context of oncology practices and MID services, any prescription provided is in the context of an established, long-term, close relationship between an oncologist and their established patients. Patients are not selecting oncologists for potentially life-saving care based on whether they can receive medications at home, which is a small component of the overall treatment relationship. Similarly, oncologists are very unlikely to overprescribe oral chemotherapy prescriptions, or select an inappropriate medication for a patient based on the pharmacy that fills the prescription, or based on whether or not a patient receives the medication via home delivery.

On behalf of The Network's 2,500 physicians and 1.4 million cancer patients treated annually, we ask you to support H.R. 5526, the Seniors' Access to Critical Medication Act, during the Energy and Commerce Health Subcommittee markup to ensure patients maintain access to their medications.

Thank you,

Jasey Cardenas
Associate Director, Federal Government Relations | jasey.cardenas@mckesson.com

The US Oncology Network | *m* 202.316.9862 | 505 9th Street NW, Suite 901, Washington, D.C. 20004

January 11, 2024

The Honorable Buddy Carter
United States House of Representatives
2432 Rayburn House Office Building
Washington, DC 20515

The Honorable Kathy Castor
United States House of Representatives
2052 Rayburn House Office Building
Washington, DC 20515

The Honorable Dr John Joyce
United States House of Representatives
152 Cannon House Office Building
Washington, DC 20515

The Honorable Dr Kim Schrier
United States House of Representatives
1110 Longworth House Office Building
Washington, DC 20515

Dear Representatives Carter, Representative Castor, Representative Joyce, and Representative Schrier:

As organizations that care deeply about the health and safety of children, we offer our strong support for the *Emergency Medical Services for Children Program Reauthorization Act of 2024.* The EMSC program has made landmark improvements to the emergency care delivered to children all across the nation. As the only federal program dedicated to improving emergency care for children, EMSC has brought vital attention and resources to this important population.

Just this year, 30 million children will visit the emergency department, and emergencies involving children can occur anytime, anywhere. [i] Children have unique physiological, emotional, and developmental characteristics that require specialized emergency care. Research shows that taking steps to prepare for children's unique health needs in emergency departments is associated with 60-70% fewer deaths.[ii] The EMSC program is designed to improve emergency care for children and adolescents – no matter where they live, attend school, or travel.

Through EMSC, all states and territories have received state partnership grants to expand and improve their capacity to reduce and respond to emergencies. EMSC funding is used to equip hospitals and ambulances with the tools they need to treat pediatric emergencies, to provide pediatric training to paramedics and first responders, and to improve the systems that allow for efficient, effective pediatric emergency medical care. Additionally, EMSC funding has helped to improve pediatric capacity and transport of pediatric patients and address emerging issues such as pediatric emergency care readiness through the National Pediatric Readiness Project and pediatric emergency medical services in rural and remote areas.

Initiated in 2016, the EMSC Innovation and Improvement Center (EIIC) is working to accelerate improvements in the quality of care and outcomes for children who are in need of urgent or emergency care through an infrastructure that ensures routine, integrated coordination of quality improvement activities. The EIIC was invaluable during the surge in pediatric respiratory illnesses seen in late 2022 that strained healthcare facilities, staff, and resources across the U.S. EIIC created recommendations and resources to support the immediate response to the surge of pediatric patients and to guide planning and preparation for future surges.

EMSC has been successful in improving care for children. Emergency departments and pre-hospital EMS personnel have more appropriate medication, equipment, training, and systems in place to treat children. For example, doctors and nurses are better able to manage pediatric emergencies such as traumatic brain injuries, pediatric seizures, and bronchiolitis. The majority (90%) of EMS agencies in the US have consistent availability to online medical direction when treating a pediatric patient and 85% have off-line medical direction that includes protocols inclusive of pediatric patients. In the hospital setting, almost two thirds (67%) of hospitals have interfacility transfer agreements and 50% have interfacility transfer guidelines that incorporate recommended pediatric components. Looking ahead, EMSC aims to ensure all EDs are ready to care for children through the implementation of the National Pediatric Readiness Project, a national quality improvement initiative to ensure EDs have the essential guidelines and resources in place.

Your bill would reauthorize the EMSC program to continue its vital work for an additional five years. We thank you for your leadership in authoring this critical legislation for children and appreciate your long-standing commitment to the quality of the emergency care children receive. We look forward to working with you in support of enactment of this legislation.

Sincerely,

Academic Pediatric Association
American Academy of Pediatrics
American Ambulance Association
American College of Emergency Physicians
American College of Surgeons
American Pediatric Society
Association of Maternal & Child Health Programs
Association of Medical School Pediatric Department Chairs
Children's Hospital Association
Children's Hospital of Philadelphia
Emergency Nurses Association
First Focus Campaign for Children
March of Dimes
National Association of Emergency Medical Technicians (NAEMT)
National Association of Pediatric Nurse Practitioners
National Association of State EMS Officials
National League for Nursing
Nemours Children's Health
Pediatric Policy Council
Society for Pediatric Research
The National Alliance to Advance Adolescent Health
The Paramedic Foundation

[i] Newgard CD, Lin A, Malveau S, et al. Emergency Department Pediatric Readiness and Short-term and Long-term Mortality Among Children Receiving Emergency Care. JAMA Netw Open. 2023;6(1):e2250941. doi:10.1001/jamanetworkopen.2022.50941

[ii] https://media.emscimprovement.center/documents/Pediatric_Readiness_Outcomes_-_2023_Q5q8cow.pdf

March 12, 2024

The Honorable Chairman Brett Guthrie
House Energy and Commerce Committee
Health Subcommittee
2434 Rayburn House Office Building
Washington, DC 20515

The Honorable Ranking Member Anna Eshoo
House Energy and Commerce Committee
Health Subcommittee
272 Cannon House Office Building Office Building
Washington, DC 20515

Re: Energy and Commerce, Subcommittee on Health, markup of the Dr. Lorna Breen Health Care Provider Protection Act (H.R. 7153) and other bills.

Dear Chair Guthrie and Ranking Member Eshoo:

Thank you for today's markup of the Dr. Lorna Breen Health Care Provider Protection Act, legislation critical to assisting providers in addressing the stress of the of today's health care workplace.

The Dr. Lorna Breen Health Care Provider Protection Act acknowledges the critical role the healthcare workforce plays in protecting patient and public health and advances initiatives that support healthcare workforce mental health and well-being. The American Society of Health-System Pharmacists (ASHP) is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. The organization's more than 60,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 80 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

Unfortunately, the pharmacy workforce, like the rest of the healthcare workforce, is experiencing alarming rates of occupational burnout, moral injury, and stress. ASHP has been addressing workforce well-being within our organization and the profession of pharmacy for decades. Our commitment is embedded within ASHP's strategic plan, vision statements, policy positions, standards, resources, and programming. The Dr. Lorna Breen Health Care Provider Protection Act enables ASHP, and 43 other organizations, to receive funding from the Health Resources and Services Administration (HRSA) to assist providers in addressing workforce stress. Through the HRSA Health and Public Safety Workforce Resiliency Training grant, we have reached over 4,300 pharmacists, pharmacy technicians, pharmacy residents, and student pharmacists in a curriculum-based, virtual learning community that aims to empower local action to mitigate occupational burnout and create cultures of well-being in healthcare organizations.

ASHP thanks you for holding this markup and looks forward to working with you on this and other workforce legislation. If you have any questions or if ASHP can assist your office in any way, please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

Tom Kraus
American Society of Health-System Pharmacists

March 11, 2024

The Honorable Cathy McMorris Rodgers
2188 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Tom Cole
2207 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Rosa DeLauro
2413 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Pete Stauber
2136 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Eleanor Holmes Norton
145 Cannon House Office Building
Washington, D.C. 20515

Dear Representatives Rodgers, DeGette, Cole, DeLauro, Stauber and Norton:

The Global Down Syndrome Foundation (GLOBAL), with the support of our esteemed colleagues listed below, write to express our gratitude and unequivocal support for the bipartisan legislation you have introduced, the DeOndra Dixon INCLUDE Project Act of 2024 (H.R. 7406), to authorize the INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE) Project at the National Institutes of Health (NIH).

Congress had long recognized Down syndrome as "a fertile area for research investments" and "an ideal candidate for a trans-NIH initiative"; but for two decades, Down syndrome was one of the least funded genetic conditions at NIH. On October 25, 2017, House Appropriations Labor, Health and Human Services, and Education Subcommittee Chairman Tom Cole (R-OK) and Ranking Member Rosa DeLauro (D-CT) held the first ever hearing on Down syndrome research. The hearing increased awareness that people with Down syndrome, compared to the general population, are highly predisposed to certain diseases like Alzheimer's disease and autoimmune conditions, yet are highly protected from others like solid tumors such as breast cancer or prostate cancer. It also raised serious questions about the fact that for decades people with Down syndrome were excluded from lifesaving clinical trials research.

Thankfully, this landmark hearing began a seven-year increase in Down syndrome research funding from $35 million in fiscal year 2017 to an estimated $143 million in fiscal year 2024. Based on the encouragement of the Congress, the hearing also led to the establishment of the INCLUDE initiative, a trans-NIH effort based in the Office of the Director, which is advancing science that will improve the lives of people with Down syndrome as well as typical individuals. To date, INCLUDE has provided 556 unique Down syndrome awards from 18 different NIH institutes and there are now at least 12 clinical trials that include repurposed drugs to treat Alzheimer's, multiple autoimmune diseases, cognition deficit, and Regression Disorder.

This trans-NIH structure for Down syndrome research ensures that major crosscutting issues and opportunities are identified and will allow multiple NIH institutes to collaborate on a coordinated research plan that harmonizes planning, funding, and the sharing and disseminating research results. Named in memory of GLOBAL's most beloved and accomplished self-advocate, DeOndra Dixon, who tragically passed away in 2020 at the age of 36, this legislation honors her and all individuals with Down syndrome.

We deeply appreciate all your leadership to ensure that people with Down syndrome are not left behind but rather are provided the opportunity to live healthier and longer lives and therefore reach their true potential. Your efforts are transforming the lives of over 400,000 people with Down syndrome in the U.S. and potentially benefitting 60% of Americans who suffer from diseases that people with Down syndrome are highly protected or from or predisposed to. You are also sending a clear message that people with Down syndrome and their families are an important valued part of our society and world, and for that we are forever grateful. We urge Congress to quickly pass the DeOndra Dixon INCLUDE Project Act and look forward to working with you to achieve this goal.

Gratefully,

Michelle Sie Whitten
President & CEO

Esteemed Colleagues and Supporters:
Adult Down Syndrome Clinic, Denver Health
Advocate Medical Group Adult Down Syndrome Center
Alzheimer's Association
Alzheimer's & Cognition Center, University of Colorado
Alzheimer's Impact Movement (AIM)
Anna & John J. Sie Center for Down Syndrome, Children's Hospital Colorado
Arc Thrift
Bellucci Translational Hearing Center, Creighton University
BioFrontiers Institute, University of Colorado Boulder
Black Down Syndrome Association
Cardiovascular Research and Exercise Lab, University of Nevada, Las Vegas
Down Syndrome Clinic and Research Center, Kennedy Krieger Institute
Down Syndrome Diagnosis Network
Down Syndrome Medical Interest Group-USA
Down Syndrome Program, Boston Children's Hospital
Down Syndrome Neurology Program, Children's Hospital Los Angeles
GLOBAL Membership Advisory Board (alpha):
- *Down Syndrome Alliance of the Midlands*
- *Down Syndrome Association of Greater Cincinnati*
- *Down Syndrome Association of Greater St. Louis*

Down Syndrome Association of Jacksonville
Down Syndrome Association of Louisville
Down Syndrome Connection of the Bay Area
Down Syndrome Guild of Dallas
North Carolina Down Syndrome Alliance
Intellectual and Developmental Disabilities Division, Colorado State University Prevention Research Center
International Mosaic Down Syndrome Association
Jane and Richard Thomas Center for Down Syndrome at Cincinnati Children's Hospital Medical Center
Linda Crnic Institute, University of Colorado Anschutz Medical Campus
Rueckert-Hartman College for Health Professionals, Regis University
United Coalition for Down Syndrome (alpha):
Down Syndrome Affiliates in Action
GiGi's Playhouse Down Syndrome Achievement Centers
LuMind IDSC Foundation
National Down Syndrome Congress
National Down Syndrome Society
University of Pittsburgh Adult Down Syndrome Center, University of Pittsburgh Medical Center

Fiscal Footnote: Big Senate Gift to Drug Maker

By Eric Lipton and Kevin Sack

- Jan. 19, 2013

WASHINGTON — Just two weeks after pleading guilty in a major federal fraud case, Amgen, the world's largest biotechnology firm, scored a largely unnoticed coup on Capitol Hill: Lawmakers inserted a paragraph into the "fiscal cliff" bill that did not mention the company by name but strongly favored one of its drugs.

The language buried in Section 632 of the law delays a set of Medicare price restraints on a class of drugs that includes Sensipar, a lucrative Amgen pill used by kidney dialysis patients.

The provision gives Amgen an additional two years to sell Sensipar without government controls. The news was so welcome that the company's chief executive quickly relayed it to investment analysts. But it is projected to cost Medicare up to $500 million over that period.

Amgen, which has a small army of 74 lobbyists in the capital, was the only company to argue aggressively for the delay, according to several Congressional aides of both parties.

Supporters of the delay, primarily leaders of the Senate Finance Committee who have long benefited from Amgen's political largess, said it was necessary to allow regulators to prepare properly for the pricing change.

But critics, including several Congressional aides who were stunned to find the measure in the final bill, pointed out that Amgen had already won a previous two-year delay, and they depicted a second one as an unnecessary giveaway.

"That is why we are in the trouble we are in," said Dennis J. Cotter, a health policy researcher who studies the cost and efficacy of dialysis drugs. "Everybody is carving out their own turf and getting it protected, and we pass the bill on to the taxpayer."

The provision's inclusion in the legislation to avert the tax increases and spending cuts that made up the so-called fiscal cliff shows the enduring power of special interests in Washington, even as Congress faces a critical test of its ability to balance the budget.

Amgen has deep financial and political ties to lawmakers like Senate Minority Leader Mitch McConnell, Republican of Kentucky, and Senators Max Baucus, Democrat of

Montana, and Orrin G. Hatch, Republican of Utah, who hold heavy sway over Medicare payment policy as the leaders of the Finance Committee.

It also has worked hard to build close ties with the Obama administration, with its lobbyists showing up more than a dozen times since 2009 on logs of visits to the White House, although a company official said Saturday that it had not appealed to the administration during the debate over the fiscal legislation.

Aides to Mr. Hatch and Mr. Baucus, and a spokeswoman for Amgen, said the delay would give the Medicare system and medical providers the time they needed to accommodate other complicated changes in how federal reimbursements for kidney care were determined.

"Sometimes when you try to do too much and too quickly, you screw up," said Antonia Ferrier, a spokeswoman for Mr. Hatch. The goal, an Amgen spokeswoman said in a written statement, is "to ensure that quality of care is not compromised for dialysis patients."

But the measure runs counter to a five-year effort in Washington to control the enormous expense of dialysis for the Medicare program by reversing incentives to overprescribe medication.

Amgen's success also shows that even a significant federal criminal investigation may pose little threat to a company's influence on Capitol Hill. On Dec. 19, as Congressional negotiations over the fiscal bill reached a frenzy, Amgen pleaded guilty to marketing one of its anti-anemia drugs, Aranesp, illegally. It agreed to pay criminal and civil penalties totaling $762 million, a record settlement for a biotechnology company, according to the Justice Department.

Amgen, whose headquarters is near Los Angeles and which had $15.6 billion in revenue in 2011, has a deep bench of Washington lobbyists that includes Jeff Forbes, the former chief of staff to Mr. Baucus; Hunter Bates, the former chief of staff for Mr. McConnell; and Tony Podesta, whose fast-growing lobbying firm has unusually close ties to the White House.

Amgen's employees and political action committee have distributed nearly $5 million in contributions to political candidates and committees since 2007, including $67,750 to Mr. Baucus, the Finance Committee chairman, and $59,000 to Mr. Hatch, the committee's ranking Republican. They gave an additional $73,000 to Mr. McConnell, some of it at a fund-raising event for him that it helped sponsor in December while the debate over the fiscal legislation was under way. More than $141,000 has also gone from Amgen employees to President Obama's campaigns.

What distinguishes the company's efforts in Washington is the diversity and intensity of its public policy campaigns. Amgen and its foundation have directed hundreds of thousands of dollars in charitable contributions to influential groups like the Congressional Black Caucus and to lesser-known groups like the Utah Families

Foundation, which was founded by Mr. Hatch and brings the senator positive coverage in his state's news media.

Amgen has sent large donations to Glacier PAC, sponsored by Mr. Baucus in Montana, and OrrinPAC, a political action committee controlled by Mr. Hatch in Utah.

And when Mr. Hatch faced a rare primary challenge last year, a nonprofit group calling itself Freedom Path sponsored advertisements in Utah that attacked his opponent, an effort that tax records released in November show was financed in large part by the Pharmaceutical Research and Manufacturers of America, a trade group that includes Amgen.

In some cases, the company's former employees have found important posts inside the Capitol. They include Dan Todd, one of Mr. Hatch's top Finance Committee staff members on health and Medicare policy, who worked as a health policy analyst for Amgen's government affairs office from 2005 to 2009. Mr. Todd, who joined Mr. Hatch's staff in 2011, was directly involved in negotiating the dialysis components of the fiscal bill, and he met with "all the stakeholders," Mr. Hatch's spokeswoman said, not disputing when asked that this included Amgen lobbyists.

For years, Amgen used its clout in Washington to lobby for generous Medicare payments for its blockbuster drug, Epogen, which fends off anemia in dialysis patients.

The Medicare program covers most costs associated with treating severe renal disease, regardless of a patient's age, and the dialysis market continues to grow steadily. In 2010, the government's kidney program was spending $1.9 billion on injectable anti-anemia drugs like Epogen.

But nearly a decade ago, evidence started to surface that questioned the effectiveness and safety of Epogen at the levels being used.

Researchers found that Medicare's practice of reimbursing providers with separate payments for the drugs and for dialysis treatments encouraged overprescription because the providers made healthy profits with each dose. They also found that high doses posed cardiovascular risks to patients.

Congress reversed the incentive in 2008 by requiring Medicare to pay a single, bundled rate for a dialysis treatment and related medications starting in 2011. With providers potentially profiting more by prescribing less Epogen, use of dialysis drugs dropped by nearly 25 percent.

Image

Senators Max Baucus, left, and Orrin Hatch, in June at a Finance Committee meeting, have received contributions from Amgen.Credit...Stephen Crowley/The New York Times

But the blow was softened for Amgen and other kidney care companies with a few favors from Congress. Among them was a two-year delay in the inclusion of certain oral drugs, Sensipar among them, in the new bundled payment system. That meant demand for Sensipar would not decline and Amgen would maintain control over pricing.

With that two-year exclusion set to expire in 2014, Amgen's lobbyists began making rounds again on Capitol Hill last fall. In private meetings with staff members of the House Ways and Means and Senate Finance Committees, they argued for another two-year delay, several Congressional aides said.

Committee staff members had been meeting regularly in Room S-124 of the Capitol to negotiate a package of Medicare cuts needed to prevent a large scheduled reduction in doctors' fees. The kidney program was on the table because a new report by the Government Accountability Office had found that Medicare had overpaid for dialysis by up to $880 million in 2011.

The discussions about cutting dialysis reimbursement began late last fall with little focus on a delay for oral drugs, but it was eventually endorsed by leading staff members for Mr. Baucus and Mr. Hatch, Congressional aides said.

Aides to the senators said the delay made sense because the Government Accountability Office had warned in early 2011 that federal regulators should take care in setting compensation levels for the drugs.

But others on Capitol Hill saw no justification for further delay.

"It is disappointing," said a Democratic Congressional aide who declined to be named because of the issue's sensitivity, "since the status quo encourages prescribing of oral drugs based on financial incentives rather than on best clinical practices."

Mr. Hatch's spokeswoman, Ms. Ferrier, said the involvement of Mr. Todd, the former Amgen employee, had not been inappropriate and that dozens of staff members on Capitol Hill handled matters that might benefit former employers.

"They have to leave their previous lives behind," Ms. Ferrier said. "And Dan has done just that."

After the House was sidelined late in the fiscal negotiations, the Senate gained control of the final bill-writing process, and the provision requested by Amgen was inserted into the legislation by Senate staff members.

Aides to Mr. Baucus and Mr. Hatch emphasized that the White House and Senate leadership, including Mr. McConnell, had the final word on the bill.

A spokesman for Mr. McConnell praised the parts of the legislation related to Medicare, while a White House spokesman declined to comment, saying the matter was decided by players on Capitol Hill.

Many lobbyists and Congressional aides said they first learned of the language when the final bill was posted publicly, only hours before being approved. It called for cutting $4.9 billion over 10 years by lowering Medicare payments for dialysis, but left hundreds of millions on the table by extending the oral drug delay.

At this point, opponents had no way to challenge the provision, as there was a single vote on the entire fiscal package. Mr. Baucus and Mr. Hatch voted in favor.

Aides to the senators said some heavy donors had won and others had lost in the Medicare negotiations — proof that the legislative outcome was based on the merits. “What is the best policy for Montanans and people across the country lies at the heart of every decision Chairman Baucus makes,” said Meaghan Smith, a spokeswoman for Mr. Baucus. “It’s as simple as that.”

Statement for the Record Submitted by
Stacey Y. Brayboy
Senior Vice President, Public Policy & Government Affairs

Markup of
The House Subcommittee on Health of the Committee of Energy and Commerce

U.S. House of Representatives
March 12th, 2024

March of Dimes began our fight for moms and babies more than 80 years ago as an organization dedicated to eradicating polio in the U.S., a goal that we achieved. We continue that fight today as we work to address some of the biggest threats to moms and babies, such as premature birth and maternal mortality, through research, education, programs and advocacy.

March of Dimes' ongoing work to improve maternal and infant health is more important than ever as our nation is in the midst of a dire maternal and infant health crisis. Rates of preterm birth are increasing; the U.S. is one of the most dangerous places to give birth in the developed world; and stillbirth rates continue to unacceptably grow in the U.S.

March of Dimes strongly endorses the SHINE for Autumn Act (H.R. 5012) and the Maternal and Child Health Stillbirth Prevention Act (H.R. 4581), and looks forward to the passage and signing of this impactful legislation this Congress.

OUR NATION IS IN THE MIDST OF A MATERNAL AND INFANT HEALTH CRISIS

Nearly every measure of the health of pregnant women, new mothers, and infants living in the U.S. is going in the wrong direction. In many communities, infant mortality rates exceed those in developing nations.[i] Approximately every 12 hours, a woman dies due to pregnancy-related complications.[ii]

Each year, about 700 women die from complications related to pregnancy.[iii] For every maternal death, another 70 women suffer life-threating health challenges. That's over 50,000 women each year.[iv] While other countries have reduced their maternal mortality rates since the 1990s, the U.S. maternal mortality rate continues to rise.[v]

Nationwide, five percent of counties have less maternity access than just two years ago. These areas of combined low or no access affect up to 6.9 million women and almost 500,000 births in the U.S. In maternity care deserts alone—approximately 2.2 million women of childbearing age and almost 150,000 babies are affected. Maternity care deserts are counties where there is a lack of maternity care resources, where there are no hospitals or birth centers offering obstetric care and no obstetric providers. The 2022 report describes a two percent increase in counties that are maternity care deserts since the 2020 report. That is 1,119 counties and an additional 15,933 women with no maternity care.[vi]

Since 2008, March of Dimes began releasing our Report Card, one thing that has remained constant: an alarmingly high preterm birth rate. In 2022, over 380,000 babies were born preterm—10.4% of all births—earning our nation a D+ for the second year in a row.

Stillbirth is a pregnancy loss of a baby at or after 20 weeks of pregnancy. Stillbirth impacts 1 in 160 births, and each year 21,000 babies are stillborn in the United States.[vii] Unfortunately, a minimum of 25% of stillbirths are preventable with the implementation of adequate prevention and education efforts. That is at least 5,250 children who are lost and families who come home to an empty nursery.

H.R. 5012, "Stillbirth Health Improvement and Education for Autumn Act of 2023" or SHINE for Autumn Act and H.R. 4581, "Maternal and Child Health Stillbirth Prevention Act of 2023"

Despite medical innovations, stillbirth rates are getting worse. Stillbirth occurs in all races, ethnicities, income levels, and to women of all ages – leaving no pregnancy immune. However, there are longstanding and persistent racial, ethnic, age, and educational disparities. For example, nearly all races have higher rates than whites but Blacks and Native Americans have about twice the rate of stillbirth of other groups.[viii]

Stillbirth has serious physical and psycho-social consequences on parents and families. Women suffer from serious forms of anxiety, depression, loss of self-esteem and guilt, sometimes aggravated by the insensitive health system, as well as strained marital relationship and financial burdens. Depression alone is two to four times more common in women who have experienced a stillbirth than women who had given birth to a liveborn infant. The physical impacts are also significant with women more likely to die during stillbirth and having a morbidity rate four times higher than live birth.[ix]

Due to information provided through vital records having significant issues with quality control, this significantly impacts the ability of researchers to better understand stillbirth rates and the later creation of effective, targeted programs to educate and prevent stillbirth. To provide some scope of this problem, one review of 27 studies found that a fetal autopsy revealed a change in diagnosis or additional findings in 22% to 76% of cases.[x]

Despite these numbers, stillbirth has not been afforded the same attention as other critical areas of public health. This bill will take critical steps to invest in research and data collection to better understand stillbirth in the U.S., with the goal of lowering the stillbirth rate. Additionally, it will provide critical resources to the CDC, NIH, and local state departments of health to improve stillbirth data collection and increase education and awareness around the issue of stillbirth. It is the beginning of a longer-term solution towards the prevention and reduction of incidences of stillbirth. We must also ensure that states and organizations trying to add families are able to legally stand-up crucial programs to ensure safe and healthy pregnancies, and care if a stillbirth occurs.

Without a strong foundation, we cannot build impactful and lifesaving programs to prevent stillbirth and educate both practitioners and families. These bills will allow us to better track and research stillbirths and who is impacted and the role disparities have in negatively impacting infant and parental health, and then use that information to positively impact the growing rates of stillbirth among families.

CONCLUSION

March of Dimes thanks the Subcommittee for focusing attention on one of the nation's most important public health challenges. Our nation must invest in new policies to prevent stillbirth and educate expecting families. With your help, we can make strides to prevent pregnancy loss, preterm birth, end preventable maternal deaths, and improve the health of children through better prevention. March of Dimes stands ready to work with you to achieve that change and hopes that 2024 will be the year we take these important steps toward ending this crisis harming so many of unborn children and their families through the passage of the SHINE for Autumn Act (H.R. 5012) and the Maternal and Child Health Stillbirth Prevention Act (H.R. 4581).

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[viii] Ibid

[ix] Ibid

[x] Http://journals.sagepub.com/doi/abs/10.1177/0887302x07303626 | ... (n.d.-a). https://www.researchgate.net/publication/328039672_httpjournalssagepubcomdoiabs10117708873O2X07303626