Volume 2 Issue 2 Fall 2025

Hypothesis

PERSPECTIVES INSIGHTS & THOUGHT LEADERSHIP IN THE LIFE SCIENCES

Two Patients Faced Chemo. The One Who Survived Demanded a Test to See if It Was Safe.

INSIDE THIS ISSUE

Medical minds meet here.

We gather thought leaders from around the continent and organize large-scale medical symposia that afford our partners the chance to build relationships with the clinical community and stay up-to-date on the current conversations in multiple disease areas. Ask us how you can be part of our conferences by reaching out to **info@catalytichealth.com**

CONTENTS

Hypothesis
PERSPECTIVES INSIGHTS & THOUGHT LEADERSHIP IN THE LIFE SCIENCES
Volume 2 Issue 2 Fall 2025

Letter From Our Editor-in-Chief

Dear Readers,

Another year is coming to a close and, as always, it's been a tremendously interesting year in the healthcare space.

Our magazine is evolving. You'll notice some differences in this issue---particularly as we look to curate more original content for you. As we scour the healthcare news on a regular basis, we've decided to bring you interesting stories which highlight issues that impact you and, hopefully, which give you pause about how you think about healthcare. There's a lot of information out there and handpicking a few key stories is difficult work and not scientific. We choose what we like and what we think you want to read. Let us know if you have an interesting story that you want us to put in a future issue of the magazine.

We hope you enjoy this new format. We're not completely moving away from interviews with patients, doctors, or senior executives in the Canadian life-sciences space. Instead, we will occasionally sprinkle those in as opposed to making them core features of every issue. We'll still have our popular "People on the Move" and "Product Newswire" sections for our readers.

We hope you enjoy this new format and drop us a line at **info@catalytichealth.com** to tell us what you think!

Rohit

Editor-in-Chief
Hypothesis Magazine

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Rohit Khanna is the Managing Director of Catalytic Health, a leading life-sciences communication, publishing, and strategy firm. He holds a B.A. from McGill University, an M.B.A. from Queen's School of Business, an MSc. from the London School of Economics & Political Science and a Master of Public Health in Epidemiology from Harvard School of Public Health. His first book entitled *Misunderstanding Health: Making Sense of America's Broken Health Care System* was published in October 2021 by Johns Hopkins University Press. He can be reached at rohit@catalytichealth.com

A Time of Reflection

You know, what with it being the end of the year and all that stuff.

By Rohit Khanna, MBA, MSc, MPH

As always happens, the calendar turns to December, and I find myself musing about how fast the days and months seem to go by. "It was just the beginning of the year", I proclaim to anyone who will listen. No one listens. This is why I try and produce a year-in-review column of the most important healthcare stories of the year, with the usual caveats: sometimes the biggest stories or headlines make the list. Sometimes the most interesting ones do. Sometimes it's both. Sometimes it's neither. Let me know if you agree by dropping me a line at **rohit@catalytichealth.com**. Here we go.

1. It's still the year (maybe decade or century) of Wegovy. And Ozempic. And Mounjaro. GLP1-RAs are everywhere. And they're not just helping us lose weight (although they do an incredible job of that); they also seem to have some renal and cardioprotective benefit. And now manufacturers have teamed up with the Trump administration to make them cheaper and bring them directly to patients. And companies (see Pfizer and Novo Nordisk) keep chasing other companies (see Metsera) for their research assets.

2. AI Doctors are here! Platforms like Doctronic (**https://www.doctronic.ai/**) are now available to provide you with fast, free medical advice. Except, there's a catch. If you actually want to have a video chat with a "top" doctor it'll cost $39. As always, you are encouraged to read the fine print, which I've graciously provided for you: *Always discuss Doctronic output with a doctor. Doctronic is an AI doctor, not a licensed doctor, does not practice medicine, and does not provide medical advice or patient care. By using Doctronic, you agree to our Terms of Service & Privacy Policy.* We thought the unchecked and unregulated world of Dr Google was bad. Just wait. What could possibly go wrong?

3. Longevity is dead. Now there's an ironic statement. What started as a quasi-movement for a small group of fervent believers morphed into a 'plaything' for the zillionaires like Bezos, Thiel, and Ellison who have

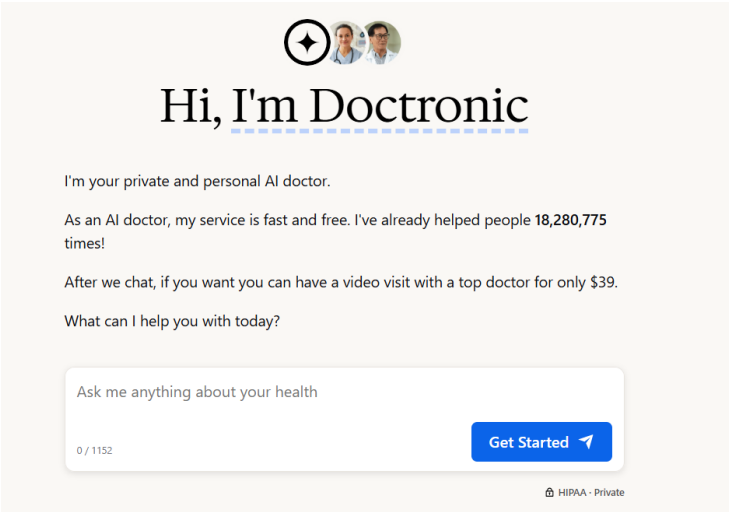

Photo courtesy of doctronic.ai.

thrown gaudy sums of money at startups aimed at "rejuvenation". And then Google/Calico and AbbVie ended their decade-long partnership. Maybe we're not meant to live to be a thousand years old?

4. As the longest government shutdown in U.S. history has just ended, the impact on the Affordable Care Act (ACA) is still unknown. According to news reports, "the ACA subsidies, also known as tax credits -- which help cover the cost of premiums -- were the sticking point in the shutdown. The tax credits were part of the original ACA legislation passed during the Obama administration and were enhanced in 2021 under the Biden administration to expand eligibility and lower income contribution caps. The enhanced premium tax credits are set to expire at the end of the year."[1] How this will affect Americans and their health care costs remains to be seen. Suffice to say, costs won't go down.

5. Bill 2 in Quebec is, perhaps, the biggest homegrown story of the year. The bill, "which is set to take effect in the new year, links doctors' compensation to performance targets relating to the number of patients they care for. It also imposes fines of up to $500,000 per day on doctors who take "concerted action" to challenge the government's policies."[2] Will droves of doctors leave Quebec? Will the government be forced to relent?

6. Canada lost its measles-elimination status in 2025. Yes, you read that right. According to a recent article in The New York Times, "the World Health Organization considers measles eliminated until it has spread unchecked for a year. Canada is set to be the first Western country since the coronavirus pandemic to lose its elimination status, according to W.H.O. data."[3] At least we're number one in something.

7. Despite the overturning of Roe v Wade, abortion rates in America have not declined as widely expected. In fact, they have held steady and, according to some research, gone up: "in the two years since the Supreme Court ruling that overturned Roe v. Wade, the total number of abortions nationally has slightly increased. The most recent data from the Society for Family Planning's #WeCount project show that there were 1.14 million abortions in 2024, up from 1.05 million abortions in 2023. For most of the decade prior to the Dobbs ruling, there was a steady decline in abortion rates nationally, with a slight uptick in the years just before the ruling.[4] Given the predictions, this is remarkable. And a testament to a myriad of factors, including dedicated people across the health care spectrum, timely legislation, and the power of the internet where abortion pills can be ordered online and shipped nationwide through the mail.

8. Long COVID is a real thing. And it's affecting millions and millions of people worldwide. We need to move faster at finding a treatment. And we have to stop calling it brain fog and look at it for what it is. According to Dr. Monica Verduzco-Gutierrez who is the chair of rehabilitation medicine at the University of Texas Health Science Center at San Antonio, "It's not just fog, it's a brain injury, basically."[5]

9. Psychedelics, psilocybin, and other 'non-traditional' approaches to disease management are still on the outside looking in. Their promise has been promised for years. Regulators aren't convinced. Neither is the traditional medical community. For patients with, say, treatment-resistant depression or PTSD, this matters little. The don't care about RCTs and statistical significance. They want to get better where every other treatment option has failed. We owe them a chance.

A happy and healthy holiday season to all. See you in 2026!

References

1. *https://abcnews.go.com/Health/government-shutdown-ended-future-aca/story?id=127503888*
2. *https://www.cbc.ca/news/canada/toronto/260-quebec-doctors-apply-ontario-licences-after-bill-2-9.6973978#:~:text=Quebec's%20Bill%202%2C%20which%20is,to%20challenge%20the%20government's%20policies.*
3. *https://www.nytimes.com/2025/11/06/world/canada/canada-measles-elimination-measles.html*
4. *https://www.kff.org/womens-health-policy/abortion-trends-before-and-after-dobbs/*
5. *https://www.nytimes.com/2023/11/13/upshot/long-covid-disability.html*

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Two Patients Faced Chemo. The One Who Survived Demanded a Test to See if It Was Safe.

By Arthur Allen

This article originally appeared on June 4th, 2025 at https://kffhealthnews.org/news/article/chemotherapy-drug-f5u-capecitabine-toxicity-test-death-prevention/.

We are grateful to KFF Health News for making this available to our readers as part of their commitment to sharing stories about the complexities of healthcare.

Introduction

JoEllen Zembruski-Ruple, while in the care of New York City's renowned Memorial Sloan Kettering Cancer Center, swallowed the first three chemotherapy pills to treat her squamous cell carcinoma on Jan. 29, her family members said. They didn't realize the drug could kill her.

Six days later, Zembruski-Ruple went to Sloan Kettering's urgent care department to treat sores in her mouth and swelling around her eyes. The hospital diagnosed oral yeast infection and sent her home, her sister and partner said. Two days later, they said, she returned in agony — with severe diarrhea and vomiting — and was admitted. "Enzyme deficiency," Zembruski-Ruple texted a friend.

The 65-year-old, a patient advocate who had worked for the National Multiple Sclerosis Society and other groups, would never go home.

Covered in bruises and unable to swallow or talk, she eventually entered hospice care and died March 25 from the very drug that was supposed to extend her life, said her longtime partner, Richard Khavkine. Zembruski-Ruple was deficient in the enzyme that metabolizes capecitabine, the chemotherapy drug she took, said Khavkine and Susan Zembruski, one of her sisters. Zembruski-Ruple was among about 1,300 Americans each year who die from the toxic effects of that pill or its cousin, the IV drug fluorouracil known as 5-FU.

Doctors can test for the deficiency — and then either switch drugs or lower the dosage if patients have a genetic variant that carries risk. The FDA approved an antidote in 2015, but it's expensive and must be administered within four days of the first chemotherapy treatment.

Newer cancer drugs sometimes include a companion diagnostic to determine whether a drug works with an individual patient's genetics. But 5-FU went on the market in 1962 and sells for about $17 a dose; producers of its generic aren't seeking approval for toxicity tests, which typically cost hundreds of dollars. Doctors have only gradually understood which gene variants are dangerous in which patients, and how to deal with them, said Alan Venook, a colorectal and liver cancer specialist at the University of California-San Francisco.

> ***"They never said why they didn't test her. If the test existed, they should have said there is a test."***

By the time Zembruski-Ruple's doctors told her she had the deficiency, she had been on the drug for eight days, said Khavkine, who watched over his partner with her sister throughout the seven-week ordeal.

Khavkine said he "would have asked for the test" if he had known about it, but added "nobody told us about the possibility of this deficiency." Zembruski-Ruple's sister also said she wasn't warned about the fatal risks of the chemo, or told about the test.

"They never said why they didn't test her," Zembruski said. "If the test existed, they should have said there is a test. If they said, 'Insurance won't cover it,' I would have said, 'Here's my credit card.' We should have known about it."

Photo courtesy of freepik.com.

Guidance Moves at a Glacial Pace

Despite growing awareness of the deficiency, and an advocacy group made up of grieving friends and relatives who push for routine testing of all patients before they take the drug, the medical establishment has moved slowly.

A panel of the National Comprehensive Cancer Network, or NCCN — specialists from Sloan Kettering and other top research centers — until recently did not recommend testing, and the FDA does not require it.

In response to a query from KFF Health News about its policy, Sloan Kettering spokesperson Courtney Nowak said the hospital treats patients "in accordance with NCCN guidelines." She said the hospital would not discuss a patient's care.

On Jan. 24, the FDA issued a warning about the enzyme deficiency in which it urged health care providers to "inform patients prior to treatment" about the risks of taking 5-FU and capecitabine.

On March 31 — six days after Zembruski Ruple's death — the network's expert panel for most gastrointestinal cancers took a first step toward recommending testing for the deficiency.

Worried that President Donald Trump's FDA might do nothing, Venook said, the panel — whose guidance shapes the practices of oncologists and health insurers — recommended that doctors consider testing before dosing patients with 5-FU or capecitabine.

However, its guidance stated that "no specific test is recommended at this time," citing a lack of data to "inform dose adjustments."

Sloan Kettering "will consider this guidance in developing personalized treatment plans for each patient," Nowak told KFF Health News.

The new NCCN guidance was "not the blanket recommendation we were working toward, but it is a major step toward our ultimate goal," said Kerin Milesky, a public health official in Brewster, Massachusetts, who's part of an advocacy group for

testing. Her husband, Larry, died two years ago at age 73 after a single treatment of capecitabine.

European drug regulators began urging oncologists to test patients for deficiency in May 2020. Patients with potentially risky genetics are started on a half-dose of the cancer drug. If they suffer no major toxicity, the dose is increased.

A Lifesaving Ultimatum?

Emily Alimonti, a 42-year-old biotech salesperson in upstate New York, chose that path before starting capecitabine treatment in December. She said her doctors — including an oncologist at Sloan Kettering — told her they didn't do deficiency testing, but Alimonti insisted. "Nope," she said. "I'm not starting it until I get the test back."

The test showed that Alimonti had a copy of a risky gene variant, so doctors gave her a lower dose of the drug. Even that has been hard to tolerate; she's had to skip doses because of low white blood cell counts, Alimonti said. She still doesn't know whether her insurer will cover the test.

Around 300,000 people are treated with 5-FU or capecitabine in the United States each year, but its toxicity could well have prevented FDA approval were it up for approval today. Short of withdrawing a drug, however, U.S. regulators have little power to manage its use. And 5-FU and capecitabine are still powerful tools against many cancers.

At a January workshop that included FDA officials and cancer specialists, Venook, the NCCN panel's co-chair, asked whether it was reasonable to recommend that doctors obtain a genetic test "without saying what to do with the result."

But Richard Pazdur, the FDA's top cancer expert, said it was time to end the debate and commence testing, even if the results could be ambiguous. "If you don't have the information, how do you have counseling?" he asked.

Two months later, Venook's panel changed course. The price of tests has fallen below $300 and results can be returned as soon as three days, Venook said. Doubts about the FDA's ability to further confront the issue spurred the panel's change of heart, he said.

"I don't know if FDA is going to exist tomorrow," Venook told KFF Health News. "They're taking a wrecking ball to common sense, and that's one of the reasons we felt we had to go forward."

On May 20, the FDA posted a Federal Register notice seeking public input on the issue, a move that suggested it was considering further action.

Venook said he often tests his own patients, but the results can be fuzzy. If the test finds two copies of certain dangerous gene variants in a patient, he avoids using the drug. But such cases are rare — and Zembruski-Ruple was one of them, according to her sister and Khavkine.

Many more patients have a single copy of a suspect gene, an ambiguous result that requires clinical judgment to assess, Venook said.

A full-gene scan would provide more information but adds expense and time, and even then the answer may be murky, Venook said. He worries that starting patients on lower doses could mean fewer cures, especially for newly diagnosed colon cancer patients.

> ***"If you don't have the information, how do you have counseling?"***

Power Should Rest with Patients

Scott Kapoor, a Toronto-area emergency room physician whose brother Anil, a much-loved urologist and surgeon, died of 5-FU toxicity at age 58 in 2023, views Venook's arguments as medical paternalism. Patients should decide whether to test and what to do with the results, he said.

"What's better — don't tell the patient about the test, don't test them, potentially kill them in 20 days?" he said. "Or tell them about the testing while warning that potentially the cancer will kill them in a year?"

"People say oncologists don't know what to do with the information," said Karen Merritt, whose mother died after an infusion of 5-FU in 2014. "Well, I'm not a doctor, but I can understand the Mayo Clinic report on it."

The Mayo Clinic recommends starting patients on half a dose if they have one suspect gene variant. And "the vast majority of patients will be able to start treatment without delays," Daniel Hertz, a clinical pharmacologist from the University of Michigan, said at the January meeting.

Some hospitals began testing after patients died because of the deficiency, said Lindsay Murray, of Andover, Massachusetts, who has advocated for widespread testing since her mother was treated with capecitabine and died in 2021.

In some cases, Venook said, relatives of dead patients have sued hospitals, leading to settlements.

Kapoor said his brother — like many patients of non-European origin — had a gene variant that hasn't been widely studied and isn't included in most tests. But a full-gene scan would have detected it, Kapoor said, and such scans can also be done for a few hundred dollars.

The cancer network panel's changed language is disappointing, he said, though "better than nothing."

In video tributes to Zembruski-Ruple, her friends, colleagues, and clients remembered her as kind, helpful, and engaging. "JoEllen was beautiful both inside and out," said Barbara McKeon, a former colleague at the MS Society. "She was funny, creative, had a great sense of style."

"JoEllen had this balance of classy and playful misbehavior," psychotherapist Anastatia Fabris said. "My beautiful, vibrant, funny, and loving friend JoEllen."

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Glucagon-Like Peptide-1 Receptor Agonists and Pay-Per-Click Direct-to-Consumer Advertising

Daniel Eisenkraft Klein, PhD, MSc; Marco Zenone, PhD, MSc; Aaron S. Kesselheim, MD, JD, MPH

This article originally appeared on October 31, 2025, at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2840795/.

We are grateful to JAMA Network Open for making this available to our readers.

Introduction

Direct-to-consumer advertising (DTCA) of prescription drugs remains commonplace in the US, accounting for billions of dollars of expenses each year and influencing patients' and physicians' perceptions of health issues and treatments.[1] DTCA has made broad use of pay-per-click (PPC) advertising, in which advertisers target users based on their search queries and online behavior.[2] With PPC, companies bid on keywords related to their products and pay when someone clicks their advertisements.

Prescription drug promotion is regulated by the Food and Drug Administration (FDA), and manufacturers must follow certain rules, including that advertising be truthful, balanced, and accurate, while disclosing key information.[3] This study explores how PPC advertising is used in the pharmaceutical context by analyzing a large dataset of keyword ads linked to Ozempic.com to identify key components of digital promotion.

> ***Prescription drug promotion is regulated by the Food and Drug Administration (FDA), and manufacturers must follow certain rules, including that advertising be truthful, balanced, and accurate, while disclosing key information.***

Methods

To explore the phenomenon of PPC DTCA, we evaluated the case of semaglutide (Ozempic), a GLP-1RA FDA approved for diabetes.[4] Our cross-sectional study analyzed publicly available data on paid search advertisements for the drug's website in the US from April 2022 to March 2024 using Semrush, a tool for keyword and PPC analysis.[5] Semrush offers a reliable tool for examining strategies,[6] providing estimated data on traffic, identifying paid Google ads, estimating costs, and understanding the keywords advertisers use to reach users.

Our study followed Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines. Our publicly available data were exempt from ethics review per the Common Rule, and we relied on descriptive analyses conducted in Excel version 16 (Microsoft) and Semrush Guru.

Keyword	Total traffic cost, US $
Trulicity	203578
Mounjaro	113668
Trulicity side effects	67820
Tirzepatide	52042
Foods to avoid with Trulicity	43274
Mounjaro side effects	26429
Trulicity dosage	25180
Semiglutide	24511
Trulicity compalints	18852
Side effects of Trulicity	17352
Trulicity coupon	16765
Munjaro	16051
Trulicity dosing	13849
Semaglutide near me	13601
Mounjaro cost	10641
Byetta	10445
Manjaro drug	10393
Mounjaro dosage	10023
Bydureon	9765

Table 1. *Top 20 Keywords That Do Not Contain the Brand Name Ozempic, by Traffic Cost, April 2022 to March 2024.*

Keyword	Paid traffic
Ozempic for weight loss	113811
Ozempic weight loss	77218
6 week plan Ozempic weight loss results	14703
How to get Ozempic for weight loss	13452
Ozempic weight loss before and after pictures	9608
Trulicity weight loss	8345
Weight loss drug Ozempic	7426
Ozempic and weight loss	6762
Ozempic weight loss side effects	6503
Mounjaro weight loss	5429
Trulicity for weight loss	413
6 week belly Ozempic weight loss before and after	4177
Mounjaro for weight loss	4066
How does Ozempic work for weight loss	3960
Ozempic dosing for weight loss	3868
Weight loss Ozempic	3415
Weight watchers Ozempic	2654
How to get prescribed Ozempic for weight loss	2594
Ozempic for weight loss side effects	2521

Table 2. *Top Weight-Related Keywords by Traffic, April 2022 to March 2024.*

Results

In the case of Ozempic, an estimated $7.5 million was spent on more than 15 000 paid keywords over 2 years, generating 2.4 million paid visits to the drug's website. More than 3500 of the keywords (23%) contained no mention of the drug (**Table 1**), including misspellings of the brand name. Substantial spending covered weight-loss-related terms, including *Ozempic for weight loss* ($302 757) and *Ozempic weight loss* ($188 626), as well as keywords linked to competitors' drugs such as *Trulicity* ($203 578) and *Mounjaro* ($113 668). More than 600 keywords included *Mounjaro* and more than 1000 keywords included *Trulicity*, including T*rulicity side effects, side effects of Trulicity*, and *Trulicity complaints*.

In the cohort, 1729 keywords (11%) contained the term weight (**Table 2**). These keywords led to more than 358 000 website visits via advertisements, constituting 14% of paid keyword visits.

Discussion

PPC advertising prioritizes company websites over other sources, an outcome that may not be apparent to users expecting search results to reflect informational relevance or objectivity. Manufacturers' websites inevitably emphasize medications' benefits, risks, and alternatives in ways designed to drive prescriptions.

Ozempic's website has been promoted in response to a diverse set of search keywords that include other prescription drugs. PPC advertising may allow companies to promote their drugs for non-FDA-approved uses; for example, individuals searching weight keywords may be targeted with an Ozempic paid advertisement. While Ozempic has been shown to help them lose weight, it is not FDA approved for weight loss. This approach may influence consumer behavior by increasing the likelihood that individuals, including those for whom the drug may not be FDA approved or clinically indicated, initiate conversations with their clinicians that lead to a prescription. This single-case analysis limits generalizability, and the relatively modest spending observed may reflect regulatory caution, strategic targeting, or reliance on other digital channels.

The relatively modest spending observed may reflect regulatory caution, strategic targeting, or reliance on other digital channels.

Future research should assess whether similar PPC strategies are used across other products or manufacturers. While the FDA provides guidance for manufacturers' use of social media, this does not cover search engines. In response, the FDA could issue guidelines about or seek to review PPC content to prevent patients from being misled.

References

1. *U. S. Government Accountability Office. Prescription drugs: Medicare spending on drugs with direct-toconsumer advertising. 2021. Accessed April 26, 2024. https://www.gao.gov/products/gao-21-380*
2. *Google. Google ads—get customers and sell more with online advertising. 2024. Accessed April 26, 2024. https://ads.google.com/intl/en_ca/home/*
3. *Center for Drug Evaluation and Research. The bad ad program. Food and Drug Administration. December 17, 2024. Accessed January 17, 2025. https://www.fda.gov/drugs/office-prescription-drug-promotion/badad-program*
4. *Blum D. What is Ozempic and why is it getting so much attention? The New York Times. November 22, 2022. Accessed April 21, 2024. https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html*
5. *Patel NG, Hwang TJ,Woloshin S, Kesselheim AS. Therapeutic value of drugs frequently marketed using directto- consumer television advertising, 2015 to 2021. JAMA Netw Open. 2023;6(1):e2250991. doi:10.1001/jamanetworkopen.2022.50991*
6. *Reyes-Lillo D, Morales-Vargas A, Rovira C. Reliability of domain authority scores calculated by Moz, Semrush, and Ahrefs. Prof Inf. 2023;32(4). doi:10.3145/epi.2023.jul.03*

Accepted for Publication: August 25, 2025

Published: October 31, 2025.
doi:10.1001/jamanetworkopen.2025.38718

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Author Contributions: Author x had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: All authors.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Eisenkraft Klein.
Critical review of the manuscript for important intellectual content: All authors.
Statistical analysis: Eisenkraft Klein.
Obtained funding: Kesselheim.
Administrative, technical, or material support: Zenone.
Supervision: Kesselheim.

Conflict of Interest Disclosures: Dr Kesselheim reported serving as an expert witness on behalf of the Federal Trade Commission in a case against pharmacy benefit managers related to insulin, in a case on behalf of a class of patients against Gilead related to its tenofovir-containing products, and in a case on behalf of a payer against J&J related to availability of biosimilar Stelara.

No other disclosures were reported.

Funding/Support: Dr Kesselheim's research was supported by Arnold Ventures.

Role of the Funder/Sponsor: The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Data Sharing Statement: See Supplement.

The second annual

TOP 20 UNDER 40

IN LIFE SCIENCES

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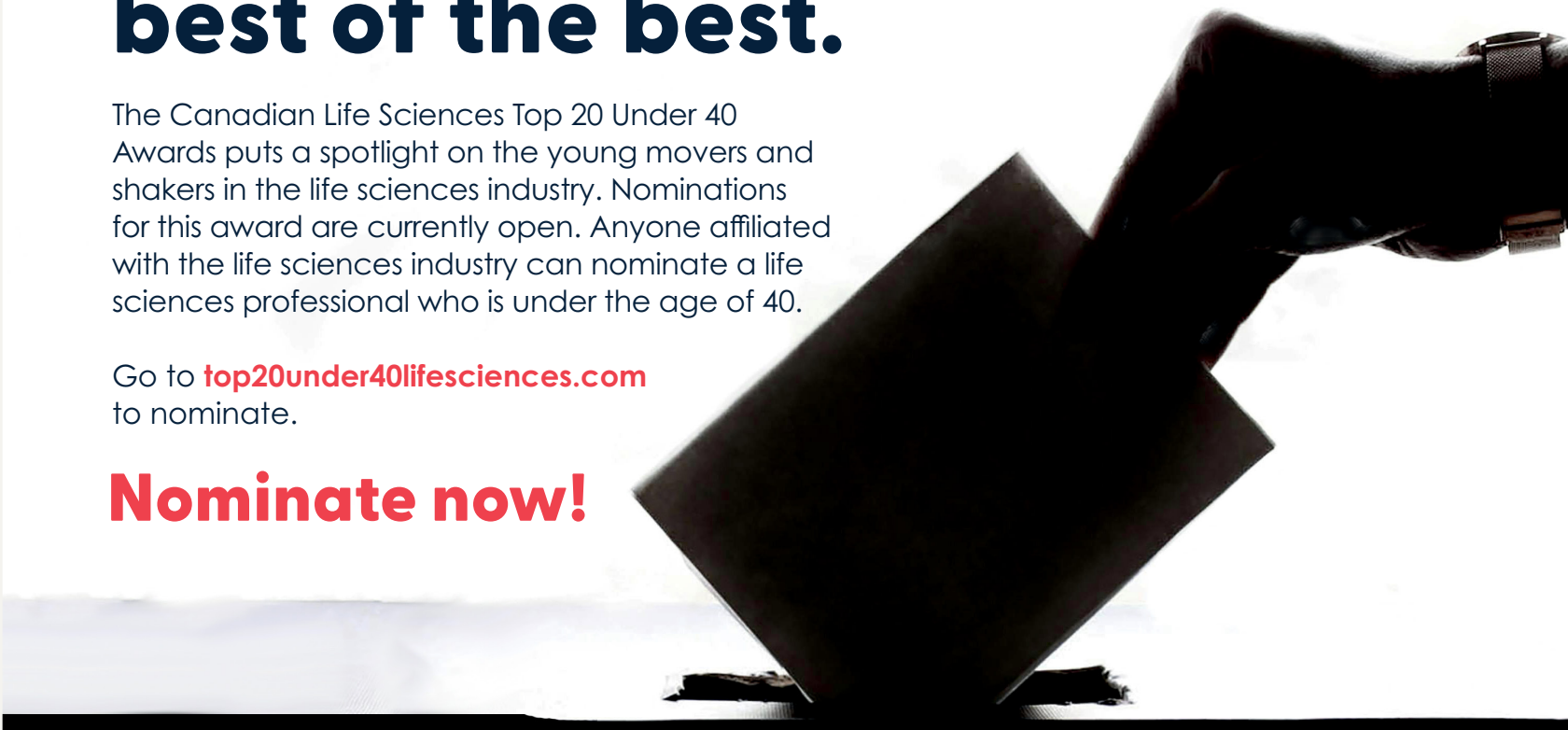

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JANUARY 2026

Alzheimer's Awareness Month

Firefighter Cancer Awareness Month

FEBRUARY 2026

AMD Awareness Month

World Cancer Day – February 4*

Congenital Heart Disease Awareness Week – February 7 to 14*

International Childhood Cancer Day – February 15*

Mental Health Nurses Day – February 21

Rare Disease Day – February 28

JAN

Firefighter Cancer Awareness Month

January is Firefighter Cancer Awareness Month, a time make sure fire fighters have the necessary tools and guidance to develop life-saving protocols for cancer prevention and to support those with a cancer diagnosis within their departments.

Photo courtesy of unsplash.com.

FEB

AMD Awareness Month

During February, people across Canada take time to educate themselves about age-related macular degeneration (AMD) an eye disease that causes gradual loss of central and detailed vision, primarily affecting people over the age of 55.

Photo courtesy of pexels.com.

FEB 7–14

Congenital Heart Disease Awareness Week

Every year, from February 7–14, we take the time to promote awareness of congenital heart disease (CHD), a condition that affects millions of adults and children worldwide.

Photo courtesy of freepik.com.

Source: www.canada.ca/en/health-canada/services/calendar-health-promotion-days.html
Events marked with an asterisk (*) take place on the same day every year.

MARCH 2026

Brain Health Awareness Month
Colorectal Cancer Awareness Month
Epilepsy Awareness Month
Liver Health Month
Multiple Myeloma Awareness Month
Pharmacy Appreciation Month (PAM)
Kidney Health Month
World Obesity Day – March 4
World Lymphedema Day – March 6*
International Women's Day – March 8*
World Glaucoma Week – March 10 to 16
Brain Awareness Week – March 16 to 22
World Down Syndrome Day – March 21*
World Tuberculosis Day – March 24*

MAR

Kidney Health Month

March is Kidney Health Month in Canada, a time to educate people on the risks and causes of kidney diseases.

Photo courtesy of freepik.com.

APRIL 2026

HIE Awareness Month
IBS Awareness Month
Parkinson Awareness Month
Rosacea Awareness Month
World Autism Awareness Day - United Nations – April 2*
World Health Day – April 7*
World Hemophilia Day – April 17*
National Immunization Awareness Week – April 23 to 30*

APR 17

World Hemophilia Day

April 17th is World Hemophilia Day, a day for people to help advocate for all those who suffer from inherited bleeding disorders.

Photo courtesy of pexels.com.

Source: www.canada.ca/en/health-canada/services/calendar-health-promotion-days.html
Events marked with an asterisk (*) take place on the same day every year.

Information on the Latest Drug Approvals and Reimbursement Milestones

VABYSMO® (faricimab injection), produced by **Roche**, is now publicly funded for macular edema secondary to Retinal Vein Occlusion (RVO) in Ontario.

Takeda's FRUZAQLA™ (fruquintinib) has been publicly reimbursed in Quebec for the treatment of metastatic colorectal cancer (mCRC).

Lilly's Verzenio® (abemaciclib) increases overall survival in HR+, HER2-, high-risk early breast cancer after two years of therapy.

RINVOQ® (upadacitinib), developed by **AbbVie,** receives Health Canada Notice of Compliance (NOC) for giant cell arteritis in adults OR AbbVie's RINVOQ® (upadacitinib) receives Health Canada Notice of Compliance (NOC) for giant cell arteritis in adults.

LEO Pharma announces Health Canada approval of **Anzupgo®** for treatment of moderate to severe chronic hand eczema.

Health Canada approves **Roche's Columvi®** (glofitamab) as the first bispecific antibody in Canada for relapsed or refractory diffuse large B-Cell lymphoma after initial therapy.

Health Canada grants marketing authorization for an additional indication of **Bayer's NUBEQA®** (darolutamide) for the treatment of metastatic castration-sensitive prostate cancer (mCSPC).

Leqvio®, produced by **Novartis Pharmaceuticals**, advances toward broader access with agreement between Novartis and the pan-Canadian Pharmaceutical Alliance.

Health Canada approves **Novo Nordisk's Ozempic®** to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease.

Health Canada approves **Bristol-Myers Squibb's** dual immunotherapy **OPDIVO®** plus **YERVOY®** for colorectal and liver cancers.

Pfizer Canada and **BioNTech** receive Health Canada approval of **LP.8.1 variant** adapted COVID-19 vaccine.

VABYSMO® (faricimab injection), developed by **Roche**, is now publicly funded in Quebec for macular edema secondary to retinal vein occlusion (RVO), including its pre-filled syringe (PFS) format.

Health Canada approves **KEYTRUDA®** (pembrolizumab), from **Merck**, for patients with resectable locally advanced head and neck squamous cell carcinoma (HNSCC) tumours that are PD-L1 (CPS-positive), as neoadjuvant treatment followed by adjuvant treatment combined with radiotherapy with or without cisplatin, and then continued as monotherapy.

Health Canada has authorized **CSL's ANDEMBRY®** (garadacimab) as once-monthly treatment for hereditary angioedema (HAE).

Alexion, AstraZeneca Rare Disease reaches an agreement with the pan-Canadian Pharmaceutical Alliance (pCPA) for **Ultomiris** for the treatment of adults with neuromyelitis optica spectrum disorder (NMOSD) and adults with generalized myasthenia gravis (gMG).

AstraZeneca's Imfinzi® approved in Canada as first and only perioperative immunotherapy for muscle invasive bladder cancer.

Kye Pharmaceuticals announces the approval of **DYANAVEL® XR** (amphetamine extended-release) tablets and oral suspension for the treatment of adults and children with ADHD.

Abbott's dissolving stent receives Health Canada approval for treating blocked arteries below-the-knee.

Mint Pharmaceuticals announces partnership with **Bayer Canada** to distribute **ADALAT® XL®** (nifedipine extended-release tablets) 30 mg tablets in Canada.

Lilly's Ebglyss® for moderate-to-severe atopic dermatitis (eczema) listed on Quebec's public drug formulary.

QULIPTA® (atogepant), from **AbbVie**, is now publicly reimbursed in Quebec for chronic migraine and CGRP Class Review published.

New subcutaneous formulation of **Bristol-Myers Squibb's OPDIVO®** receives positive INESSS recommendation for multiple tumour types.

Health Canada approves **MacuMira Retinal Microcurrent Stimulation Device** to improve vision for dry AMD patients nationally.

AbbVie's VRAYLAR® (cariprazine) is now publicly reimbursed in Alberta.

Health Canada approves **Bylvay™** (odevixibat) from **Medison Pharma** for the treatment of cholestatic pruritus in patients with Alagille Syndrome.

Health Canada approves **AbbVie's ELAHERE®** for certain types of platinum-resistant ovarian cancers.

GSK's RSV vaccine Arexvy included in publicly funded prevention programs for older adults in Canada.

AbbVie's ELAHERE® receives positive reimbursement recommendation by Canada's Drug Agency for certain types of platinum-resistant ovarian cancers.

Libtayo® (cemiplimab for injection), from **Regeneron**, is now reimbursed in seven provinces for advanced non-small cell lung cancer and locally advanced basal cell carcinoma.

Libtayo® (cemiplimab for injection) from **Regeneron**, now reimbursed in Québec for advanced non-small cell lung cancer.

AstraZeneca's ENHERTU® approved in Canada as the first and only HER2-directed therapy for patients with HR-positive HER2-low or HER2-ultralow metastatic breast cancer, following disease progression after one or more endocrine therapies.

Health Canada grants **LSL Pharma Group** approval to commercialize six new **sterile ophthalmic solutions**.

ABRYSVO® from **Pfizer**, receives expanded public funding across Canadian provinces for the 2025–2026 RSV season.

Health Canada grants authorization for **LEQEMBI®** (lecanemab) from **Eisai**, for the treatment of early Alzheimer's disease.

Sanofi's Dupixent® (dupilumab injection) approved in Canada for adults with inadequately controlled Chronic Obstructive Pulmonary Disease (COPD).

Sanofi's high-dose influenza vaccine demonstrates superior protection for older adults against hospitalization vs standard-dose.

Pfizer Canada announces Health Canada approval for a new indication for **ABRYSVO®** for adults aged 18–59 who are at increased risk for RSV-related lower respiratory tract disease.

Sogroya® (somapacitan injection) produced by **Novo Nordisk**, now available in Canada as the first and only once-weekly treatment for both children and adults living with growth hormone deficiency.

Incyte Canada announces Health Canada approval of **Opzelura®** (ruxolitinib) cream for the treatment of atopic dermatitis in children ages 2–11.

CSL Behring signs letter of intent with pan-Canadian Pharmaceutical Alliance (pCPA) for public reimbursement of **HEMGENIX®** (etranacogene dezaparvovec), the first gene therapy for hemophilia B.

Product Newswire

Health Canada approves **Kye Pharmaceuticals' AGAMREE®** (vamorolone) as the first treatment for Duchenne muscular dystrophy in Canada.

Organon Canada announces the availability of **NDUVRA®** (tapinarof cream), 1%, for the topical treatment of plaque psoriasis in adults.

VYLOY® (zolbetuximab) from **Astellas Pharma**, in combination with chemotherapy for advanced gastric or gastroesophageal junction cancer, is now funded in both Ontario and Quebec.

Merck Canada and the pan-Canadian Pharmaceutical Alliance (pCPA) successfully complete negotiations for **WINREVAIR®** (sotatercept).

AbbVie's LUPRON DEPOT® receives Health Canada approval for a new strength for the treatment of advanced prostate cancer.

Arcutis Canada announces Health Canada approval of **ZORYVE®** foam 0.3%, the first steroid-free topical foam for scalp and body psoriasis, for adults and adolescents ages 12 and older.

Sun Pharma Canada Inc. acquires commercial rights to **LEVULAN® KERASTICK®**.

Rezurock®, developed by **Sanofi-Aventis**, is now covered in Quebec for people living with chronic graft-versus-host disease (GVHD).

argenx announces that the **VYVGART®** SC prefilled syringe for self-injection in chronic inflammatory demyelinating polyneuropathy has been authorized for sale by Health Canada.

Roche's VABYSMO® (faricimab injection) pre-filled syringe is now publicly funded through the Ontario Drug Benefit (ODB) program.

How a Diabetes Diagnosis Sparked Life-Changing Transformation

An Interview with Malcolm Kelly

Malcolm Kelly, Director of Sales at Gilead Sciences, took charge of his health in his late 40s, after being diagnosed with diabetes. He spoke to Hypothesis, about his initial denial, what motivated him to radically change his diet, and why everyone should be more proactive about their health.

Can you start by telling us a bit about yourself?

I grew up near Brampton, a very diverse, multicultural community. I started my career 25 years ago as an emergency nurse. I practiced full time in the emergency department for several years before deciding to enter the pharmaceutical industry. I continued to pick up casual shifts as a nurse, but I stopped practising during the pandemic. On the pharma side, I was promoted from sales rep to marketing director and eventually sales director. I've worked for startups as well as major pharmaceutical companies. I'm married with two boys, who are 21 and 18. I also played rugby up until about seven years ago, which was probably 10 years too long.

When did you find out you had diabetes?

I've been a big guy my whole life. I'm 6'5 and I weighed over 320 pounds for a very long time. My grandmother and my mother have diabetes. As an emergency nurse, I've treated many people with diabetes, but I ignored the symptoms when they were happening to me. Those symptoms included frequent urination, as well as feeling tired and thirsty all the time. Eventually, I couldn't ignore the symptoms anymore and I went to my family doctor.

> ***"When my doctor informed me that I was diabetic, at age 47, I felt disgusted with myself, angry, and in denial."***

When my doctor informed me that I was diabetic, at age 47, I felt disgusted with myself, angry, and in denial. I took a video of myself where I shared my feelings and frustrations. Later, every time I felt my diet or lifestyle was slipping, the rawness of the video reminded me why I needed to stay disciplined.

Initially, I decided to radically change the way I ate. I lost about 35 pounds, just with diet. But my blood sugar remained too high. I was then put on metformin, which is the typical first-line therapy for diabetes. My blood sugar continued to go up, however, even after my metformin dose was doubled. I was then placed in the care of an endocrinologist, who prescribed Ozempic. Over a very short period of time, I ended up losing another 35 pounds. My blood sugar dropped down to 5.2 mmol/L, which meant I was effectively in remission.

Another key part of my success was a continuous glucose monitor. This was not indicated for type two diabetics at the time, but I paid for it out of pocket. By wearing the monitor, I could see, almost in real time, how certain foods and activities would affect my blood sugar.

For the last couple of years, I've been in complete control of my diabetes. My blood sugar is, I dare say, at a normal level. I continue to manage it aggressively. I recently added Jardiance because it is protective against cardiovascular events, and it can more effectively lower blood sugar, compared to metformin. I've also switched from Ozempic to Mounjaro, which activates both the glucagon-like peptide-1 (GLP-1) and gastric inhibitory polypeptide (GIP) receptors, to increase insulin production. Some people ask me if I'm worried about the side effects of these medications and I say, "The side effects are all positive. These medications reduce inflammation in the brain, the kidney and the heart."

Thank you for sharing your journey. There are so many positive lessons for our readers, and I love the takeaway of recording a video to remind yourself of how far you've come. How did you stay motivated to maintain a healthier diet?

I learned about what sugar does to the body, and that knowledge made me want to avoid it. My family was supportive. They never questioned my choices. For example, if we were having pizza for dinner, I would eat the toppings of only one piece of pizza. I would avoid rice, buns, and potatoes. Once I recognized that my diabetes is genetic, I stopped blaming myself and instead focussed on what I could do to take care of myself.

Photo courtesy of freepik.com.

I'm not afraid of the word diabetes anymore. I'm actually proud of it. When I'm ordering coffee, I say that I'd like a medium coffee with two sweetener packets because I'm a diabetic. In a strange way, I wish I was diagnosed earlier, because I would have made positive changes earlier. At a younger age, I could have gotten a chance to see how losing 70 pounds makes me feel.

Are you talking to your sons about their familial diabetes risk?

We don't directly discuss it, but some of my lifestyle changes have rubbed off on my children. My sons and my wife will now look at nutritional labels. We are all more attuned to the foods we buy. We consider if there is an option with a higher protein and fiber count and lower carbohydrate count, for example. My children are both athletes, and studying kinesiology, so they know what they need to fuel their bodies.

How do you think your career in the pharmaceutical industry has affected how you manage diabetes?

Because of my career as a pharmaceutical professional and nurse, I know where to find information and how to interpret clinical trials. But I think anyone can do research and be proactive. I encourage people to be inquisitive and ask questions. If they're not getting helpful answers from their family practitioner, they can get a referral to a specialist.

> ***In a strange way, I wish I was diagnosed earlier. At a younger age, I could have gotten a chance to see how losing 70 pounds makes me feel.***

I think too many people don't question what their practitioner says. People should ask many questions, including why the doctor is recommending a therapy and what other options are available.

What do you think prevents people from being proactive about their diabetes?

I think people don't understand how serious diabetes is and, and how far-reaching the implications are for other organs in the body. I have a friend who I keep telling "You're diabetic." I tell him that he should get testing because the treatments today are fantastic. Now, he's purchased a Dexcom glucose monitor, and he's monitoring his blood glucose just to prove a point. I think it's very powerful to be able to see your blood sugar levels on your iPhone. I know people who don't have type two diabetes who are using these monitors just so they can see which foods spike their blood sugar.

I agree – people often don't make the connection between diabetes and kidney, heart, or eye problems. I'm curious about your opinion from a policy perspective. How can governments encourage lifestyle modifications to stave off chronic disease?

Before I was made aware of it by my disease, I knew that too much sugar led to health problems, but I didn't care. Now, I think it's wrong that there are cereals with 30 grams of sugar that parents feed their children for breakfast, or that many children have sugary granola bars as a daily snack because parents think that the oats make them healthy. I think the government should step in and start limiting the amount of sugar that companies can put in packaged goods. Let's not forget that sugar is the main cause of inflammatory diseases, which are the bane of humanity. Even cancer consumes sugar to survive. I think humanity would greatly benefit from a war on sugar.

When I was in high school, there was a tremendous number of people on the sidewalk smoking. Now, you drive by high schools, there might be one or two. The changes that we make now from a policy perspective may take time to take effect, but they can improve health for generations.

What more do you think the pharmaceutical industry can do to address the epidemic of type 2 diabetes?

I think industry should do a better job at promoting wellness. People should be more aware of the signs and symptoms of common conditions like diabetes. I think artificial intelligence could be leveraged in education. For example, there could be a tool where people can enter information like their weight, height, age, symptoms, and family history and receive credible information about their health, as well as lifestyle interventions that they should adopt to prevent diseases.

Malcolm Kelly, Director of Sales at Gilead Sciences

Malcolm started his professional career as a Registered Nurse. After working full-time in the Emergency Department, he transitioned to industry starting in Pharmaceutical Sales. He continued to practice Nursing causally for more than 25 years. Malcolm has enjoyed a long career in Pharmaceuticals where he held several progressive roles including Sales Representative, Director of Marketing and Director of Sales at both large and start up Pharmaceutical companies. Malcolm has extensive experience in Virology, Infectious Diseases, Dermatology, managing biologics. Malcolm and his wife Kim are proud parents to their 2 sons and enjoying watching them grow and play football at STFX University in Nova Scotia. Malcolm enjoyed playing rugby for 30 years, coaching and administrative roles in Milton Minor Hockey as President for 10 years and now coaching a high level of Minor Football in Burlington. Malcolm was diagnosed with Type II Diabetes over 4 years ago and has managed to turn this diagnosis into a positive opportunity to optimize his health.

Modern Launch: The New Playbook for Brand Commercialization in Pharma

Luke Greenwalt, VP and Lead, U.S. Thought Leadership & Innovation, IQVIA,
Brian Lasky, Sr. Principal and Lead, U.S. Launch Center of Excellence, IQVIA

This article originally appeared on October 20, 2025, at www.iqvia.com.

This blog is part of an ongoing series, A Brave New World: Finding life science success in modern markets.

Introduction

Launching a new pharmaceutical product has always been a high stakes endeavor. But in today's environment, the rules have changed. The traditional 6- to 12-month window for measuring launch success has expanded into a 36-month horizon, driven by evolving payer dynamics, shifting provider behaviors, and increasingly complex patient engagement strategies. This new reality demands a recalibration of expectations, investments, and strategic planning.

The Harsh Truth: Launch Conditions Are Tougher Than Ever

Pharma manufacturers are facing the harshest launch conditions in recent history. First-year sales performance has declined across the board, regardless of therapeutic innovation or disease area. Uptake curves are shallower, adoption is slower, and payer restrictions are more aggressive.

In fact, in a recent study of 559 launches, only 1 in 10 products launched between 2020 and 2024 exceeded $100M in first-year sales, compared to 1 in 5 during the 2015–2019 period. Even more striking, among the launches studied over the last decade, only 11 surpassed $1B in their first year, half of which occurred in the last three years, driven by glucagon-like peptide-1s (GLP-1s) and RSV vaccines. These figures underscore the growing difficulty of achieving commercial success but also highlight that it is still possible.

Three Forces Reshaping Launch Performance

The modern launch environment is shaped by three interdependent forces:

1. Payer control and access suppression

Payers are exerting unprecedented control over new therapies. Launch year rejection rates have climbed steadily, with durable rejections now affecting over 60% of new patients for many brands. Even when coverage is technically available, abandonment rates, where patients choose not to fill prescriptions, are rising, often due to high out-of-pocket costs.

Manufacturers are increasingly reliant on transitional assistance programs to overcome these barriers, but such support is not sustainable in the long term. The takeaway: access is no longer guaranteed, when achieved it costs more than ever, and payer engagement must begin well before launch.

2. Provider adoption lag and share of voice

Healthcare provider adoption rates vary for new launches as some are slower to adopt new therapies. A recent analysis of over 26,000 oncology providers across all launches between 2012–2025 revealed that only 20% of providers consistently adopted a new product within the first two years post launch. It was much more common to see adoption occur in years three and four than any other period following launch. This could be driven by early questions on drug efficacy, the need for evidence beyond Phase III

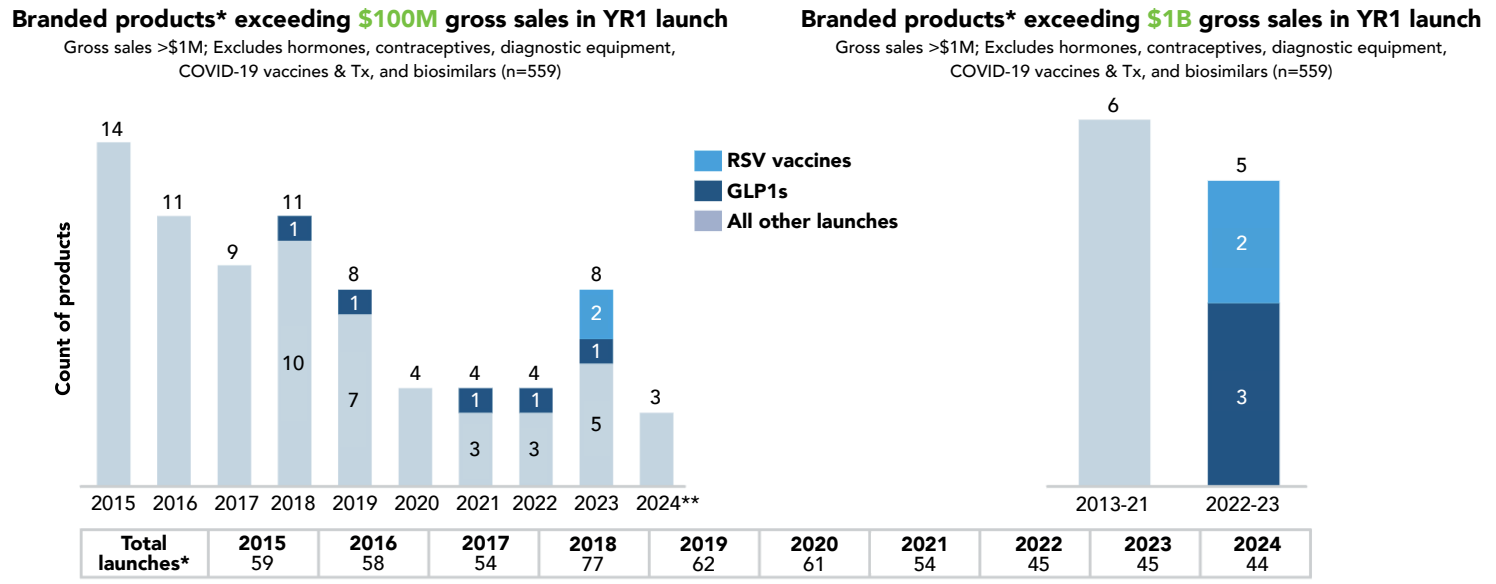

Figure 1. *Gross sales in YR1 launch for branded products.*

Source: *IQVIA Launch Encyclopedia.*

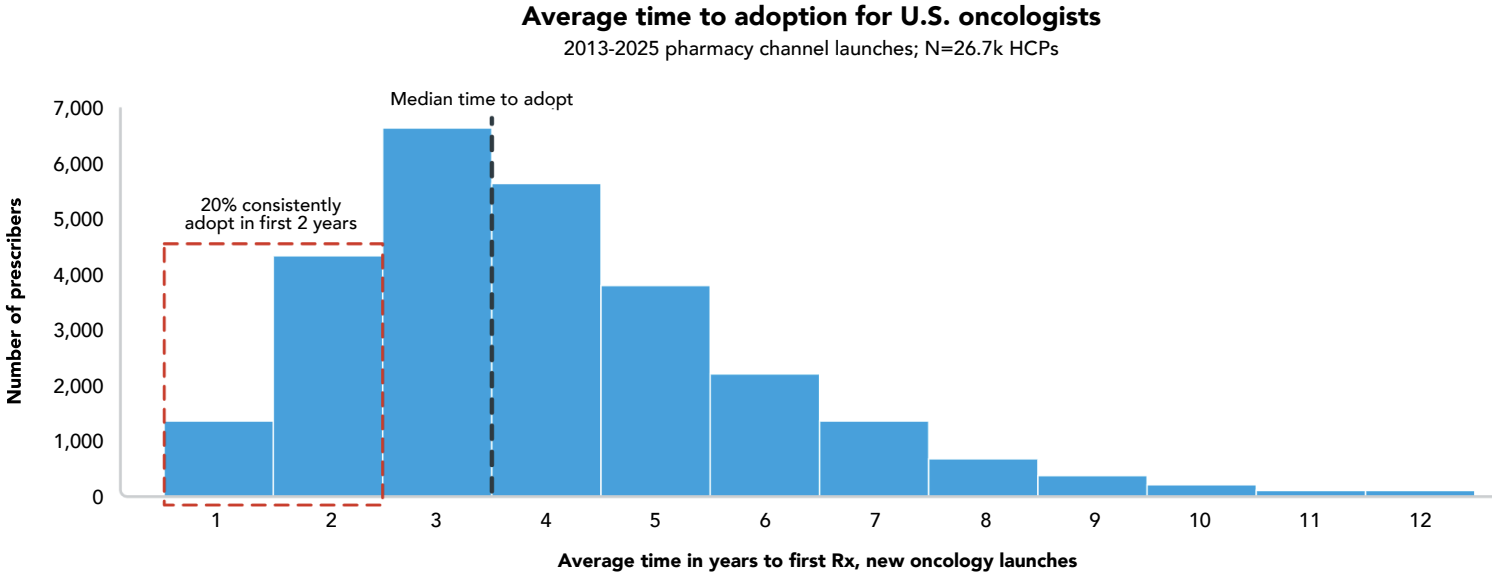

Figure 2. *Average time to adoption for U.S. oncologists.*

Source: *IQVIA Analysis; Launch Success Encyclopedia; Physician Targeting Library, LAAD 2013-2025, Xponent 2013-2024*

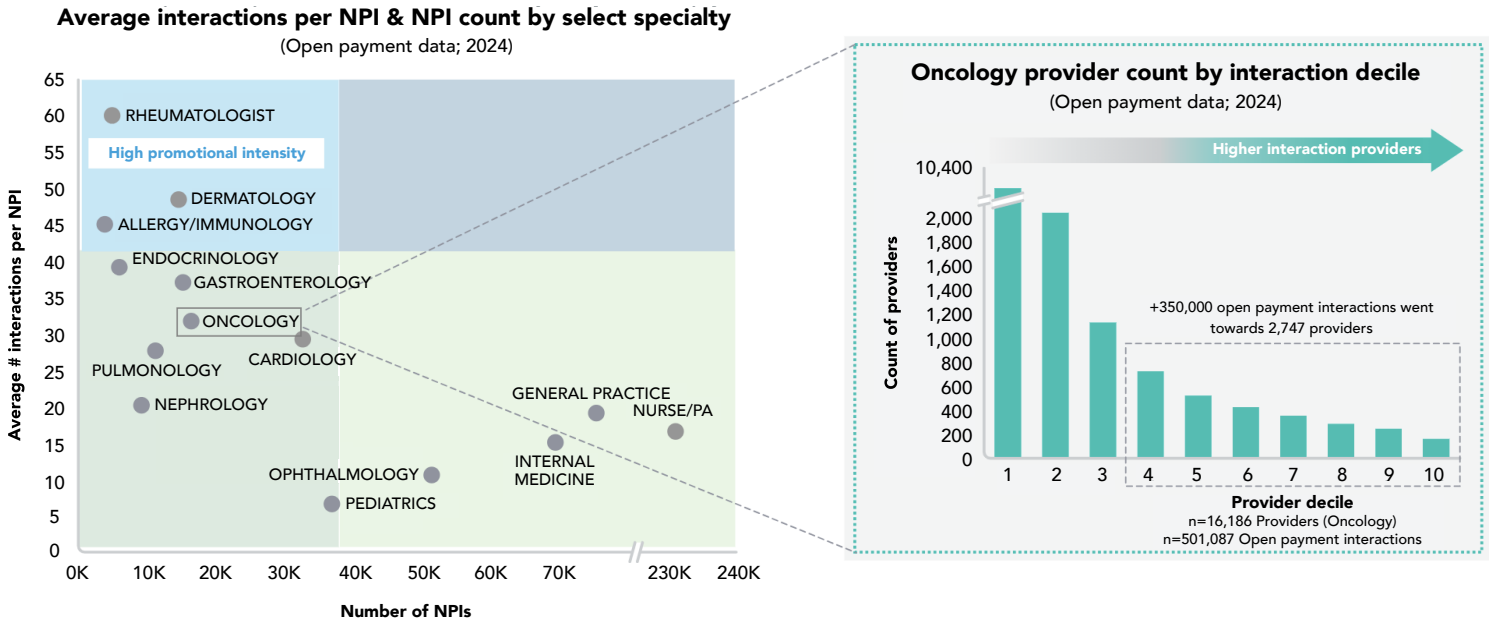

Figure 3. *Average interactions per NPI & NPI count by select specialty.*

Source: *Open Payment Data; IQVIA Physician Targeting Library*

Abbreviations: NPI: *National Provider Identifier*

clinical trials, the role of key opinion leaders in their network, or payer coverage obstacles in a complex payer environment. Regardless, understanding provider adoption behavior across all launches, not just within the therapeutic area of interest, is now a required launch strategy.

This lag is compounded by promotional intensity. In highly competitive specialties like oncology with many launches, complex regimens, and clinical pathways, manufacturers must invest heavily to be heard. Conversely, in less promotionally intense areas, a smaller investment can yield a louder share of voice. Understanding these dynamics is critical to optimizing promotional mix and spend as well as understanding the level and cost of effort required to activate providers.

In a study of the Medicare Open Payment Data (MOPD), often referred to as the Sunshine Act data, competitive intensity in high launch volume specialties becomes clear. Medicare Open Payments Data is a publicly available, federally mandated database of financial relationships between the healthcare industry and physicians and teaching hospitals, as required by the Affordable Care Act. Comparing the number of Open Payments to the number of prescribers within a specialty demonstrates just how much activity is occurring and how it is concentrated. It is no surprise that the most competitively intense specialties are those with the highest number of launches.

Consider oncology as a case study. Broadly, there were 501,087 MOPD interactions against 16,187 unique oncology providers in 2024. That averages just over 30 interactions per prescriber. Breaking out the distribution of interactions in oncology demonstrates the high level of activity concentrated in a relatively small number of providers. With over 350,000 MOPD interactions against 2,747 providers, the level of aggregate noise competing for share of mind is high. Pharmaceutical manufacturers must understand the totality of promotional effort that goes into a specialty when designing launch strategies. Both underinvesting and overinvesting carry consequences.

3. Patient Activation and Consumerism

Patients are increasingly influential in therapy selection, especially in chronic and lifestyle-related conditions. Direct-to-Consumer (DTC) strategies are being deployed earlier and more aggressively, reflecting a shift toward consumer-driven healthcare. However, patient activation alone is insufficient without payer coverage, provider endorsement, and an effective patient support program to prevent leakage.

Manufacturers must orchestrate a coordinated, three-pronged engagement strategy that targets patients, providers, and payers simultaneously that can drive uptake and sustain momentum.

The New Launch Window: 36 Months to Success

One of the most critical challenges in modern launch is the phenomenon of launch suppression, characterized by a plateau or decline in performance after the initial six months. This trend often leads to premature budget cuts and reduced promotional activity as launches fail to meet internal forecasts. The expectation gap between post-launch performance and pre-launch assumptions can be stark. Knowing the real drivers and barriers of performance earlier can both highlight and accelerate necessary remediations.

However, trends tend not to deviate past six months unless the launch plan accounts for environmental changes. Success may not be visible in the first year, but with the right strategy, growth can continue well into the second and third years.

Success may not be visible in the first year, but with the right strategy, growth can continue well into the second and third years.

Given these dynamics, brand performance expectations and forecasting must reflect significant milestones over a 36-month launch window, rather than the traditional 12-months. Staging investments to happen when those milestones are reached can prevent investing too far in front of market readiness. In launch, to use a football term, it is very easy to outkick your coverage.

Manufacturers must recognize that:

- Medicare access may take years to open up
- Prescriber habits evolve slowly beyond early adopters
- Payer negotiations and formulary placement are constant challenges
- Evidence or Key Opinion Leader support is often required to activate certain stakeholder segments

Cutting funding or scaling back promotional efforts at the 12-month mark, especially those based on outdated performance expectations, can be fatal. Brands that continue to invest strategically beyond year one are more likely to achieve sustained growth and ROI.

Optimized Indication Strategy

Indication stacking is also a critical but often overlooked consideration in launch planning. Bimzelx offers a compelling example of how a modern launch strategy can yield strong results, even in a competitive and suppressed market environment. Launched in late 2023, Bimzelx achieved notable sales despite spending significantly less than its peers during launch.

Within its first year, Bimzelx added three additional indications: psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis. Later in 2024, it expanded further into hidradenitis suppurativa. This rapid indication stacking allowed Bimzelx to broaden its prescriber base and patient reach quickly.

What makes Bimzelx's success particularly noteworthy is its optimized promotional spending. Compared to competitors, Bimzelx operated with a comparatively leaner budget but achieved similar uptake. This demonstrates that strategic targeting can outperform brute force promotional intensity.

However, this approach to additional indications may not be universally applicable. The decision to stack or sequence indications should be guided by product characteristics, therapeutic adjacency, lifecycle strategy, and payer preferences. There is no one-size-fits-all method, but every product needs a strategy.

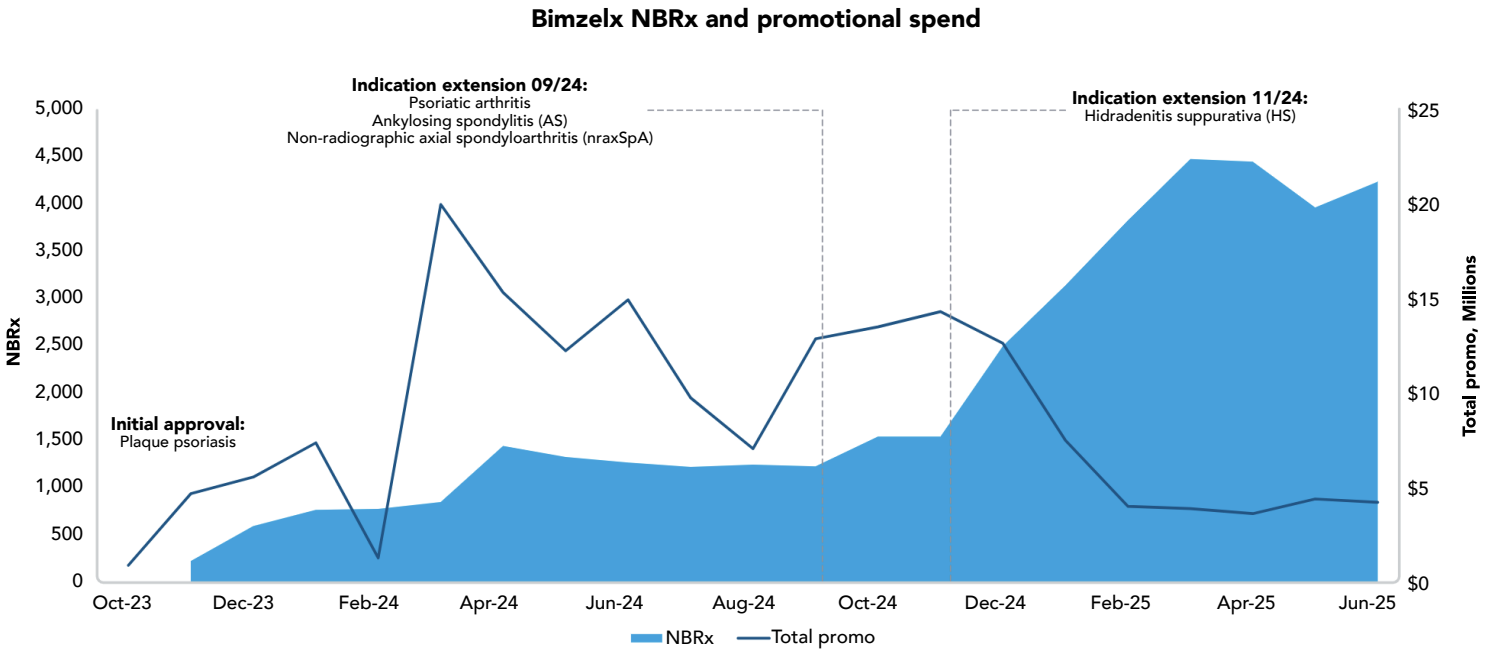

Figure 4. *Bimzelx NBRx and promotional spend.*

Source: *National Sales Executive; Launch Center of Excellence, IQVIA; publicly available information from the FDA*

Abbreviations: NBRx: *New-to-Brand Prescription*

Rethink, Reinvest, Realign

Pharma manufacturers must embrace the modern launch paradigm with a renewed mindset. The call to action is clear:

- **Think long term:** Success may take thirty-six months, not six.
- **Think above brand:** Understanding physician, system, and market behavior means expanding study to look at all brands not just those within a therapeutic area or class.
- **Invest strategically:** Don't cut funding prematurely, rather align spend with uptake curves, market dynamics, and stage investment based upon milestones.
- **Engage holistically:** Activate patients, persuade payers, and educate providers in parallel. Think multi-dimensional on how evidence can be used across stakeholders.
- **Customize your approach:** Tailor strategies by specialty, geography, and therapeutic area.

The modern launch environment is complex, but it is navigable. With the right data, insights, and execution, manufacturers can overcome suppression, unlock access, and achieve meaningful impact.

Who's Doing What and Who's Going Where

Andrew Balram has started a new position as Senior Manager, Marketing, Specialty Business at ***SUN PHARMA.***

Shawn Ferron has taken up a new role as the Sales Team Lead & Medical Representative at ***Kye Pharmaceuticals***.

Malcolm Kelly has embarked on a new role as Director of Sales - National at ***Gilead Sciences***.

Lorry Podrebarac has joined the ***Kye Pharmaceuticals*** sales team.

Shawna Boynton is starting a new position as Director, Marketing, Aesthetics at ***Galderma***.

Tanya Calero has joined ***argenx*** Canada as Associate Director of Marketing.

Hillary Wen has taken up a new role in rare diseases, focusing on HAE with ***BioCryst***.

Nathalie Faubert has joined ***Kye Pharmaceuticals*** as Medical Representative.

Natalie Boucratie was promoted to Sr. Director, Head of Legal and Compliance at ***Gilead Sciences***!

Ryan Forsythe has started a new position as Therapeutic Specialist, Dermatology at ***AbbVie***.

Andrea Mulder has embarked on a new role as Associate Director of Marketing, Rare Diseases at ***Recordati Rare Diseases Canada***.

Nathalie Lavoie has taken up a new role as Représentante en soins primaires Migraine with ***AbbVie***.

Danielle Portnik has started a new position as Country Manager & Head of Business, Canada for ***Emergent BioSolutions***.

People on The Move

Steven Elmes is starting a new position as Vice President, Medical Affairs at ***Taysha Gene Therapies***.

Laurene Redding has embarked on a new role as Head, Market Access & Government Relations at ***Gilead Sciences/ Kite Pharma***.

Alexandre Boulerice-Raymond has taken up a new role as Territory Sales Manager, Aesthetics at ***Salient Medical Solutions***.

Robin Hunter has started a new position as General Manager at ***Elvium***.

Dominique Vezina has joined ***Kye Pharmaceuticals*** as a Medical Representative.

Nichol Pelchat has taken up a new role as Associate Director, Marketing, Contraception at ***Organon Canada***.

Chiming Yang has embarked on a new role as Executive Medical Science Liaison at ***Ipsen Biopharmaceutical Canada, Inc.***

Mike Principe is starting a new position as Director of Sales, Ontario and Atlantic Canada at ***The Stevens Company.***

Matthew Bergamin has started a new position National Sales Manager Hematology at ***GSK***.

Emma Davis has embarked on a new role as Strategic Pricing Manager at ***AstraZeneca.***

Peter Klingvall has taken up a new role as Alberta Territory Manager at ***ViiV Healthcare***.

Maria Campbell is starting a new position as Patient Affairs and Advocacy Manager at ***GSK***.

Derek Thériault has embarked on a new role as National Sales Director at ***Knight Therapeutics Canada***.

Ryanne Kosick has started a new position as Oncology Marketing Manager at ***Bayer***.

Shaun Hebert has taken up a new role as Customer Engagement Training (CET) - Oncology Brand Training Manager at ***Pfizer***.

Catherine Paquette is starting a new position as Senior Manager, Government Relations & Access, ON, at ***Pfizer***.

Brent Humber embarked on a new role as District Manager, Hematology at ***AbbVie***.

Zosia Slupski is joining ***Kye Pharmaceuticals*** as Marketing Manager.

Paul Zuckernick has started a new position as Kerendia Account Specialist at ***Bayer***.

Rob Bonsor has joined ***Kye Pharmaceuticals*** as Medical Representative in Eastern Ontario.

Hannah Van Hofwegen has taken up a new role as Territory Manager, Eastern Ontario & Maritimes at ***Neodent***!

Marian Staite is starting a new position as Medical Science Liaison at ***Arcutis Biotherapeutics***!

Nancy Tomasino-Prete has taken up a new role as Manager of Medical Education - Infection Prevention and Surgical Solutions, North America, at ***Solventum***!

Heidi Brunner-Bindi has embarked on a new role as Director of Sales, Primary Care, Vaccines, at ***GSK***!

Dave Crosier has started a new position as Territory Business Manager at ***Knight Therapeutics Canada***!

Pascal Safi has started a new position as National Sales Manager, Plastic Surgery & Regenerative Medecine at ***Allergan Aesthetics,*** an ***AbbVie Company***!

Rob Rafanan has taken up a new role as Canadian Sales Manager at ***Methapharm***!

Taline Movsessian has been promoted to Associate Vice President, Medical Affairs at ***Eli Lilly and Company***!

Mary Arsanious has started a new position as Immunology Lead at ***BioScript Solutions***!

Jeff Tam is starting a new position as Associate Director, Commercial Hematology at ***Eli Lilly and Company***!

Erin Webb has joined ***FORUS Therapeutics Inc*** as Therapeutic Area Manager, Hematology/Oncology!

Lara Coudsi has embarked on a new position as Regional Manager, Hematology for ***BeOne Medicines***!

Brad Donoff has taken up a new role as Territory Business Manager - Neurology at ***Knight Therapeutics Canada***!

Lisa Kolomaya has joined ***FORUS Therapeutics Inc*** as Therapeutic Area Manager, Hematology/Oncology!

Alain Beaurivage has started a new position as National Sales Manager - Dermatology CSU at ***Regeneron***!

James Scrivens has embarked on a new role as Medical Lead - Oncology at ***GSK***!

Laura D'Antico has started a new position as Regional Sales Manager and National Oncology Lead at ***Knight Therapeutics Canada***!

Please submit your selection for our "People on the Move" section, celebrating the advancements of your colleagues, for upcoming issues via email to info@catalytichealth.com.