pharmaphorum

deepdive

Pharma vs. the Inflation Reduction Act

A legal showdown is brewing in the US as pharma companies challenge the constitutionality of Medicare drug pricing reforms

September 2023:
Communications & Commercialisation

How to evaluate an omnichannel solution

Celebrating 75 years of the NHS

EU pharmaceutical reform: balancing access, innovation, and concerns

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Deep Dive: Communications & Commercialisation 2023

As we enter into the closing months of 2023, it's hard to deny that the year so far has been dominated by one of the most contentious and polarising topics in healthcare – drug pricing.

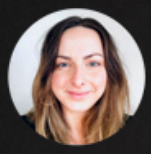
Little over a year since President Joe Biden signed the controversial Inflation Reduction Act (IRA) into law, it's safe to say that the fight over the provisions aimed at lowering prescription drug costs is heating up. As of today, nine companies have filed lawsuits challenging the constitutionality of the new law, arguing that the IRA's provisions may restrict investments in research development and curb innovation.

While the legislation may be a bitter pill for the industry to swallow, for patients the benefits are a welcome rebalance of power between pharma stakeholders and publicly appointed government representatives.

To help break down the core arguments for each side of the IRA debate, pharmaphorum editor-in-chief Jonah Comstock unpacks each legal challenge and explores the broader impact of the IRA for both industry and patients.

Elsewhere in this issue of Deep Dive, we take a look back at the storied history of the UK's National Health Service to mark the organisation's 75th anniversary, plus Lumanity's Gagandeep Sawant and Lindsay Lare offer a simple framework to help guide companies along their journey of choosing the right omnichannel partner.

For all this and more, read on.



Eloise
Eloise McLennan – editor, Deep Dive

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Celebrating 75 Years of the NHS: A timeline

Since its inception in 1948, the National Health Service (NHS) has played a crucial role in providing accessible healthcare to millions in the United Kingdom. Over its history, the NHS has undergone significant changes, impacting the lives of both patients and healthcare professionals. To celebrate 75 years of the organisation, join us as we take a journey through time to explore some key milestones that shaped one of the world's most recognisable health systems.

Pre-1948

Pre-1948 – Out of the frying pan, into the fire

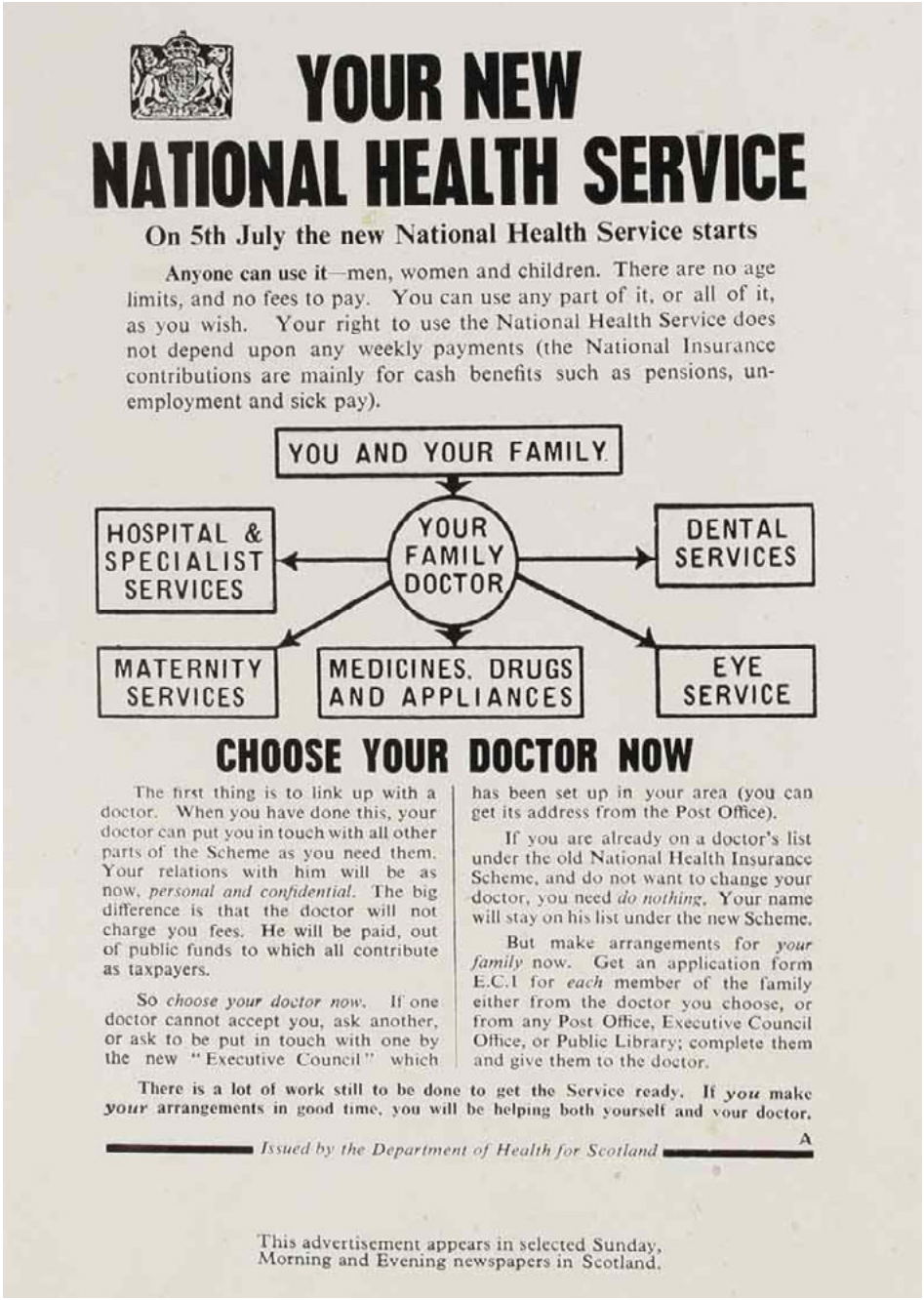
Although the NHS as we know it would not take shape until much later in the decade, in 1942, a report by economist Sir William Beveridge, written during the darkest days of WWII, laid out a revolutionary idea for a post-war nation that would provide the blueprint for social policy in Britain.

"A revolutionary moment in the world's history is a time for revolutions, not for patching," he wrote.

Public hunger for change had been mounting for some time. Before the NHS, general practice covered workers aged between 16 and 70 under the National Insurance Act of 1911, but this did not extend to their families or children, for whom medical attention came hand in hand with a hefty price tag. Even those who could afford the expense were not guaranteed treatment. Underfunding and the ravages of war had reduced the health service to near bankruptcy.

Pain and discomfort were widely considered an unpleasant reality of life, to be endured with the famed British stiff upper lip mentality. But after two world wars, the nation was ripe for change – beginning with the government.

When Clement Attlee's Labour party won the 1945 general election, the creation of a national health system was a top priority. Charismatic Welshman Aneurin "Nye" Bevan was tasked with bringing this ambitious vision to life as the new health minister. He set out three founding principles around which the new health service would be built: that it should be available to all, regardless of wealth or status, that it be free at the point of delivery, funded via general taxation, and with responsible application.



YOUR NEW NATIONAL HEALTH SERVICE

On 5th July the new National Health Service starts

Anyone can use it—men, women and children. There are no age limits, and no fees to pay. You can use any part of it, or all of it, as you wish. Your right to use the National Health Service does not depend upon any weekly payments (the National Insurance contributions are mainly for cash benefits such as pensions, unemployment and sick pay).

CHOOSE YOUR DOCTOR NOW

The first thing is to link up with a doctor. When you have done this, your doctor can put you in touch with all other parts of the Scheme as you need them. Your relations with him will be as now, *personal and confidential*. The big difference is that the doctor will not charge you fees. He will be paid, out of public funds to which all contribute as taxpayers.

So *choose your doctor now*. If one doctor cannot accept you, ask another, or ask to be put in touch with one by the new "Executive Council" which has been set up in your area (you can get its address from the Post Office).

If you are already on a doctor's list under the old National Health Insurance Scheme, and do not want to change your doctor, you need *do nothing*. Your name will stay on his list under the new Scheme.

But make arrangements for *your family* now. Get an application form E.C.1 for *each* member of the family either from the doctor you choose, or from any Post Office, Executive Council Office, or Public Library; complete them and give them to the doctor.

There is a lot of work still to be done to get the Service ready. If *you* make *your* arrangements in good time, you will be helping both yourself and your doctor.

Issued by the Department of Health for Scotland A

This advertisement appears in selected Sunday, Morning and Evening newspapers in Scotland.

National Health Service leaflet, May 1948. Image courtesy of The National Archives, public domain, via Wikimedia Commons

On the surface, these all seem highly uncontroversial proposals, and yet, almost immediately, Bevan found himself fighting an uphill battle. Not only was much of the country's healthcare infrastructure war-damaged, but fierce opposition raged from all fronts: consultants, doctors, the Conservative Party, and even his own peers in the Labour cabinet.

For the next three years, Bevan battled the British Medical Association (BMA) at the negotiating table. The conflict grew increasingly public as each side traded blows in the media – Bevan was denounced as "a complete and uncontrolled dictator" and the BMA accused of engaging in "a squalid political conspiracy". Finally, after the BMA threatened to boycott the new service in 1947, a deal was brokered. General practitioners would retain control over their surgeries, operating as a small business, while consultants could both work for the service and retain their private patients. As a disgruntled Bevan put it, he "stuffed their mouths with gold".

1948 – A bold new beginning

At just 13 years old, it's unlikely that little Sylvia Diggory wholly understood her importance in British history when she was admitted to Park Hospital (now Trafford General Hospital) in Manchester for liver problems on 5th July 1948. As the first patient to be treated on the NHS, Diggory received an unusual visitor at her bedside – Aneurin Bevan, the health minister himself, had come to meet the little girl whose treatment would signal a turning point for healthcare in the UK.

With the service now in operation, for the first time, the UK Government assumed responsibility for the provision of preventative and curative healthcare services for the entire population.

To the outside observer little had changed – at least superficially. The arrival of the NHS brought with it no additional doctors or nurses to mark the transition; rather, a tectonic shift in the way that healthcare functioned in the UK. Its impact may not have been immediately apparent, but the waves of change were in motion, to be felt for years to come.

Aneurin Bevan, Minister of Health, on the first day of the National Health Service. Image Courtesy of University of Liverpool Faculty of Health & Life Sciences from Liverpool, United Kingdom, CC BY-SA 2.0 , via Wikimedia Commons

1950s – The cost of a cure

Unfortunately, as is often the case, expenditure quickly exceeded predicted expectations. With an expected cost of £176 million, it seemed that architects of the NHS had significantly underestimated just how in demand the service would be. In fact, by the end of 1948, initial estimates would be utterly dwarfed by the nearly £400 million price tag.

To manage rising costs, in the early 1950s, Prime Minister Clement Attlee's government proposed charging patients for prescriptions, glasses, and dental care, alongside plans to transfer money from the National Insurance Fund to finance rearmament.

For Bevan, by now the labour minister, this decision was a step too far. Sticking by his staunch opposition to any imposed charges on the NHS, in 1951 Bevan resigned. His parting remarks before Parliament made clear his position on the proposed cuts as he chastised then Chancellor of the Exchequer Hugh Gaitskell's plan to "mutilate" the health services, stating, "The Health Service will be like Lavinia – all the limbs cut off and eventually her tongue cut out, too."

While Gaitskell and the broader Attlee administration would be ousted from power only a few months later, plans to introduce charges remained. In 1952, the newly elected Conservative government, led by Winston Churchill, recommended a one shilling (5p by today's standards) prescription charge, a two-pence increase in national insurance contributions, hospital 'amenity' charges, and charges for dental treatment.

Young Red Cross nurses, 1950s
Young Red Cross volunteers from London in training at a hospital. Image courtesy of British Red Cross via Flickr

In the years following Bevan's departure, the NHS continued to thrive as discoveries and capabilities expanded the range of available treatments. Perhaps the most notable came from a group of rather ordinary scientists – and one extraordinary discovery.

In 1953, James D Watson and Francis Crick, with invaluable contributions from Rosalind Franklin and Maurice Wilkins, developed a model for a helical structure of DNA. Their discovery proved to be one of the most important scientific breakthroughs to date and helped to revolutionise the study of disease and enhance medical treatment in the NHS and abroad.

The NHS continued to make significant achievements late into the 1950s. Throughout the decade, antibiotics became more widely available for civilian use. These medications became a cornerstone of modern medicine, used to treat a wide range of bacterial infections, including pneumonia, urinary tract infections, and skin infections. Moreover, in 1958, a staple feature of primary care was born, introducing routine vaccination programmes for children under 15. The first such effort, which targeted polio and diphtheria, proved highly successful, dramatically reducing cases of both illnesses.

1960s

1960s – Breaking the norm

The decade kicked off with a bang as, in late 1961, then Minister for Health Enoch Powell (yes, that Enoch Powell) announced to the House of Commons that 'birth control pills' could now be prescribed on the NHS.

This decision to provide contraceptive services represented a significant departure from the past reluctance to offer birth control through the NHS. The contraceptive pill, a revolutionary breakthrough in reproductive health, played a pivotal role in this change. Developed during the 1950s by American scientists led by Dr Gregory Pincus and championed by women's rights campaigner Margaret Sanger, the pill, known as Enovid in the USA, was licensed in 1960. Clinical trials conducted in Birmingham, Slough, and London during 1960 paved the way for its approval by the Ministry of Health for availability on the NHS.

With the pill's inclusion in NHS services, the early 1960s witnessed a rapid increase in prescriptions from general practitioners. The market saw the emergence of multiple brands, with the number of available brands growing from five in 1963 to fifteen in 1966. This accessibility resulted in a surge of patients seeking birth control pills through their GP surgeries. By 1970, approximately 700,000 married women between the ages of 16 and 40 were obtaining the pill through their GPs, marking a significant shift in family planning.

Bottle of Enovid 10mg Oral Contraceptive. Image courtesy of Science History Institute, public domain, via Wikimedia Commons

While the contraceptive pill was breaking the mould of reproductive healthcare, the 1960s also witnessed significant progress in the field of organ transplantation. The decade saw the first successful kidney transplant at Edinburgh Royal Infirmary, involving identical twins. Additionally, in 1968 South African-born surgeon Donald Ross conducted the first heart transplant at the National Heart Hospital in London. Furthermore, in a first for Europe, Professor Sir Roy Calne performed the Continent's first liver transplant at Addenbrooke's Hospital in Cambridge.

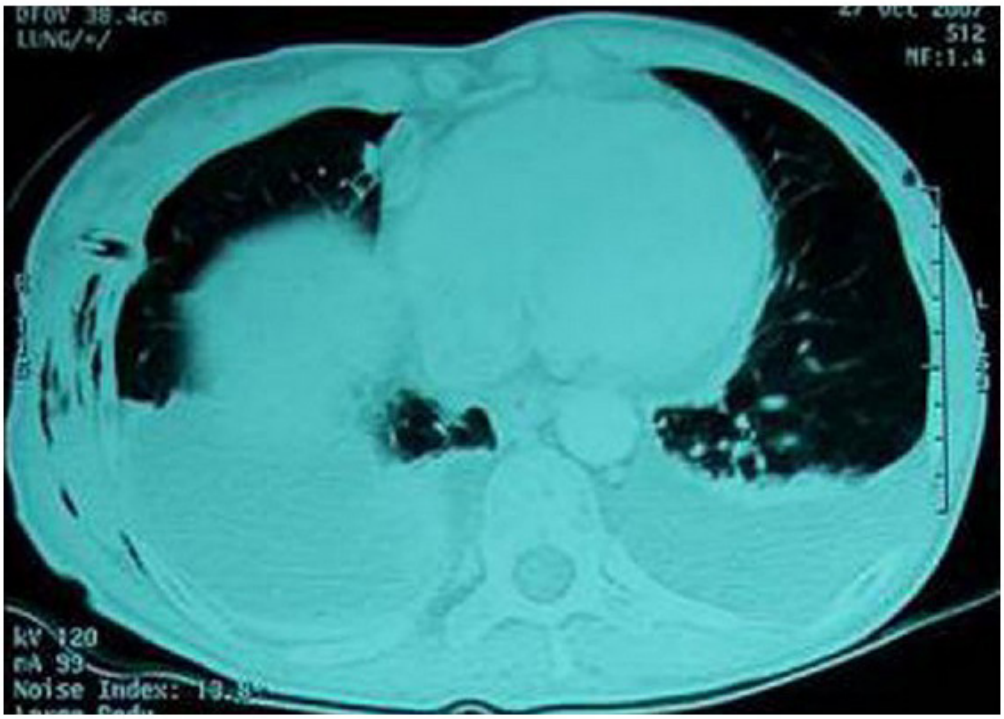
1970s

1970s – CT scans and IVF pioneers

In 1972, a medical breakthrough revolutionised the way doctors examined the human body. The introduction of CT scans allowed for the production of three-dimensional images from a series of two-dimensional X-rays. This innovation provided clinicians with a powerful tool to diagnose and treat a wide range of medical conditions, greatly enhancing the precision and effectiveness of healthcare.

One of the most iconic moments in the history of the NHS occurred in 1978, when Louise Brown, the world's first test-tube baby, was born. This remarkable achievement was the result of in-vitro fertilisation (IVF), a pioneering technique developed by Dr Patrick Steptoe. IVF opened up new possibilities for couples struggling with infertility and reshaped the landscape of reproductive medicine.

Amidst these medical breakthroughs, the NHS underwent a significant transformation in 1974, following the enactment of the NHS Reorganisation Act 1973. This legislation represented a sweeping structural and administrative reform of the healthcare system. It unified the previously separate administrative structures for hospital services, family practitioner services, and personal health services into a single, integrated system.



CT scan showing bilateral pleural effusions. Image courtesy of Laskaridis L1, Kampantais S, Toutziaris C, Chachopoulos B, Perdikis I, Tahmatzopoulos A, Dimitriadis G, CC BY 3.0 , via Wikimedia Commons

The Act abolished regional hospital boards and hospital management committees, replacing them with regional health authorities (RHAs) and 90 area health authorities (AHAs). These new entities were entrusted with the planning and delivery of healthcare services, streamlining the management of the NHS. Moreover, the Act vested the Secretary of State for Health and Social Security with responsibility for school health, consolidating healthcare oversight.

1980s – A changing of the guard

The 1980s were a pivotal period in the history of the NHS, marked by a unique blend of challenges, resilience, and groundbreaking research, particularly in the context of the emerging HIV/AIDS epidemic.

At the outset of the 1980s, the NHS was already grappling with financial constraints that demanded efficiency improvements and cost-saving measures. The need to allocate resources effectively became more critical than ever.

The NHS faced a defining moment in 1983, following an inquiry into the effective use and management of manpower and resources. Authored by Sir Roy Griffiths, a director of J Sainsbury's plc, the Griffiths Report made several recommendations that led to the introduction of general management in the NHS.

Major shifts of power occurred following the introduction of general management, with the introduction of the health services supervisory board and, later, the NHS Management Board putting an end to the era of consensus management.

In another highly controversial move, the government, led by Prime Minister Margaret Thatcher, introduced the contentious 'Internal Market' reforms. This policy aimed to introduce competition within the NHS, with the goal of improving efficiency and care quality. These reforms generated passionate debates within the healthcare community, with some fearing that they might compromise the core principles of a publicly funded healthcare system.

Prime Minister Margaret Thatcher arriving at 10 Downing Street in London after winning the 1979 general election. Image courtesy of Press Association via Flickr

While these challenges persisted, the 1980s also witnessed notable achievements in the field of medical research and patient care. As the HIV/AIDS crisis unfolded globally, the NHS played a significant role in HIV research and care. In 1983, the NHS established specialised clinics to provide comprehensive care and support for HIV-infected individuals, contributing to the early understanding and management of the disease.

Furthermore, the NHS actively participated in HIV/AIDS research, collaborating with international partners to develop treatments and therapies. These efforts would eventually lead to significant breakthroughs in the fight against HIV/AIDS.

1990s

1990s – Enter the 'NICE' era

With the advent of the 1990s, the NHS witnessed significant progress in pharmacological advancements. New drugs, such as statins for cholesterol management and proton pump inhibitors for acid reflux, transformed the treatment of chronic conditions.

The 1990s also marked a change in the way that organ donation is conducted in the UK. Although organ donor cards had been in use since the late 70s, there was no central donor registry, which meant that those without cards or informed next-of-kin, may not be able to donate, even if they would have chosen to. Following a five-year public campaign, the NHS Organ Donor Register was set up in 1994 for people wishing to donate their organs.

For nearly 50 years, decisions surrounding which drugs qualified for funding were typically made at the local level. However, there were growing concerns that patients across the country were being denied treatments that other areas could access. Dubbed the 'postcode lottery', this inequality in prescribing fuelled demand for a nationwide approach to determining what therapies should be available on the NHS.

In 1999, this call for change was answered in the form of the National Institute for Clinical Excellence (now known as the National Institute for Care Excellence) – or NICE, for short.

With Sir Michael Rawlins appointed NICE's first chairman, and Sir Andrew Dillon named the chief executive, the organisation got off to a rapid, and rather tumultuous start. Just a few months after being established, NICE set to work on conducting its first drug appraisal – an antiviral treatment for flu, developed by one of the world's most influential pharmaceutical companies. After a robust review, NICE determined that there was not enough evidence to show the drug reduced the severity of the illness, that it wasn't cost effective, and that it therefore should not be used by the NHS.

Unsurprisingly, said pharma company was not overly pleased with this outcome, with a chairman reportedly threatening to consider transferring the business out of the UK unless the decision was overturned. However, this controversial move cemented NICE as a tough, but fair sparring partner for the pharma industry.

2000s

2000s – A new millennium

The NHS embraced the digital age moving into the new millennium. In 2000, the organisation added to its ongoing NHS Direct pilot programmes in contact centres around England, until the entire country was covered by the telephone service. The same year the NHS direct website launched, empowering patients to access reliable health information online, and inadvertently foreshadowing the growth of telehealth and telemedicine services.

Amid these milestones, the 2000s also saw Great Ormond Street Hospital (GOSH) launch the world's first gene therapy trials for children born without functioning immune systems. Dubbed 'bubble boy', by the media, due to his vulnerability to even the most minor infection, Rhy Evans was just a year old when he became the first child in the UK to be treated with gene therapy. At the time, children with his condition – Severe Combined Immunodeficiency – had a life expectancy of one to two years. Thanks to this pioneering treatment, and the staff at GOSH, Evans is now in his 20s.

Furthermore, the decade was defined by the ambitious 2000 NHS Plan, which outlined a strategic vision to modernise and improve healthcare services. This comprehensive plan aimed to reduce waiting times, enhance patient care, and introduce new treatments and services. The plan also marked an important step in establishing closer relationships between the private sector and the NHS to make better use of the facilities in the private sector.

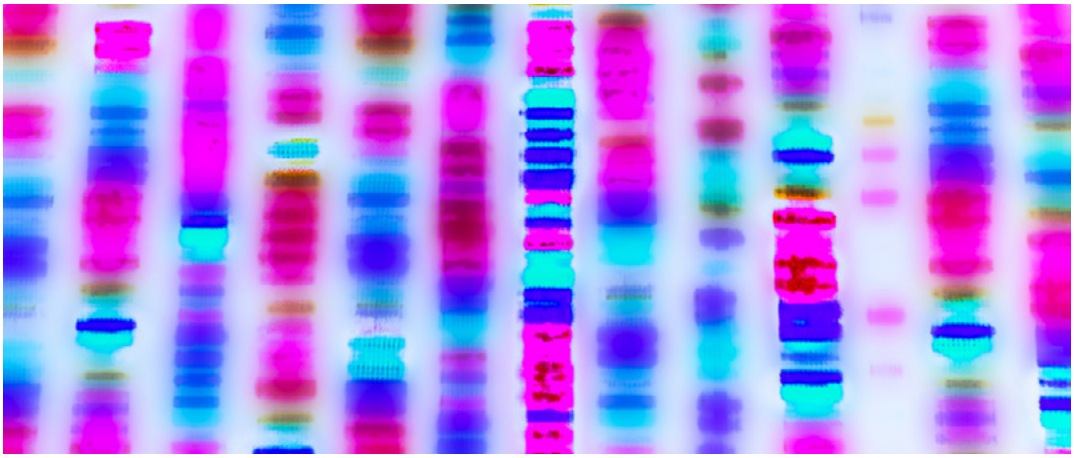
2010s – Genomic medicine revolution

The 2010s marked a turning point in cancer treatment, with the rise of immunotherapy. The NHS championed groundbreaking immunotherapies, harnessing the body's immune system to combat cancer cells, and offering hope to patients with previously untreatable malignancies.

For patients in Scotland, the decade began with celebrations, as the Scottish Government announced the abolishment of prescription charges. However, this only applies to those issued on Scottish prescription forms (GP10) and dispensed in Scottish pharmacies.

One year later, in 2012, the UK announced the launch of the 100,000 Genomes Project, an ambitious initiative led by Genomics England, which aimed to sequence 100,000 whole genomes from cancer patients and individuals with rare diseases. NHS England established 13 NHS Genomics Medicine Centres across the country, enabling patients and family members to participate, and establishing the infrastructure to make genomic medicine a routine part of NHS care. Five years later, in December 2018, news broke that the programme had reached its goal, becoming the first nation in the world to apply whole genome sequencing at scale in direct healthcare.

Not content with advancing personalised healthcare, in 2013 the NHS established the Cancer Drugs Fund. This national initiative compiled a comprehensive list of fast-track drugs, ensuring uniform access to cutting-edge cancer treatments across the entire country. Patients, no matter where they lived, could now benefit from the latest therapies, offering newfound hope in the battle against cancer.



Building on the groundwork of HIV treatments developed over previous decades, in 2017 NHS England embarked on the world's largest PrEP (Pre-Exposure Prophylaxis) implementation trial to combat HIV infection. This groundbreaking effort demonstrated the NHS's commitment to tackling public health challenges head-on and protecting vulnerable populations.

As the decade drew to a close in 2019, the NHS unveiled its Long-Term Plan, introducing Primary Care Networks. This ambitious initiative aimed to enhance the coordination of care and improve patient outcomes. With a commitment to invest at least £4.5 billion over the next five years, the NHS signalled its dedication to ensuring that healthcare remained at the forefront of innovation.

2020s – Navigating the pandemic

The 2020s commenced with a historic global challenge – the COVID-19 pandemic. In December of 2019, the first known case of COVID-19 was reported in the UK. This marked the beginning of an international public health crisis that would profoundly impact healthcare systems worldwide, with the NHS at the forefront of the battle.

As NHS workers soldiered on to battle the virus and the general public took to the streets in a rare showcase of united public support, a glimmer of hope emerged in December 2020, when 90-year-old grandmother Margaret Keenan made history: she became the first person in the world to receive the Pfizer COVID-19 jab outside of a clinical trial. This milestone heralded the start of the COVID-19 vaccination campaign, a monumental effort to protect the population against the virus.

In the midst of the pandemic, the NHS continued to prioritise innovation and patient care. In 2022, NHS England struck a groundbreaking deal for what was dubbed the 'world's most expensive drug'. As a result of this agreement, the gene therapy Libmeldy offered newfound hope to babies and young children suffering from metachromatic leukodystrophy (MLD), an extremely rare hereditary disorder that over time causes the nerves in the brain and other parts of the body to malfunction.

Furthermore, the NHS made a significant stride in healthcare access, with the launch of the Innovative Medicines Fund. This initiative aims to expedite patient access to promising new drugs, recognising the importance of timely and innovative treatments.

NHS superhero street art on Hilly Fields, Brockley, South London. Image courtesy of Loco Steve via Flickr

2023 – An uncertain future

Over the course of 75 years, the NHS has evolved into a beacon of exemplary healthcare, touching the lives of millions and continually pushing the boundaries of medical innovation.

As of 2023, the NHS is one of the largest employers in the world, employing 1.6 million people and treating an estimated one million patients every 36 hours.

It may not be perfect, and there is much work to be done to preserve those core values set out by its creators, but we look forward to a future where the NHS continues to lead the way in shaping the healthcare landscape for generations to come.

Photos taken at the Nurses' Protest at Trafalgar Square on Saturday 12 September 2020. Image courtesy of Garry Knight via Flickr

About the author

Eloise McLennan is the editor for pharmaphorum's Deep Dive magazine. She has been a journalist and editor in the healthcare field for more than five years and has worked at several leading publications in the UK.

Inside the Inflation Reduction Act's upcoming legal battles

Nine plaintiffs – six pharma companies and two alliances of industry groups – have sued the government over the price negotiation provisions of the Inflation Reduction Act (IRA), employing at least seven distinct legal arguments.

To hear pharma executives speak – and I have, at ASCO, Bio, and Reuters Pharma – this law could threaten pharma's business model and seriously curtail incentives for new drug development. But patient groups say that these companies are overstating the effect of a law that merely returns to the government a power it ought to have had for the last 20 years.

What's in the bill?

The IRA allows for negotiation on 60 drugs, starting with 10 in 2026 and adding the other 50 over the following three years.

The Act puts a lot of guardrails on what drugs can be chosen for that lot. They must be among the 50 most expensive Part D drugs and the 50 most expensive Part B drugs. They can't include small molecule drugs that have been on the market for under nine years or biologics on the market for less than 13 years. Orphan drugs and plasma-derived products are also excluded.

The law sets an upper limit for negotiated prices, but not a lower limit. It provides criteria that the Department of Health & Human Services (HHS) must consider in negotiating the price, but not a weighting for those criteria. And, crucially, the government wields a fairly large stick to encourage pharma companies to come to the table – threatening them with a 65% to 95% excise tax (which, due to the complex way the law is written, could amount to a 1,900% penalty) if they don't charge the agreed-upon price.

Nor can pharma companies practically opt out altogether – the Act requires that, to pull out, they must stop selling to Medicare and Medicaid completely, not just for the drug in question (although it might be possible to work around this restriction with corporate re-organisation).

How we got here

The IRA passed in 2022, but in many ways the story of its contentious drug negotiation provisions began nearly 20 years before that, when the Medicare Prescription Drug, Improvement, and Modernization Act passed in 2003.

That law, orchestrated by controversial Louisiana congressman W.J. "Billy" Tauzin, included a provision that banned Medicare from negotiating on the prices of the drugs it covers.

"The government negotiates for everything from aircraft carriers to copy paper," David Mitchell, founder of Patients for Affordable Drugs Now, told pharmaphorum. "But they managed to get this sweetheart deal where they did not have to negotiate [prescription drug prices], and they could, in fact, dictate the price. For about 19 years, they kept winning. Then last year, finally, because more than 80% of Americans insisted on having it done, they had had enough."

Pharma fires back

The Act only allows for negotiation on 60 drugs. Nonetheless, the difference between no negotiation and some negotiation is big, and pharma companies are not taking the shift in fortunes lying down.

"Put simply, the price setting provisions in the IRA are bad policy," PhRMA's CEO, Stephen Ubl, said in a recent press conference. "They threaten our industry's ability to research and develop new treatments and cures. They put access to innovative medicines at risk for Americans today, and in the future. And they jeopardise providers ability to prescribe the treatments they believe are in the best interest of their patients."

Their primary objection? What constitutes negotiation when it comes to a law that essentially requires pharma companies to take the price offered to them by the government, pay an extraordinarily high excise tax, or else pull out of Medicare and Medicaid entirely.

"In reality this 'Drug Price Negotiation Program' is a sham," Merck writes in the lawsuit that kicked off the flurry of litigation. "It involves neither genuine 'negotiations' nor real 'agreements'. Rather, once HHS unilaterally selects a drug for inclusion in the programme, its manufacturer is compelled to sign an 'agreement' promising to sell the drug to Medicare beneficiaries at whatever 'fair' price the agency dictates, which must represent at least a 25% to 60% discount."

Nicholas Bagley, a University of Michigan law professor who specialises in administrative law and healthcare law, says that the companies' various arguments all stand on the same foundation –that participating in Medicare isn't really voluntary.

"[Pharma companies] say it's not really a free choice because there's so much economic pressure put on [them]," he told pharmaphorum. "But on that front, the law is abundantly clear. That economic pressure of the kind that they're complaining about – which is, well, you're showering so much money on me, I can't afford to turn my back on it – that doesn't count as coercion. That's just a very tempting offer. So, they've got a problem on their hands because this is not a compulsory programme. It just feels compulsory to them."

The innovation question

Pharma companies are also concerned about the effect the law will have on drug development processes.

Because drugs only become eligible for negotiation after a certain period – nine years for small molecule drugs and 13 years for biological products – the law will start a clock when a drug first enters the market. For drugs with multiple indications this could incentivise companies to hold back on releasing drugs until they are cleared and ready for all indications, keeping drugs out of the hands of patients.

"Many cancer medicines in the US launch first in an orphan indication and broaden use over time to additional populations," AstraZeneca, one of the plaintiffs, said in a statement. "One example is Lynparza (olaparib), a small-molecule cancer medicine approved in 2014 in the US for a small group of late-line ovarian cancer patients [...] If the IRA had been in place, significant disincentives would have existed for pursuing the late-line ovarian cancer approval in the US, an indication which has benefitted patients in great need of this unique medicine for their rare condition."

More broadly, pharma believes this law will stifle innovation by limiting the ability of drugs to recoup their R&D costs – including the costs of other, failed drugs. But Mitchell doesn't buy it.

"We believe that the IRA will stimulate innovation," he said. "Why? Because right now the drug companies can choose to raise prices on old drugs at will, to hit profit targets, to trigger executive bonuses. This will force them to bring better drugs, innovative drugs, to market so they can charge higher prices for them."

It's far from a settled question, but it is one that the nonpartisan Congressional Budget Office attempted to answer when it analysed the effects of the bill, estimating that it would result in 15 fewer new drugs being released over the next 30 years. However, the accuracy of that prediction is a matter of some debate, with other analyses producing much higher numbers.

The legal challenges

The nine filed lawsuits span seven jurisdictions, prompting critics to suggest that pharma's overall strategy here is to maximise the chances that at least one will reach the Supreme Court. Some plaintiffs have also filed injunctions seeking to halt the start of negotiations until the lawsuits are resolved.

Here is a breakdown of the lawsuits so far:

PLAINTIFF	JURISTICTION	1ST AMENDMENT	5TH AMENDMENT	8TH AMENDMENT	DUE PROCESS	SEPARATION OF POWERS	OTHER
Merck	Washington, DC	✓	✓	✗	✗	✗	✗
PhRMA, etc	Texas	✗	✗	✓	✓	✓	✗
Janssen	New Jersey	✓	✓	✗	✗	✗	✗
Bristol Myers Squibb	New Jersey	✓	✓	✗	✗	✗	✗
Astellas	Illinois	✓	✓	✗	✓	✗	✗
Chamber of Commerce	Ohio	✓	✗	✓	✓	✓	✓
Boehringer Ingelheim	Connecticut	✓	✓	✓	✓	✗	✗
AstraZeneca	Delaware	✗	✓	✗	✓	✗	✓
Novartis	New Jersey	✓	✓	✓	✗	✗	✗

Merck, Janssen, Bristol Myers Squibb, Astellas, Boehringer Ingelheim, AstraZeneca, and Novartis have all sued in their respective districts. The other two plaintiffs are PhRMA, whose lawsuit also includes the National Infusion Center Association and the Global Colon Cancer Association, and the United States Chamber of Commerce, whose lawsuit also includes the Michigan, Ohio, and Dayton Area Chambers of Commerce.

US Secretary of HHS Xavier Becerra and Chiquita Brooks-Lasure, administrator for the Centers for Medicare and Medicaid Services (CMS), are named as the defendants in all cases.

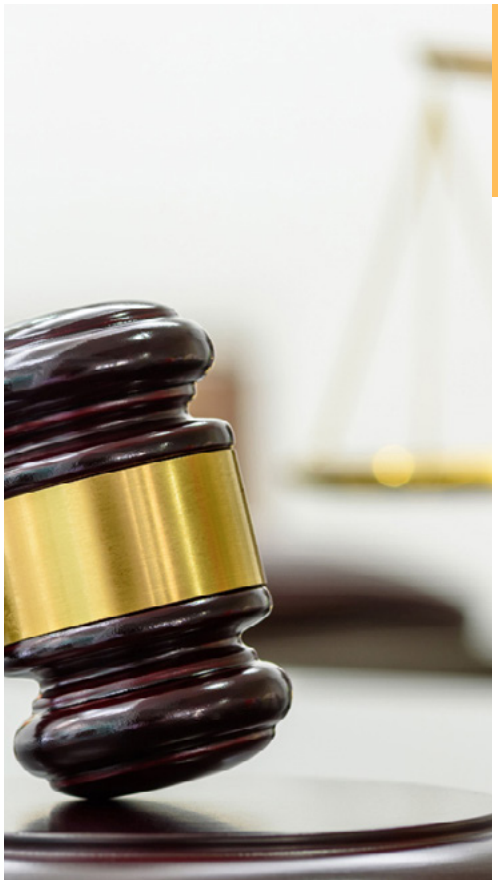
While the various lawsuits have many similarities, they are not in any respect carbon copies. The pharma company lawsuits mostly employ First and Fifth Amendment arguments, while the PhRMA and Chamber of Commerce lawsuits use the Eighth Amendment, the Constitution's due process clause, and arguments pertaining to the separation of powers and legislative authority. And a recent suit, by AstraZeneca, presents some more specific arguments based on the Administrative Procedures Act.

Below is a breakdown of each of the legal arguments, all of which challenge the constitutionality of the law.

First Amendment

Perhaps the most famous Constitutional amendment in the United States Bill of Rights, the first amendment protects American's right to free speech. This includes preventing the government from "compelling speech", except in certain cases (think Surgeon General warnings on cigarette boxes). Pharma companies argue that the law's requirement that pharma companies sign a public agreement asserting that the price is a result of negotiation and constitutes a fair price, when (as they assert) neither of those things is true, constitutes compelled speech.

This line of argument is unlikely to succeed, Bagley says, because of the nature of Medicare as a voluntary programme. Additionally, the claim only works if they can prove their assertion that the negotiation is not a true negotiation.



Fifth Amendment

The Fifth Amendment is probably best known for protecting Americans from self-incrimination – if you've ever heard someone say, "I plead the fifth", they're invoking this amendment. But it also includes the "takings" clause, which says, "nor shall private property be taken for public use, without just compensation."

"What the drug manufacturers want to say is we're kind of like public utilities here," Bagley explained. "We're required to sell our drugs. Because everybody's so dependent on them and because we can't really walk away from Medicare and Medicaid and you're not paying us enough, therefore it's basically confiscatory."

Though different on the surface, this argument has the same weaknesses as the First Amendment argument – it requires pharma companies to prove that this is government price setting, rather than the requirements for participating in a voluntary programme, which is how the courts are likely to see things.

Eighth Amendment

The Eighth Amendment is known for its provision against "cruel or unusual punishment", but it also protects citizens against "excessive fines", and that's the provision at issue here. And, to be fair to the pharma companies, they have a pretty strong case that the excise tax the government will impose if pharma companies don't pay the negotiated price is excessive.

"Put into context, this is like trying to sell your car to someone, and if they propose a price you're unwilling to accept, you have to not just give them your car, you have to give them 19 of your other cars," James Stansel, EVP, general counsel and corporate secretary at PhRMA said in their press conference. "That's absurd, and it's unconstitutional. It's also clear that Congress never actually meant for that to be a tax that would be paid. It is intended solely as a way of forcing manufacturers to take the price that the HHS sets."

For evidence that Congress never intended the tax to be paid, several lawsuits point to Congress's own revenue projections for the bill, which predicted the penalty provisions would raise no money.

But it doesn't matter if the tax is excessive if the court doesn't consider it a fine, and this is where the argument will likely run into trouble. Once again, the voluntary nature of the programme is likely to be a sticking point. Additionally, excessive fines complaints in general have a bad track record as courts are wary of overstepping their own authority, Bagley said.

Non-delegation, due process, and separation of powers

Some plaintiffs argue that the procedure that has been followed with the establishment of the negotiating process violates their Fifth Amendment rights to due process, or that giving the powers inherent in the Act to CMS, a part of the executive branch, violates the Constitution's separation of powers.

Mostly, Bagley says, these arguments employ the non-delegation doctrine, the legal theory that Article I, Section 1 of the Constitution forbids Congress from delegating its legislative power. Unfortunately for the plaintiffs, non-delegation tends to be a non-starter.

"The non-delegation doctrine has been used to strike down two statutes in the 20th century and zero in the 21st," he said. "The modern administrative state is bottomed out on broad delegations of authority, and there are hundreds of them, so it's not that it's incoherent to say, 'Gosh, CMS has a lot of power here'. It's true. But lots of agencies have lots of power that Congress has given to them in duly enacted statutes. And the courts have never said that run-of-the-mill delegations like this are constitutionally problematic."

The Administrative Procedures Act

AstraZeneca's case, one of the more recent cases to be filed, employs some novel arguments not found in the other eight and may have more success as they aim to take a scalpel, rather than a sledgehammer, to the law.

These two counts appeal, not to the Constitution, but to the 1946 Administrative Procedures Act. They argue that two particular parts of the law violate the statute: its categorisation scheme that counts different formulations and indications of the same drug as the same for negotiation purposes and its "bona fide marketing" standard used to determine whether generic competition exists (one of the factors for choosing drugs to negotiate).

Bagley, however, believes that these arguments aren't much more likely to bear fruit than the others, even when it comes to securing a temporary injunction.

"To challenge an agency action, that action has to be 'final', and you have to be 'aggrieved', meaning that it's the end of the decision-making process and the action directly affects you," he says. "CMS's guidance isn't final – it's an explanation of how the agency will going to exercise its discretion – and AstraZeneca wasn't harmed when CMS issued the guidance. Now that CMS has acted to select drugs, its decision is shielded from judicial review under the IRA. So, AstraZeneca is very likely out of luck."

The bottom line

It's not an accident that there are nine lawsuits and counting, in seven different jurisdictions. The various plaintiffs want the law struck down, and lucking out with a few sympathetic judges could get this case to the Supreme Court, a body that has made some unexpected and precedent-defying rulings of late.

But Bagley's assessment is that everything about these cases says "long shot".

"There's a good rule of thumb in lawyering that if you've got 15 claims in your complaint, it's because you have zero good ones," he said.

As different as they are, most of the claims share a single Achilles' heel: Medicare is a voluntary programme, and pharma companies can opt out.

Even if courts were inclined to support pharma in its particulars, they might not want to be responsible for the precedent that ruling against the IRA's cost negotiation provisions would set.

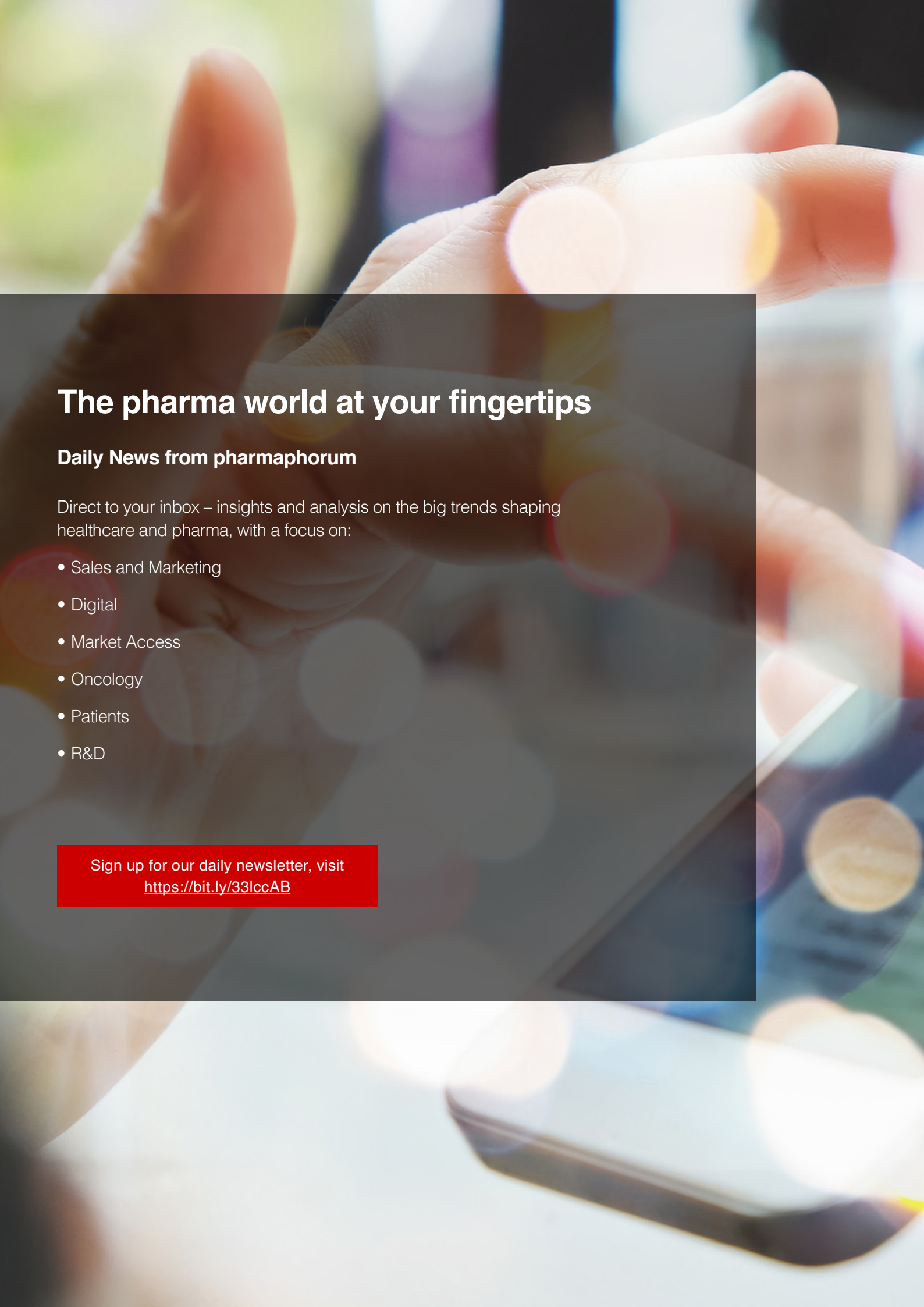
"It's effectively a claim to constitutionalise all of government contracting," Bagley said. "I think the courts are not going to have an appetite for inserting themselves into those kinds of policy debates – and they really are policy debates – about how much the federal government ought to spend for goods and services that it provides to its people."

Anything is possible, but the most likely outcome here is that pharma is going to take a hit to its profits as this law takes effect – and it will take effect quite quickly.

How bad a hit will it be? That's hard to say objectively in a moment when both sides have such strong incentives to overstate their case.

It's safe to say pharma will still make a significant profit from Medicare sales on the many drugs that aren't selected for negotiation and even on those that are. On the other hand, pharma companies are already making R&D decisions because of this law that involve cutting back on new drug development.

But one thing is for sure: for more than eight million Medicare beneficiaries who take the first 10 drugs that will be negotiated, this legislation could make a big difference in their lives.



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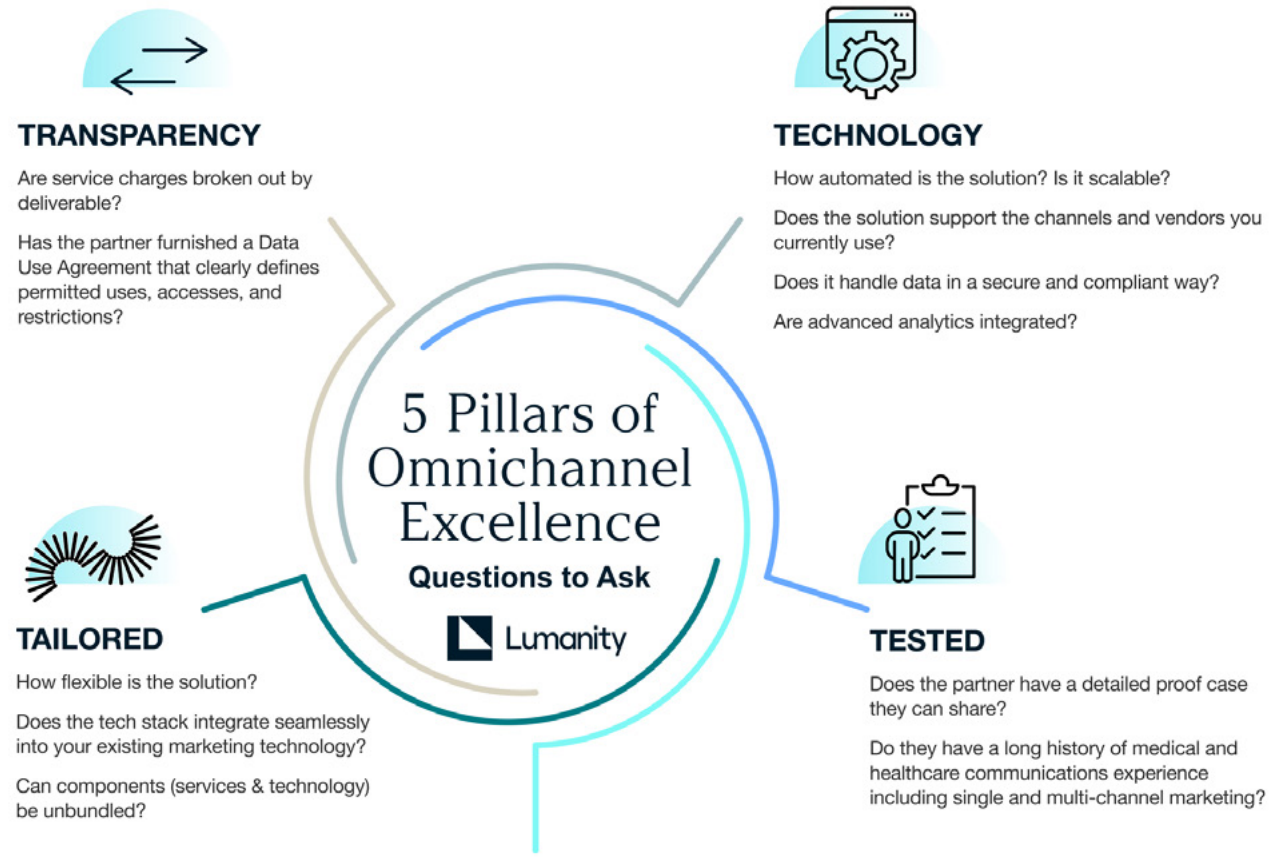
How to evaluate an omnichannel solution: A simple framework

In today's complex communications landscape, the path of information from sender to recipient is not as straightforward as it once was. Customers expect seamless and personalised interactions across various touchpoints, creating a labyrinth of engagement opportunities for marketing teams to navigate. As businesses strive to meet expectations and stay competitive in an increasingly saturated field, one engagement method continues to attract the interest of commercial and medical teams, seeking ways to get the right message to the right person: omnichannel.

"No matter how vast and comprehensive your data, when you're seeking to engage at the right time and place, data alone won't get you there. You have to integrate your marketing technology, digital channels, and data to utilise these signals as a way to understand the interests and needs of your audience," explains omnichannel marketing and analytics lead at Lumanity, Lindsay Lare. "The great thing about an omnichannel solution is you can tailor to specific individuals, making it personalised, as opposed to just an audience as a whole."

However, the path to achieving true omnichannel excellence is interwoven with a complex array of factors that collectively contribute to success. Most notably, a major undercurrent of false narratives and promises can lead teams in the wrong direction and cause confusion. Some decision points are more pivotal than others, as well, like selecting the right omnichannel partner. To help take the very first step and keep your team focused on the most important qualities and functionality, Lumanity has developed a simple but digestible framework that is deliberately void of buzz.



Technology – the digital backbone

The first, and perhaps most important, feature of successful omnichannel campaigns is technology. The systems and services are the building blocks onto which you can graft the seamless interactions that customers have come to expect in today's healthcare communications landscape.

Most companies will already have some of the basic technology components in place – salesforce enablement tools, salesforce marketing tools, customer relationship management, customer data warehouse, and customer master data sets are common examples of this. What they need, however, is integration.

"An ideal omnichannel solution should leverage these technologies and integrate all data points in a single source of truth to then effectively create audiences," says Gagandeep Sawant, software architect and technology lead for Lumanity. "The solution should then activate media plans on a strategically identified channel mix."

Integration can be the deciding factor in the success of your omnichannel journey, so it is important to ensure that your chosen omnichannel solution supports legacy systems and can align with other vendors, to create a coherent customer journey across multiple channels.

"What sets you apart and what makes a real omnichannel solution is the technology. I think that's the key component and the foundation that sets everything," explains Lare. "If you don't have the right MarTech stack, your solution is not really true omnichannel."

Another core element of omnichannel technology is scalability. Healthcare is a constantly evolving industry, so it is vital that your chosen partner offers a robust and scalable infrastructure that can accommodate increasing volumes of content and interactions across different channels.

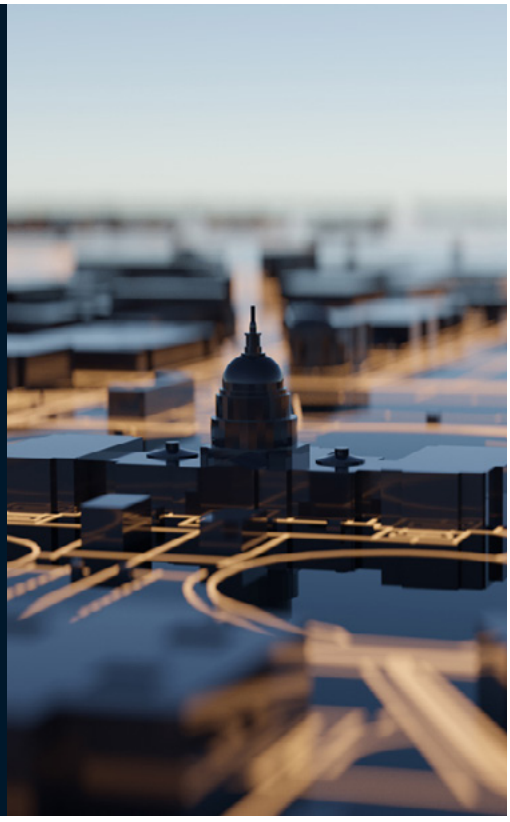
Team – a foundation of experience

Behind every successful omnichannel strategy implementation is a team of experienced individuals working in harmony to facilitate the seamless interactions that customers expect from today's marketeers.

Navigating the complex and highly regulated landscape of healthcare can be challenging for companies, particularly as implementing an omnichannel engagement model requires close collaboration across various functions. Each of these groups must be able to convey ideas and solutions clearly across those functions, or else they risk getting lost in translation. As Sawant notes, mostly, "when omnichannel efforts fail, they fail because of inter-team and/or intra-team communications."

One way to reduce the risk of miscommunication is to work with one agency of record. The advantage of working with cross-functional teams from a single partner organisation is that each of the individuals tasked with delivering various aspects of your omnichannel solution will already have experience working together and will understand the challenges of other teams, which Sawant says "eliminates a lot of the delay in getting on the same page".

"There also needs to be a level of expertise and experience within our field," adds Lare, "especially when it comes to collaborating with various stakeholders, including medical, marketing, and commercial operations."



Understanding the unique regulatory parameters that separate commercial and medical affairs offerings is just one example of why experience working with the healthcare industry – bonus points if in a multichannel capacity – can be an invaluable asset in an omnichannel partner.

As Sawant details, delivering a true omnichannel solution involves multiple different skill sets, including consulting, MarTech, creative, med comms, compliance, and project management services, to name a few. Each function needs to be aligned to produce a seamless customer experience. While individual vendors may be able to offer expertise in one specific area, there is no guarantee that each vendor will bring the same level of experience and industry expertise to the table. However, partnering with an established team with an existing record of working in the healthcare industry and collaborating between functions reduces any potential learning curve, allowing companies to hit the ground running.

Specific expertise to look for can include deep experience in audience development, media, analytics, and specific technologies, ranging from ads managers, demand-side platforms, and customer data platforms to marketing automation and even project management tools.

Transparency – trust in collaboration

Companies place great trust in the partners they invite into their circle of operation. Fostering this trust requires transparency.

One of the biggest concerns for customers in the healthcare space is personally identifiable information (PII). With data, transparency is a crucial feature, as establishing clearly defined rules around the uses, access, and restrictions permitted through the partnership will allow both parties to move forwards with a solid understanding of their roles, responsibilities, and requirements around the use of data. Cementing these details through a solid data use agreement (DUA) will help to address concerns surrounding data use and mitigate potential issues before they arise.

As Sawant notes: "Transparency is about telling the client exactly what we have, what we need, and how are we proceeding [with] using that data and making it very clear."

The second element of transparency to look for in a potential omnichannel partner is honesty in what you can achieve together. It's easy to get swept up in the excitement of new technology, but the right partner will be upfront about what is possible for your company.

"There are two different layers of transparency," explains Lare. "There's transparency with data, and there's transparency with your solution. If a client were to come to you and ask, 'Is this possible? What can we do to meet our business objectives?', if you're not transparent about your solution, how you engineered everything, and what is actually achievable with your solution then you add to the misinformation that exists around omnichannel."

Transparency surrounding costs is also a key consideration. From the outside, it's easy to assume that a bundled offering equals better value for money, but, in reality, most bundles are a mix of useful services and others that you will rarely use – with no breakdown of cost-per-item to help inform your decision. Consciously unbundling each offering allows you greater visibility over the actual value of specific deliverables, such as segmentation, journey orchestration, and technology license fees. A good partner will be willing to break down costs; beware those who will not.

Tailored – crafting solutions

Every organisation has unique ambitions and pain points when it comes to communications. For example, an established pharma company that already uses omnichannel in one area of their business will have a completely different set of needs than those from a new-to-market company with no prior advertising experience. But, whether you are looking to incorporate one specific service, or integrate an entire suite of systems, a good partner must be able to tailor its offerings to support medical, commercial, and enterprise to ensure longevity as your business needs evolve.

"A new go-to-market pharma/biotech company, in its first few months, while preparing for unbranded and branded communications, works with multiple vendor partners." explains Sawant. "Seeking a partner with broad media and engagement services ultimately helps solution for both personal and non-personal communications, including closed-loop, within an omnichannel setting."

Flexibility can also have cost-effective benefits, which can be highly advantageous for companies with tight budgets. Building on pricing transparency, if components can be unbundled, you can select only the technologies and services that provide the highest return on investment for your specific objectives. Moreover, this flexibility allows you to adapt and scale strategies as needed, without being tied to a pre-packed solution that may not suit your evolving requirements.

"Omnichannel should be a plug-and-play solution," explains Lare. "You should be able to plug in legacy products and vendors and customise your own solution. You shouldn't be forced to just use what we offer out of the box; take it or leave it."

Tested – demonstrating success

Of course, any potential omnichannel partner can proclaim their excellence in the first of the 5Ts. But, as Sawant and Lare explain, the right partner will be able to showcase how their expertise and services have helped a variety of organisations achieve omnichannel excellence.

"The big part of testing is a case study," says Sawant. "If we can show our new clients that we have done this before by working with an existing client partner on a proof of concept [and] what [...] the challenges were, the complexities – this can lay the land out for the new clients."

Armed with a proof-of-concept or case study, you can shine a light beyond the described surface and see how solidly each solution performs in practice. For Lare, having a portfolio of success stories is particularly valuable for healthcare clients looking for a partner with medical affairs experience who may be more hesitant to jump into the omnichannel pool.

"When we possess elements such as a proof of concept and experience, we can effectively demonstrate the benefits and legitimacy of implementing omnichannel within an organisation. This approach alleviates any hesitations or reservations they might have towards the subject and shows our ability to create a strategic media plan that incorporates personal and non-personal to achieve desired outcomes such as script lift or education" she explains. "Introducing novel technology and concepts, particularly in the realm of healthcare, triggers a degree of scepticism among clients. Having concrete evidence at hand to present makes the information more easily adoptable."

A clear vision for progress

Keeping pace with the ever-evolving world of healthcare communications takes work. Each company must carve out its version of the omnichannel experience by making the leap from single or multichannel or extending existing omnichannel services into other business areas. Whichever route a company is treading, choosing the right partner remains crucial.

"Having a clear vision is really important, and having a good partner," concludes Lare. "You know when you have a good partner, a good relationship, and good communication."

By holding equal weight to the 5Ts – right-fit technology, experienced teams, transparent collaboration, flexible solutions, and proven examples of success – companies can embark on their omnichannel journey with confidence that their chosen partner is right for their needs.

About the authors

Lindsay Lare, omnichannel marketing and analytics lead at Lumanity

Gagandeep Sawant, software architect and technology lead for Lumanity.

About Lumanity

Lumanity applies incisive thinking and decisive action to cut through complex situations and deliver transformative outcomes to accelerate and optimise access to medical advances. With deep experience in medical, commercial, and regulatory affairs, Lumanity transforms data and information into real world insights and evidence that powers successful commercialisation and empowers patients, providers, payers, and regulators to take timely and decisive action.

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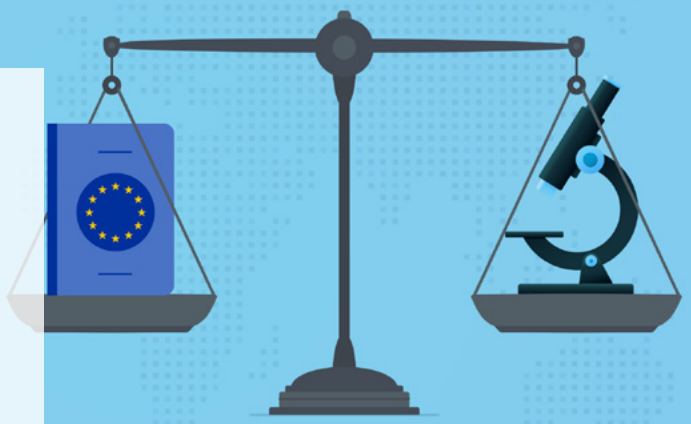
EU pharmaceutical reform: Balancing access, innovation, and concerns



After much anticipation, some leaks, and several delays, the European Commission has unveiled its latest proposal for a new regulation and directive to replace the existing provisions on medicinal products within the EU. However, the proposal has been met with widespread discontent from major stakeholders, leaving no one truly satisfied. Let's explore the driving forces behind the proposed reform, its underlying rationale, and the main areas of criticism.

Shaping the new legal framework: The '3A' formula

The EU aims to create a more appealing European market for companies interested in investing in research and development (R&D) related to medicinal products, and a more competitive landscape for the pharmaceutical industry.

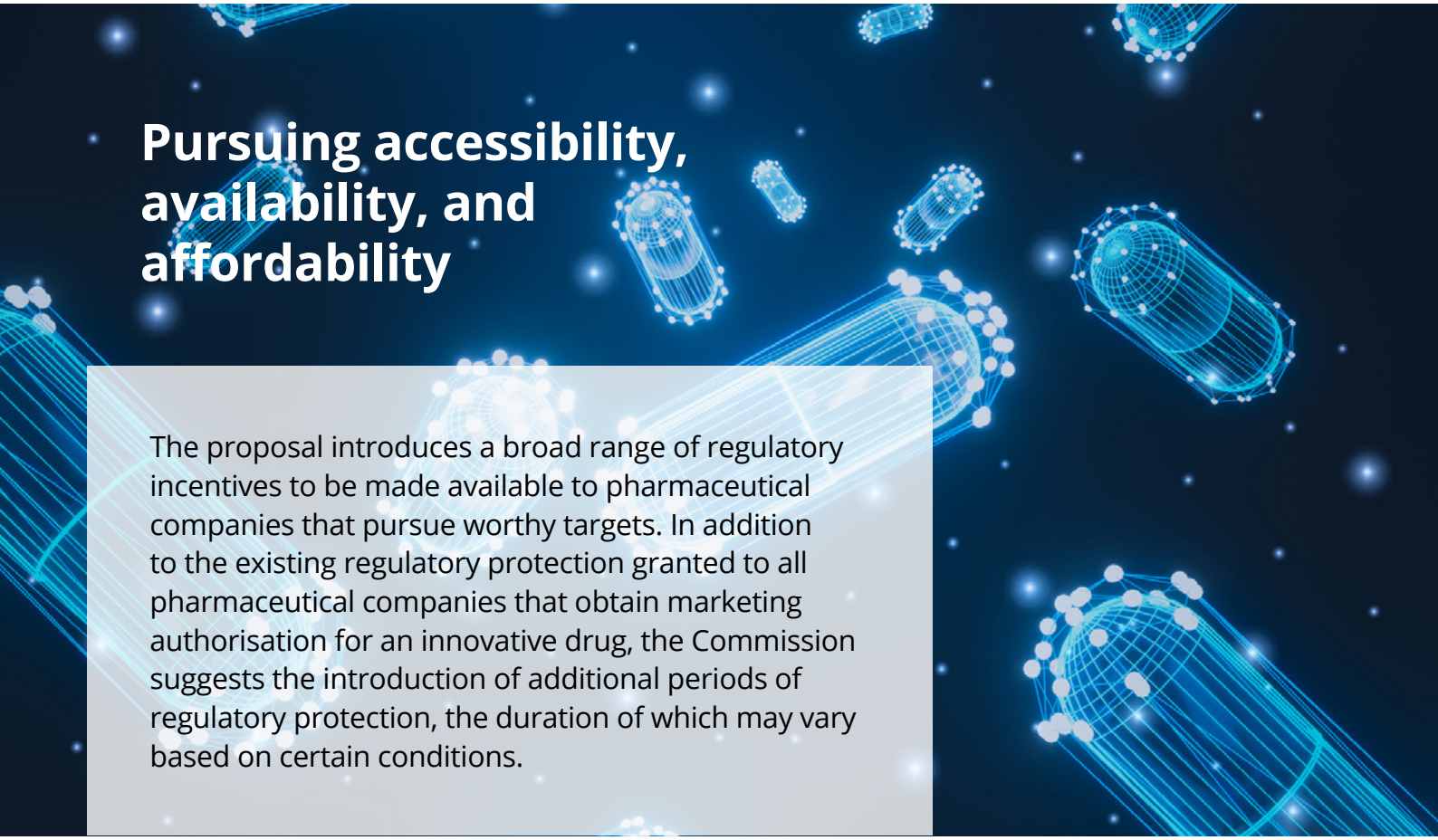
This objective is clearly outlined in the Commission communication entitled 'A Pharmaceutical Strategy for Europe', adopted on 25th November 2020 and supported by the fourth EU health programme 'EU4Health 2021-2027', established through Regulation (EU) 2021/522 on 21st March 2021.

The reform's numerous objectives include:

- Fostering pharmaceutical innovation
- Ensuring accessibility to innovative medicines across all EU member states
- Promoting economic and environmental sustainability within the pharmaceutical market.

Nevertheless, the goal of this reform remains to improve the health outcomes of European citizens. The Commission believes that all individuals should have the opportunity to access a wide range of available medicinal products at reasonable prices across all 27 EU member states.

This vision is encapsulated by the '3A' formula: accessibility, availability, and affordability.



Pursuing accessibility, availability, and affordability

The proposal introduces a broad range of regulatory incentives to be made available to pharmaceutical companies that pursue worthy targets. In addition to the existing regulatory protection granted to all pharmaceutical companies that obtain marketing authorisation for an innovative drug, the Commission suggests the introduction of additional periods of regulatory protection, the duration of which may vary based on certain conditions.

Fulfilling these conditions would render pharmaceutical companies eligible for regulatory incentives, which include marketing the authorised medicinal product in all EU member states, developing medicines that address unmet medical needs, conducting comparative clinical trials, and creating medicinal products with additional therapeutic indications (repurposed medicines).

On the other hand, the Commission recommends reducing the regulatory protection granted to 'ordinary' medicinal products from eight to six years, aiming to expedite the availability of generic and biosimilar medicinal products in the market. This approach signifies a shift away from a 'one-rule-fits-all' strategy towards a more flexible framework that rewards companies dedicated to achieving the EU's priority objectives of safeguarding public health.

Presently, manufacturers introducing innovative drugs to the market enjoy eight years of regulatory data protection and market exclusivity, with an additional two years of market exclusivity (resulting in a total of 10 years). If a new therapeutic indication is developed, an extra year of protection is granted. This system is commonly known as the '8 + 2 + 1' formula.

The proposed provisions envision a general reduction in the period of regulatory data protection and market exclusivity from eight to six years (although the proposed text is likely to undergo amendments during the ordinary legislative procedure involving the Council and the European Parliament). An extra two years would be added if the concerned medicinal product is marketed in all EU member states – unless specific member states declare their lack of interest in marketing the medicine within their territories, thereby opposing an extension.

Furthermore, an additional six months would be granted if the clinical trials supporting the initial application for marketing authorisation use a relevant and evidence-based comparator, as advised by the European Medicines Agency (controlled clinical trials). Lastly, an extra six months would be provided if the medicinal product is indicated for a serious or life-threatening disease without any available therapeutic solutions (unmet medical needs).

Under the new framework, the maximum regulatory protection (including up to nine years of data protection and the existing two years of market exclusivity, with an additional year for new therapeutic indications) could extend to 12 years for companies demonstrating exceptional adherence to these regulations, while less compliant companies would have a limit of eight years.

It is important to note that the proposed reform does not impact patent protection, which remains unaffected. However, the possibility of extending regulatory protection, even for significant durations, is considered part of this reform. Consequently, access to the generics and biosimilars market could be delayed if innovative companies are granted one or more of the regulatory incentives proposed.

The regulatory incentives approach described above aligns with the objectives of improving accessibility (by promoting the marketing of medicinal products across the EU), availability (by reducing regulatory data protection periods), and affordability (by facilitating quicker access to more affordable generic and biosimilar medicinal products). According to the Commission, the additional two years of regulatory protection for companies launching medicines in all member states is expected to enhance access by 15% throughout the EU.

Criticism and concerns: Debating the impact on innovation

The Commission's approach to the new legal framework has been met with opposition from large pharmaceutical companies, the European Federation of Pharmaceutical Industries and Associations (EFPIA), and generic and biosimilar medicine manufacturers.

They argue that shortening regulatory data protection periods would encourage them to shift their investments in R&D for new medicines to non-EU countries. Furthermore, players in the generic and biosimilar industry express concerns about the potential extension of regulatory data protection for innovators to as long as 12 years, or even 13 years for orphan exclusivity.

The way forward: Navigating negotiations and amendments

Given the circumstances, it is highly likely that the factions opposing the Commission's approach will engage in vigorous lobbying campaigns against the proposal. This will involve members of the European Parliament and government representatives from member states.

Considering that we are only at the initial stages of the ordinary legislative procedure and that the final text will likely undergo substantial amendments during parliamentary discussions, significant opposition is to be expected. However, while the Commission may display flexibility in reconsidering the time periods associated with the proposed incentives, reducing the two-year regulatory protection period for those who market the product in all member states to 18 months or one year could potentially avoid intense opposition. Yet, it is unlikely that the Commission will abandon the reward mechanism and agree to maintain the current 'one-rule-fits-all' approach.

Additionally, the Commission is unlikely to compromise on the proposed restructuring of the European Medicines Agency's organisation, which involves reducing the number of scientific committees, including the Committee on Advanced Therapies (CAT) and the Paediatric Committee (PDCO). The introduction of Temporary Emergency Marketing Authorisation (TEMA), allowing for faster authorisation of essential medicines during public health emergencies, is also unlikely to be compromised.

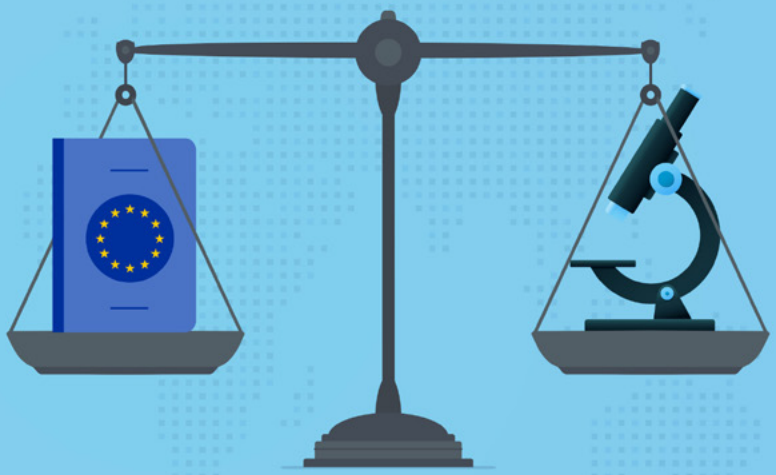
Can the Commission strike the delicate balance between promoting and protecting innovation, supporting the competitiveness and sustainability of the pharmaceutical industry, ensuring access to affordable medicines for patients, and addressing unmet medical needs? Undoubtedly, it will be a significant challenge. However, what is certain is that negotiations on the reform must – and will likely – forge ahead.

About the author

Vincenzo Salvatore

Of Counsel, Vincenzo Salvatore is leader of the Healthcare & Life Sciences Focus Team at BonelliErede. A professor of European Union law, he joined BonelliErede in 2015, bringing his specific regulatory and compliance skills in terms of clinical trials, marketing authorisation procedures, pharmacovigilance, personal data protection, promotion and marketing of medical devices, inspections, and enforcement. He has gained significant experience in complex litigation representing public and private entities before the European Court of Justice based in Luxembourg in EU law disputes.

In addition, he was head of the Legal Service at the European Medicines Agency from 2004 to 2012. Salvatore is a member of the editorial board of The European Pharmaceutical Law Review (EPLR), one of the most authoritative journals that tracks the latest legal and regulatory developments in the pharmaceutical sector.



Reinventing pharma operations: Embracing multi-resource planning technology

In the fast-paced and ever-changing pharmaceutical industry, stakeholders face a critical challenge: resolving the productivity drain caused by operational planning within rapidly evolving departmental environments. While multi-type resource management remains essential, inflexible legacy systems have often hindered it, sabotaging the quest for better communication and efficiency.

After the intense industry challenges experienced during the pandemic, significant lessons were learned. A 2022 survey of industry executives reported that 80% of respondents believe companies will embrace more agile working methods, and 70% feel that organisational structures within pharma must be simplified. These figures reinforce the point that technology which supports operational needs, reduces database administration, and improves company-wide communication is critical.

A drastic reinvention of resource planning, assignment, and scheduling is imperative to optimise capabilities and revolutionise departmental functionality. Investing in technology is vital to assist administration, enabling pharmaceutical companies to navigate staff shortages, strikes, supply chain disruptions, and other uncertainties while maintaining operational success. By prioritising the right technology, pharma stakeholders can streamline services, foster collaboration between hospitals, pharmacies, and other healthcare modalities, and ultimately enhance patient care.

Addressing the productivity drain

Operational planning has been a longstanding concern for pharmaceutical stakeholders, as it can significantly impact productivity and resource utilisation. Legacy systems that lack flexibility limit the ability to manage multiple resource types, wasting time and impacting productivity from the outset.

Enterprise technology has historically suffered from a lack of seamless usability that hinders fast and effective operational management, and crucial data has remained fixed within spreadsheets due to a lack of efficient alternatives. When designing technology for business and medical environments, the capabilities of consumer technology should guide developers. There is a vast gap between the technology people in many industries use in the workplace and the devices they use outside of the workplace. When the device in your pocket is intuitive, adaptive, responsive, and allows interactivity and a convenient flow of data that can be shared instantly, it is frustrating to encounter cumbersome interfaces, hardwired processes, and siloed systems.

In vital services such as healthcare, technology that drains efficiency has a much more severe impact than employee frustration. When data is confined within spreadsheets that must be manually updated as changes occur, communication and accessibility across departments suffer, ultimately leading to repercussions on patient care.

Embracing multi-resource planning technology can mark a significant shift, offering dynamic solutions that adapt to rapidly changing departmental environments. By eliminating the productivity drain, pharma companies can focus on core objectives, from drug development to clinical trials, without unnecessary hindrances.

Revolutionising resource management

The pharmaceutical industry's diverse resource requirements demand an innovative approach to resource management. Through technological solutions designed to enable digital transformation, pharma will be empowered for success. Multi-resource planning technology presents a radical reinvention, enabling efficient planning, assignment, and scheduling of personnel, equipment, and materials. This transformative capability optimises departmental functionality and unlocks untapped potential.

With streamlined resource allocation, pharma stakeholders can maximise available resources, minimising disruptions and enhancing productivity during challenging times. An event such as COVID-19 was unexpected. Still, it demonstrated that managing resources must provide a holistic view of resources and take advantage of the latest technologies to enhance visibility for key stakeholders and remove complications. In or outside of a global pandemic, a platform where all resources can be catalogued, viewed, and organised with the familiar drag-and-drop motion within one interface is game-changing.

Navigating uncertain environments

Pharmaceutical operations often face turbulent environments characterised by staff shortages, economic instability, and supply chain disruptions. They must also be prepared for emergency health events – potentially globally. Investing in technology that can assist administration becomes crucial to successfully support healthcare teams through uncertain periods and weather these strains.

The old systems have been effective, but can easily break down when rapid change occurs, the personnel that manage them are unavailable, or pressure suddenly overwhelms these processes. When a traditional planning and scheduling system for people, locations, and equipment must be overhauled due to an unexpected change, time and resources are lost responding to it. During such events, the operational system should support personnel, not add to the workload.

Multi-resource planning technology empowers pharmaceutical companies with real-time insights into resource availability, allowing them to adapt swiftly to unforeseen challenges. With enhanced agility, pharma stakeholders can effectively manage crises and maintain operations, safeguarding the continuity of patient care and employee wellbeing.

Streamlining services through collaboration

Collaboration between hospitals, pharmacies, and other healthcare modalities is vital to improving patient care and treatment outcomes. The last few years have outlined why it is key to have collaborative systems in place to prepare for any eventuality. More robust planning technology serves as a catalyst for fostering such collaboration. By providing a unified platform for seamless communication and resource visibility, this technology can enable different entities to work together effectively. This streamlined approach optimises the entire healthcare ecosystem and sets the tone for the future of pharma operations.

The necessity for effective resource planning and allocation in a rapidly evolving pharmaceutical landscape cannot be overstated. By embracing multi-resource planning technology, pharma stakeholders can address the productivity drain, revolutionise departmental functionality, and quickly navigate uncertain environments. This investment in technology streamlines services and encourages collaboration across healthcare services, ultimately leading to improved patient care.

As the industry evolves, companies prioritising the right technology to assist administration will be better equipped to thrive amidst challenges, ensuring success in drug development, clinical trials, and healthcare delivery. With multi-resource planning technology at their disposal, pharmaceutical professionals can unlock the industry's true potential, revolutionising patient care and transforming the future of healthcare.

About the author

Stephane Bensoussan is the head of operations at dizmo and the product owner of Planisy, the latest product powered by dizmo's technology. Through his extensive industrial and technical background, Bensoussan brings over 30 years of experience working in high-tech environments across marketing, sales, business development, operations, strategic partnerships, and R&D. He is a cross-disciplinary individual who has the ability to bring new innovations to the market.

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A pharma industry event round-up
Insights and trends

From artificial intelligence and digital therapeutics to the latest in oncological research and RNA therapeutics, from developments in the CNS field to what's what in customer experience and pharma marketing, many of the events that pharmaphorum has covered in 2023 presented a broad spectrum of insights and telling suggestion of future trends to come. Here are some snippets of the most memorable conversations from Pharma Integrates, BIO-Europe Spring, NEXT Pharma, and RNA Therapeutics.

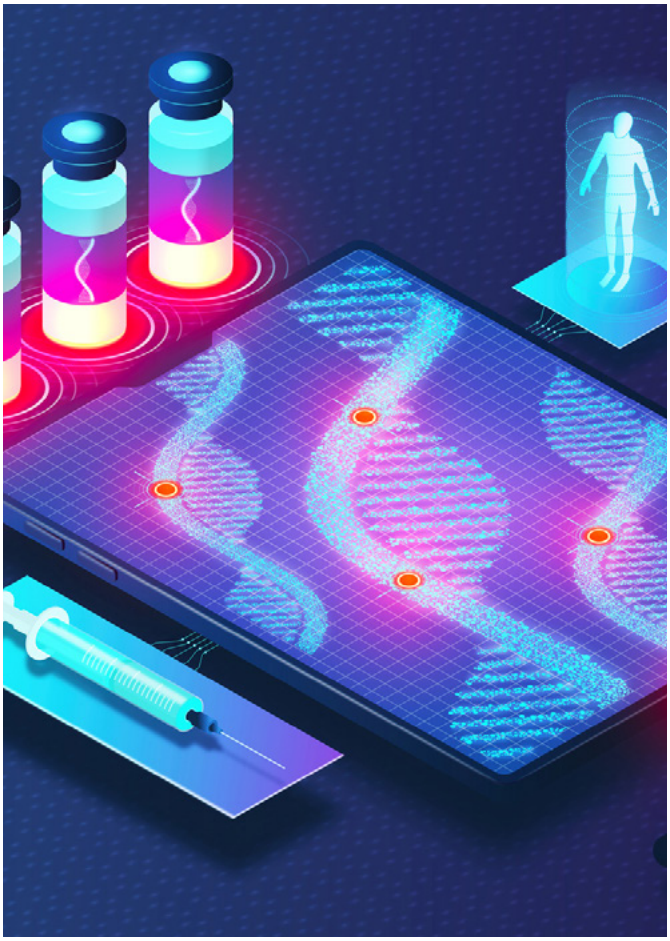
1. Pharma Integrates, London

Before we delve into the most noteworthy talking points from pharmaphorum's 2023 event coverage, it is worth exploring some of the predictions, trends, and industry issues that proceeded the arrival of the new year.

The 'Big C' proved to be a key talking point during Pharma Integrates London at the close of 2022. In a panel moderated by Linda Summerton, head of scientific affairs and oncology at Transcript, Jane Robertson, chief medical officer at Redx Pharma, reported noticeable progress in cervical, breast, and prostate cancer screening, but noted that more collaboration with academia and industry partners was needed to better identify high-risk patients and those who need a specific, directed screening programme.

Renata Crome, trustee, non-executive director, and pharmaceutical development advisor at PTEN research foundation, noted that the 'needle has moved', but not always in the right direction. Indeed, a lot more is now known about the effects on mental health and anxiety in the cancer care pathway, including the trauma of multiple biopsies.

However, Emma Kinloch, founder of Salivary Gland Cancer UK (SGA UK), caveated that if a patient has a cancer with no identifiable risk factors and is asymptomatic, that patient is unlikely to go into the system and has a low risk of overtreatment. Rather, the problems around access to screening and systemic inequalities need to be addressed.



Personalised medicine was a point not to be overlooked, of course, the crucial question being whether it works in the real world. Crome stated categorically that it's not on the agenda in poorer countries, while in richer countries personalised medicine isn't necessarily effective due to genetic variations between ethnic groups. Nonetheless, she also said that the UK is perfectly set to conduct such studies, due to its fantastic diversity of population, of ethnic groups, and cancer centres of excellence. However, there could still be more done with the models in preclinical trials.

AI: The hype, the hope, and the happenings

Although 2023 has progressed a long way in the field of AI, with conversations on developments frequently scattered with utterance of 'ChatGPT', at the turn of the new year, conference attendees were still in need of convincing.

Steve Garden, CEO of PrecisionLife Ltd, noted the technology's use in precision medicine analytics, novel target identification, and trial design, describing it as a blend of hype and hope and happening. Raminderpal Singh, CEO and co-founder of Incubate Bio, agreed, mentioning its role in Alzheimer's targets, also. However, what Singh also highlighted was the buzzword nature of it. In fact, there's nothing wrong with linear, with calculators, but the 'junk in, junk out' method of statistics, data crunching, and data cleaning, he said, seem old fashioned in comparison to the excitement around AI.

An important factor to bear in mind, though, Fordham said, were the semantics, the translation layer between the language a patient uses, for example, and the language of medical literature: a tummy ache becoming abdominal in a paper. There is a risk of overcomplication, despite being seen as a silver bullet; the risk of hype, with a lot of variables in the mix.

For Garden, the transformational quality of AI comes down to biomarkers, and the ability to distinguish between groups of patients, while for Fordham and Harwich it was clear data cleaning had become tarnished with the concept of a dusty veneer of history. This, Singh said, was down to the hype surrounding AI and similar technologies – and the salaries that go with jobs in that sector.

2. BIO-Europe Spring, Basel

While you might have caught our initial coverage of BIO-Europe Spring this year, there was so much more to the event, including conversations on dealmaking, the obesity marketplace, and the future of CNS.

Dealmaking

In a panel moderated by Susanne Weissbaecker, partner at Ernst & Young, Bristol Myers Squibb's SVP of business development in innovative technologies, Konstantina Katcheves, noted that – despite the macroeconomic situation and geopolitical volatility at the start of the year – strategy to partner for innovative medicines remained unchanged.

That said, Bradley Hardiman, head of Europe in search & evaluation, business development at Astellas Pharma Europe, said a key quality was flexibility, to which MSD's executive director of transactions, Karen McGurk, added collaboration, given that the right relationship that fits the rationale supports a partner through difficult times.

In short, "communication, communication, communication," as Hardiman put it, takes companies "back to the thesis: the value to patients."

The obesity marketplace

Melanie Senior, healthcare writer and analyst at Nature Biotech, Evaluate, IN VIVO, moderated a conversation with Alessandro Toniolo, CEO of Resalis Therapeutics, and Josua Jordi, CEO of EraCal Therapeutics, on trends in the obesity marketplace.

In the US, six times more people are obese than are fighting any type of cancer, and the health risks are multiple: from diabetes and heart disease, to depression, orthopaedic conditions, and even cancer. The American Medical Association didn't recognise obesity as a disease until around 2013, and there wasn't an effective pharmacological treatment for obesity until the middle of the pandemic – then, Novo Nordisk launched Wegovy; next, Eli Lilly & Co were in regulatory submission for Mounjaro.

With questions remaining over whether these therapies have to be taken lifelong and the true value of investment, and with the regulatory pathway in obesity particularly difficult, it's worth remembering the chequered history of this area of research, including appetite suppressants and the safety issues therein. But what crept up in discussions was the possibility that bodyweight – once thought to have a natural set weight – can be 'reset'.

What's next in CNS

The central nervous system (CNS) remained a hot topic going into 2023 and a panel discussion moderated by Christian Jung, partner at The Dementia Discovery Fund – SV Health Investors, explored the latest developments in CNS and neurodegeneration and how neuroscience is currently experiencing a renaissance.

Céline Bouquet, executive director global business development in neuroscience, ophthalmology, and rare diseases at Roche, predicted the continuing development of biomarkers for diseases such as Alzheimer's, but that endpoints for Huntington's, for example, are still being sought. It is, though, a community effort and 'long and deep investment' is required.

Florian Muellershausen, managing director at Novartis Venture Fund, noted that there are already a lot of promising pipeline programmes, but that more should be trying novel avenues, rather than aggregates – including the biological risks implicated if there is a known path forward.

Meanwhile, Rob Pinnock, director of external innovation at Biogen Idec Ltd, had been advocating for a risk containment strategy for some time. Looking at the treatment of neurological disorders only 30 years ago, back when Multiple Sclerosis (MS) was essentially untreatable – now, with the therapies available, things can actually be achieved in CNS, he said.

Nicki Thompson, CEO of Amphista Therapeutics, cautioned a step back to assess the approaches used in the space, with the route of administration still a challenge and the enormous scope of the resurgent interest in small molecules, with the ability to get to the cells that need to be targeted. However, she queried when a bifunctional molecule gets so small that it becomes a glue.

3. NEXT Pharma, Dubrovnik

Flying out to the breathtaking coastline of Croatia isn't a particularly onerous request when tasked with it, all things considered – though the wet and windy weather perhaps begged to differ – so off pharmaphorum duly went to the Adriatic. And NEXT Pharma didn't disappoint.

Opening the event was a simple question: who ignites technology and makes that fancy gadget shine? The answer is us, human beings. Pretty much everything we do leads to engagement, internal and external. With literal fire sparklers to commence the show, some opening remarks from Dario Safaric, NEXT Pharma summit chairman, had been crafted by ChatGPT.

But there is a sense of digital fatigue and what matters now, perhaps more than ever, is customer experience (CX). A sense of momentum to continued transformation is necessary and it was with that sentiment that proceedings began.

Information (technology) as a determinant of health

For Stefani Fruchtman Klaskow, director of healthcare at Google, to seek and find information is a basic human need. Having been with Google and life science organisations for over 16 years, one thing she believes to be fundamentally true is that information is the most important determinant of health: it empowers patients, and allows them to make informed decisions about their health.

However, there is an information gap that needs to be bridged and Google realises that its products have an important role to play in that process. After all, everyone should have access to useful, valid health resources, and 75% of people head online when they first have a question about their health.

In an increasingly digital world, the next phase in health communication, Klaskow said, is video. With people only remembering about half of what they're told in an appointment, and 17.4 minutes being the average length of such consultations, understanding and recall are fundamental components when it comes to patient adherence. Indeed, there has been a 38% increase in queries for health-related content on YouTube recently.

YouTube Health is built on three fundamental pillars: principles, partnerships, and platform. To give one example, when a condition like depression is searched for, a shelf of related content from accredited institutions and sources is shown, and it is reliable due to the accreditation.

AI is the third big shift, she said. First there was the internet, then mobile, and all will be done similarly with AI.

Women's health, beyond breasts and babies

While Plato and Hippocrates, the father of modern medicine, might have believed in the 'wandering womb', that it moves sideways and up and down, and while the Ancient Greeks applied scents to the vagina in the belief that it would put the womb back in place, it is shocking that such misunderstandings went centuries without being corrected. In fact, as a Nature-published study showed, women are diagnosed years later than men for the same diseases.

As Camilla Harder Hartvig, EVP and chief commercial officer at Theramex, explained during her presentation, an enormous issue that is underfunded and underserved is that creating a world that has healthier and more empowered women – if it needed to be said – means beneficial gains for families and workplaces. Or, as Hartvig put it: you can't have a thriving pharmaceutical industry without thriving women who continue to work in the industry.

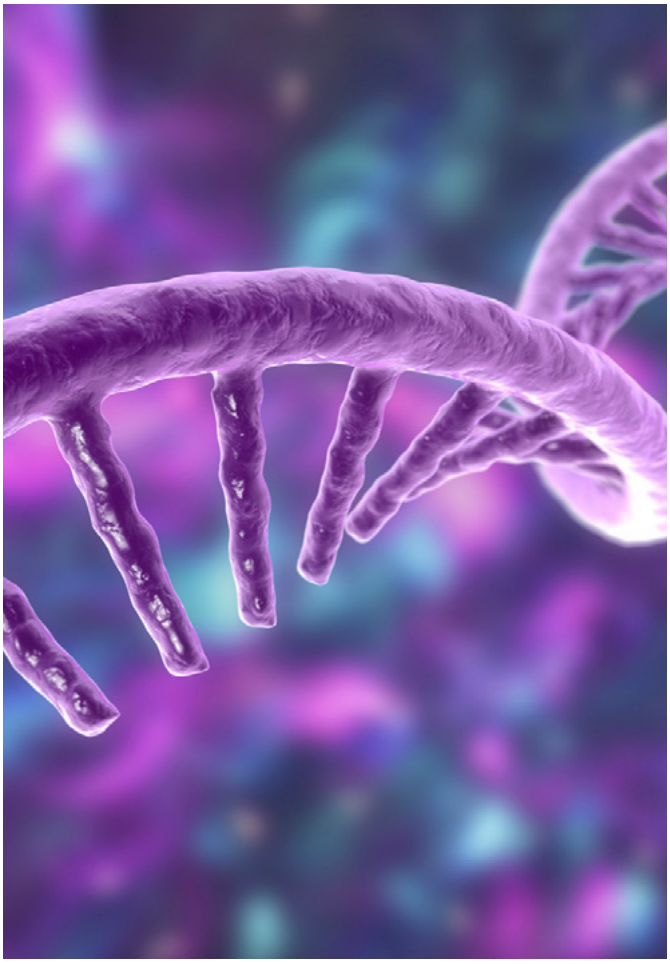
Only 4% of R&D in biopharma investment is dedicated to women's health issues specifically, despite women representing 51% of the global population. Indeed, out of 37 total prescription drugs FDA approved in 2022, only two were for specific female health conditions.

The ancient view that women are only worth making babies needs to be discarded, Hartvig insisted. An estimated 13 million women in the UK are perimenopausal or menopausal: that's a third of the workforce, which includes 38% who have thought about quitting work due to their symptoms.

4. RNA Therapeutics, London

You'll likely have caught our earlier coverage of the first day of the RNA Therapeutics conference in London, an SAE Media Group event, but on the second day of the fascinating and 14th annual RNA Therapeutics conference pharmaphorum got to delve deep beneath the surface of matters, into the very science of what makes the industry we cover tick.

RNA biology: Unmet medical needs and delivery agents



Covadonga Paneda, chief development officer at Altamira Therapeutics, presented on OligoPhore and SemaPhore for extrahepatic delivery of therapeutic RNA, the company's nanoparticles formed from a peptide and RNA, developed by Samuel Wickline at Washington University. Chemically modified and non-modified RNAs have been experimented with to tackle the challenges of instability, in often degraded models. This particular peptide is derived from melittin, which comes from bee venom, so has the drawback of exhibiting a toxicity – a toxicity which Wickline spent 10 years modifying and reducing.

Meanwhile, Virginia Castilla-Llorente, associate director at Evox Therapeutics Ltd., explored extracellular vesicles as delivery agents for RNA therapeutics, looking at exosomes as a novel therapeutic modality. A disruptive approach with differentiating attributes, essentially, exosomes are delivery and communication agents. A safe and potent modality for precision delivery of complex payloads, DeliverEX is Evox' platform for creating next generation genetic medicines, including next-gen AAV gene therapy, rapid-acting genome editing delivery, and differentiated RNA therapeutics, in conjunction with Takeda and Eli Lilly.

Also mentioning the scalability and proprietary exosome manufacturing processes, Castilla-Lorente said that it is a question of loading the drugs, including endogenous drug loading and exogenous drug loading. But an in vivo study in mice found that exosomes outcompete LNPs as a more efficient way of delivery. Ongoing research continues, however, into the stability of the mRNA – indeed, Christian Plank, chief technology officer at Ethris GmbH, later discussed the exploration of mRNA therapeutics, in his case, in the treatment of lung diseases.

Improving drug-like properties of RNA modalities

In a panel led by Professor Ekkebard Leberer, life sciences consultant at Elbicon, he noted that the growth goal is to make RNA an important third modality in addition to small molecules and modalities. Heinrich Haas, VP of formulation and drug delivery at BioNTech, posited that it's a question of doing the right thing at the right time with technology, while Christian Plank of Ethris GmbH asked what comes after vaccines. Furthermore, in the mRNA field and in artificial intelligence, how much is yet undiscovered?

Mark Cunningham head of operations at Nucleoic Acid Therapy Accelerator (NATA), stated that, if a naked RNA is placed in the body, it doesn't speak to the tissue: it has to be conjugated to the target ligand. Indeed, it is targeting, rather than delivery, that will release quite a bit of the pressure on nucleoic acid therapies, he said. The other challenge is manufacturing.

Shalini Andersson, VP of oligonucleotide discovery at AstraZeneca noted that there are remaining gaps in the knowledge on RNA biology that need to be bridged, and efforts have to be put into academia in this respect. Certainly, she said, there will be targets that can't be modulated with anything but RNA, and that is an exciting area to look towards. There will be lots of ups and downs on the journey with mRNAs, siRNAs, the separation of oligonucleotides, and the like. Plank caveated that mRNA will not be a cure for everything.

Nicole Datson, chief development officer at Vico Therapeutics, later focused on novel RNA-modulating therapies for the treatment of genetic neurological diseases, looking at the therapeutic benefits and challenges of antisense oligonucleotides (ASOs) for CNS. She explained that specific challenges remain for ASO therapeutics in CNS: biodistribution (uptake in deeper brain regions, targeting specific brain cell types, conjugating to specific cell-type specific ligands), less invasive dosing (devices, BBB passage allowing systemic dosing, e.g., LNPs), and establishing more appropriate clinical trial designs (earlier treatment, long trials, dosing regimens).

About the author

Nicole Raleigh, Web Editor

Nicole Raleigh is pharmaphorum's web editor. Transitioning to the healthcare sector in the last few years, she is an experienced media and communications professional who has worked in print and digital for over 18 years.

Will the excitement for Threads translate to life sciences brands?

The launch of Meta's Threads app on Instagram is being viewed with great anticipation and intrigue, especially after it created a buzz by reaching 100 million sign-ups within just five days of its announcement.

Touted as a strong contender to the Elon Musk-owned X – previously known as Twitter – which has long been an established name in the world of social media, the launch of Threads could not have come at a better time when the world is adjusting to the rebranding exercise.

Ever since Musk took control of the X platform in 2022, it has been mired in controversies. One such plight involved pharma giant Eli Lilly where changes to the authenticity tag 'Twitter Blue' dealt a significant blow to the company, knocking $15 billion off of its market cap. The event caused such disruption that Eli Lilly had to tender an apology for the fake tweet and the following fiasco.

All it took for a user was to create a fake Eli Lilly account, verify it for $8, and promise 'free insulin'. Prior to the rule change, notable account holders were granted the blue tick for free, after a process of due diligence to ensure that the account was authentic and fight off imposter accounts. This process of authentication changed when Musk opened the blue tick option to anyone on payment of $8, a measure that cost Eli Lilly dearly.

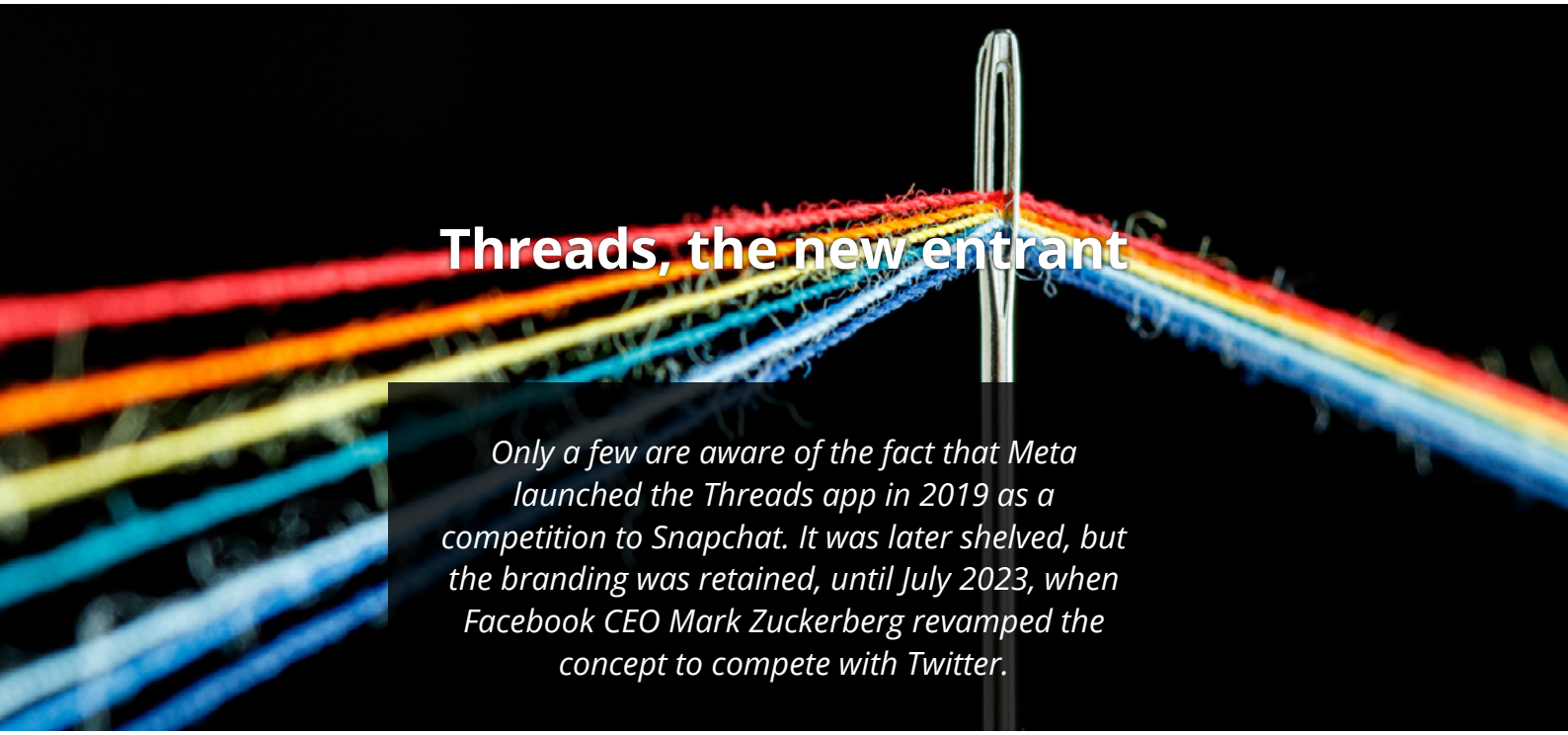
Learning the lesson the hard way after a spike in fake accounts, Twitter suspended its $8 blue tick subscription plan, but, by then, many big pharma companies, including Merck, Pfizer, and Novartis, had seen enough to stop advertising on the platform.

Pharma and the digital landscape

Compared to other sectors, pharma has been quite apprehensive about the use of digital channels for engaging healthcare professionals (HCPs), largely because industry and regulatory compliance varies from country to country and market to market.

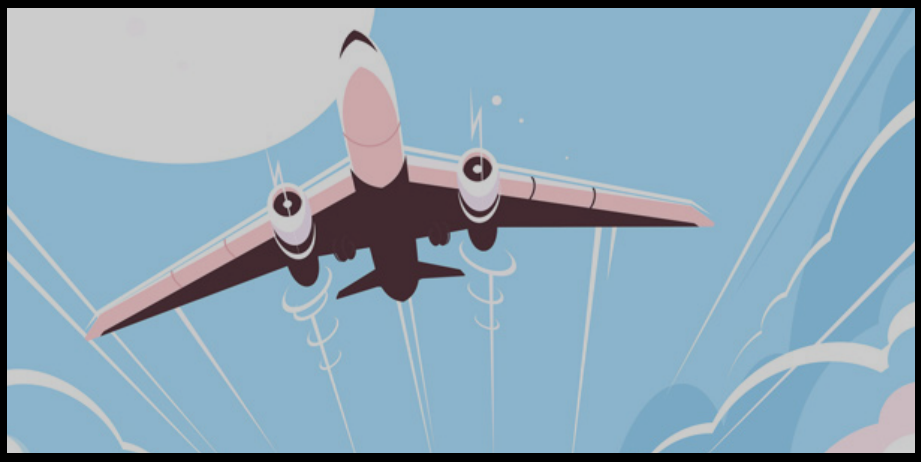
Only after the pandemic did the sector truly open up to digital, witnessing a surge in digital marketing efforts to reach HCPs for information and knowledge support. The digital realm is relatively new for pharma companies, one which they are still adapting to while getting accustomed to new technologies in the ever-evolving space.

Given all the apprehension of the past, creating a debacle-proof digital environment for pharma and life sciences brands is not just important, but essential. The digital ecosystem should instil confidence that the medium is as safe and promising as the traditional route for interacting with HCPs.



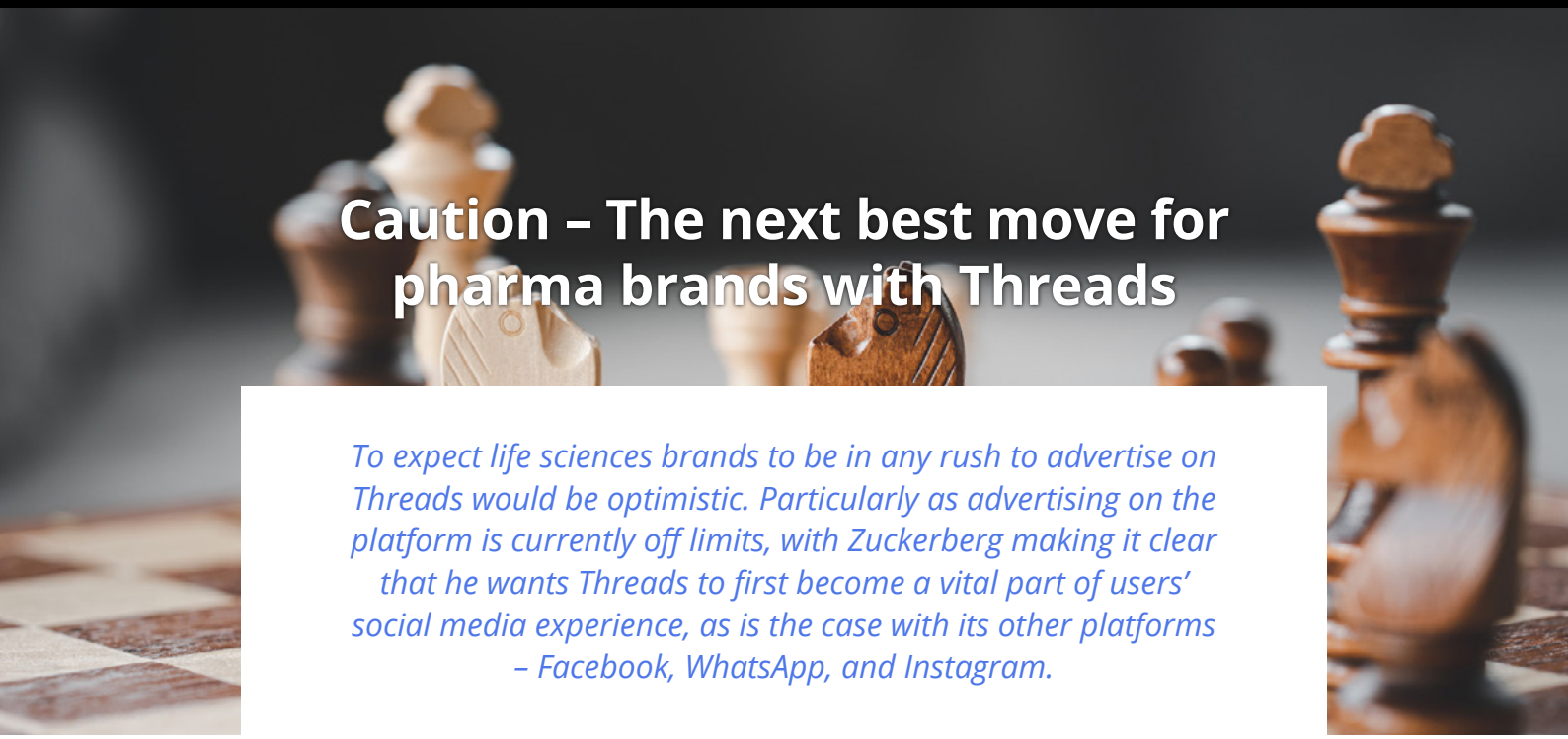
Threads, the new entrant

Only a few are aware of the fact that Meta launched the Threads app in 2019 as a competition to Snapchat. It was later shelved, but the branding was retained, until July 2023, when Facebook CEO Mark Zuckerberg revamped the concept to compete with Twitter.



If soaring popularity is any parameter to go by, the platform seems to have gained the vote of the masses. Threads broke the record of ChatGPT to cross a million sign-ups in just five days. It had taken ChatGPT and TikTok around two and nine months, respectively, to reach the same milestone. Facebook itself had taken just over four years to cross 100 million sign-ups, while for Twitter it took the platform five years to reach the milestone. Seen from that lens, the response to Threads by any measure has been nothing short of groundbreaking.

But does this huge user response mean that advertisers, especially life sciences companies, will be as keen to use the platform to reach their target audience?



Caution – The next best move for pharma brands with Threads

To expect life sciences brands to be in any rush to advertise on Threads would be optimistic. Particularly as advertising on the platform is currently off limits, with Zuckerberg making it clear that he wants Threads to first become a vital part of users' social media experience, as is the case with its other platforms – Facebook, WhatsApp, and Instagram.

When ad placements begin in the near future, pharma and life sciences brand marketers will get a clear picture of how compliant the platform is to industry and regulatory guidelines before they even consider advertising on Threads.

It will also have to be seen how HCPs respond to Threads. X, in its former Twitter days, proved quite popular with the physician fraternity – especially with digital opinion leaders – who saw the platform as a potential communication tool to help their patients, address misinformation, and advance scientific research. The platform has key physician communities, in which HCPs and fellow researchers connect with each other to share information around new treatment methods and discuss case studies.

Physicians have had a good experience with Twitter, now X, and the platform is taking a lot of critical measures to win back its lost ground. How well Threads will replicate or better the experience for physicians will set the tone for pharma marketing on the platform.

Irrespective of how new the platform is, it would certainly be a wise idea for pharma and life sciences brands to have an account on Threads to keep a tab on the direction it takes, so that they are right there to jump in the wagon when the time calls for it.

About the author

Harshit Jain MD, founder and global CEO, Doceree

Around the world in pharma events

Stay up to date with key industry meetings and conferences in 2023

Americas

iPharma Expo Boston
21-22 September
San Francisco, US
Event details

AI in Healthcare Summit
04-05 October
Boston, US
Event details

HLTH2023
08-11 October
Las Vegas, US
Event details

PHARMSCI 360
22-25 October
Florida, US
Event details

Middle East/Africa

Africa Health 2023
17-19 October
Johannesburg, South Africa
Event details

Global Health Exhibition
Saudi Arabia
29-31 October
Riyadh, Saudi Arabia
Event details

2nd Global Conference on Pharmaceuticals and Clinical Research
23-24 November
Dubai, UAE
Event details

ASLM 2023
12-15 December
Cape Town, South Africa
Event details

Europe

Economist Impact World Cancer Series
20-21 September
Brussels, Belgium
Event details

Frontiers Health
08-10 November
Rome, Italy
Event details

Health Tech Forward
21-22 November
Warsaw, Poland
Event details

GIANT health
04-05 December
London, UK
Event details

Asia Pacific

81st FIP World Congress of Pharmacy and Pharmaceutical Sciences
24-28 September
Brisbane, Australia
Event details

Reuters Pharma Japan
24-25 October
Tokyo, Japan
Event details

CPHI & PMEC India
28-30 November
Delhi, India
Event details

Clinical Trial Supply East Asia 2023
05-06 December
Seoul, South Korea
Event details

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