Steven Hadfield does not have the luxury of considering retirement. The 71-year-old from Charlotte, North Carolina, has worked multiple jobs over the past decade to help cover the steep costs of the prescription drugs he needs to treat a rare form of blood cancer and diabetes.

But drug pricing reforms unveiled in August by the Biden administration are poised to ease the financial burden facing Hadfield and millions of other Americans who struggle to pay for the drugs they need to stay alive.
From next month Medicare, the taxpayer-funded healthcare system that covers 65mn US retirees, will for the first time get the power to negotiate lower prices directly with pharmaceutical companies for 10 of the most expensive drugs. Cancer, stroke and diabetes medications made by Merck, Johnson & Johnson and Bristol Myers Squibb are among the first tranche of medications selected for negotiation.

For the US, the reforms represent the biggest shake-up in drug pricing in more than two decades. They stipulate prices must fall by at least 25 per cent for select commonly used drugs, including Januvia, a diabetes medication taken by Hadfield that costs $547 per month without rebates or discounts applied.

The US spends much more on drugs than other countries

Prescribed medicine spending per capita ($)
Dotted line = comparable country average

Source: Peterson-KFF Health System Tracker
“I’ve had to forgo or ration some of my drugs in the past due to their high costs,” says Hadfield, who as a Medicare member pays a portion of the tens of thousands of dollars his prescription drugs cost each year — $7,400 for the first seven months of 2023. “These drug-pricing reforms are finally ending Big Pharma’s one-sided pricing power and giving patients a break.”

US authorities will implement the first price cuts in 2026 and select a further 50 drugs for negotiation over the next four years. The measure is forecast to save Medicare about $100bn over a decade and cut the out-of-pocket costs that patients on these schemes must shoulder themselves. Americans pay the highest prices for prescription drugs in the developed world.

The reforms have been welcomed by patient advocates, who accuse Big Pharma of profiteering in a marketplace that has been rigged by an industry that funnels tens of millions of dollars a year of donations to politicians. The hope is that the new rules will begin to address the profound inequality that has become a defining feature of US healthcare provision.

But they are bitterly opposed by the pharmaceutical industry, which has launched lawsuits aimed at blocking reforms that were legislated last year in President Joe Biden’s Inflation Reduction Act (IRA).

Companies argue their prices are appropriate to cover the cost of the research needed to develop new medicines, estimated at $2.3bn per drug by Deloitte. Biden’s reforms are politically
motivated, they add, and will cripple innovation and stall development of life-saving medicines. Given the partisan nature of US politics, and the power of the pharmaceutical lobby, it is a moment some thought would never come. “These historic reforms follow a public debate that persisted for half a century in the US,” says Fred Ledley, director of the Center for Integration of Science and Industry at Bentley University.

“There has been a growing political consensus that something had to be done about drug prices, particularly given the huge profits generated by pharmaceutical companies,” he adds. “But it has been a polarising debate, given the potential impact of reforms on R&D budgets and what that means for global innovation.”

‘Historic change’

Drug pricing reform has been high on the political agenda in Washington for almost a decade following a litany of scandals that undermined public confidence in the pharmaceutical industry.

In 2015, then US presidential contenders Donald Trump and Hillary Clinton condemned Martin Shkreli, founder of Turing Pharmaceuticals, for raising the price of a potentially life-saving Aids and cancer medicine by more than 5,000 per cent overnight. Critics have also slammed industry leaders Eli Lilly and Biogen for charging excessive prices for treatments for common diseases such as diabetes and Alzheimer’s.

But clinching agreement in Congress on measures to bring down prices was challenging due to the strength of the industry lobby, disagreements over the best way to lower the cost and the opaque nature of the drugs market. This changed last year with the passing of the IRA, which included the drug pricing reforms alongside a swath of clean energy legislation, in a knife-edge 51-50 vote in the Senate.

“This is a historic change and a big step towards reducing drug spending in Medicare,” says Stacie Dusetzina, a professor of health policy at Vanderbilt University Medical Centre in Nashville, Tennessee.

She says US legislators explicitly banned Medicare from negotiating drug prices directly with manufacturers in 2003 when the last big reforms were agreed. This has prevented US authorities from leveraging Medicare’s purchasing power to drive down prices, a common practice deployed by national health systems in Europe and elsewhere, says Dusetzina.

“The savings achieved by negotiating prices on a small number of selected medications will benefit all Medicare members as savings to the Medicare programme will be used to fund other significant reforms in the IRA, including limits on out-of-pocket spending for members,” says Dusetzina.

Some IRA reforms have already been implemented, including a $35 cap on the monthly cost of insulin for Medicare patients. And starting in January 2025, seniors’ total out-of-pocket costs for
drugs will be capped at $2,000 a year — a change that patient advocates say will relieve an unpalatable choice facing many sick Americans to skip their medication or face bankruptcy.

“I really have a dog in this fight because the money they are talking about saving for me will be worth about $15,000 a year,” says David Mitchell, who has multiple myeloma and must take a cocktail of drugs with a total annual cost of almost $1mn to prolong his life.

Mitchell, who founded the advocacy group Patients for Affordable Drugs, should also benefit from price negotiations on Eliquis, a blood thinner he takes and which has an official price of almost $7,000 a year in the US, though usually insurers obtain discounts. The drug, which is made by BMS and Pfizer, cost Medicare $16.4bn last year — the highest amount for any of the 10 drugs selected for negotiation.

Mitchell says one of the reasons that Eliquis costs US taxpayers so much is that BMS has taken legal action to block alternative generic competitors from entering the market. In Canada, where there is a generic alternative on sale, the annual price for the same drug is less than $1,700, he says.

A BMS spokeswoman says: “protection of the intellectual property enables our ability to keep pushing the boundaries of science.”
The company adds that the $16.4bn gross annual costs of Eliquis to Medicare last year, which were cited by health authorities, is more than three times the programme’s actual spend on the blood clot drug when all rebates, discounts and fees paid to the public insurer were taken into consideration.

Companies already negotiate the price of some of their drugs with middlemen called pharmacy benefit managers. They work on behalf of health insurers, grouping large numbers of patients together from different clients in order to wring rebates from pharmaceutical companies, who in turn blame the managers for rising prices.

**US branded drugs** are marked up heavily compared to other countries, while **generic drugs** are actually cheaper

US prices v other countries, 2018 (%: 100 = price parity)

![Graph showing branded and generic drug prices in various countries](image)

**FINANCIAL TIMES** Source: ‘International Prescription Drug Price Comparisons’, Rand Corp, 2021, based on analysis of IQVIA MIDAS sales and volume data (ex biologics)
But critics of the current pricing regime allege American taxpayers and consumers are subsidising the global industry. Last year the US spent more than $600bn on medicines, almost half the total global outlay. A 2021 report by the Rand Corporation found Americans pay on average two and a half times more for prescription drugs than 32 comparable countries in the OECD. US prices for branded drugs were 3.5 times higher, it found.

The human impact of high drug prices was highlighted in a June report by the Centers for Disease Control and Prevention, which found 9mn Americans did not take their medications as prescribed in 2021 due to high costs.

**Industry bites back**

Despite failing to persuade lawmakers last year to vote down the IRA, there is still a risk the pharmaceutical industry could block the reforms. Merck, BMS, J&J, Novartis and some trade groups have launched a legal broadside against them, filing lawsuits in several different courts across the US.

These lawsuits focus on aspects of the IRA that they allege are unconstitutional. Merck claims the negotiation is “tantamount to extortion” because it involves neither genuine “negotiation” nor real agreements. The singular purpose of the IRA scheme is for Medicare to obtain prescription drugs without paying fair market value, it said in its lawsuit.

Manufacturers which do not comply with the negotiation process are liable to an excise tax, which starts at 65 per cent of a product’s sales in the US. Pfizer’s chief executive Albert Bourla has likened this aspect of the reforms to “negotiating with a gun to your head”.

Steven Hadfield, a 71-year-old from North Carolina, says: “I’ve had to forgo or ration some of my drugs in the past due to their high costs. These drug-pricing reforms are finally ending Big Pharma’s one-sided pricing power.” © Veejay Conway/FT
Industry expects private insurers to try to demand similar price cuts to those achieved by Medicare, posing a further threat to pharmaceutical sales and profits.

Many of the lawsuits warn about the negative impact that the IRA will have on innovation and drug development. Of particular concern is a rule stipulating that Medicare negotiation can begin nine years after a small molecule drug (typically a tablet) is first approved by regulators and 13 years for more complex biologic medicines.

BMS argues much of the progress in the fight against cancer is the result of post-approval research on small molecule drugs for patients. Opening up these drugs for negotiation after just nine years provides a disincentive for companies to conduct additional studies to expand their use to treat other possible diseases, it said.

BMS recently discontinued a study of a therapy called iberdomide for the treatment of patients newly diagnosed with multiple myeloma — a typically incurable type of blood cancer — due to the IRA. “We have made decisions to stop programmes,” Giovanni Caforio, BMS chief executive and chair, told the Financial Times in July.

“In the area of multiple myeloma it is now virtually impossible to develop a new medicine for newly diagnosed patients.”

AstraZeneca says the IRA drug price reforms run counter to efforts by industry and government to incentivise companies to develop new medicines to treat rare diseases. Dave Fredrickson, executive vice-president of the company’s oncology business unit, says that if the IRA had been in place in 2014 AstraZeneca may not have filed for approval and launched the drug Lynparza to treat a rare ovarian cancer suffered by a small number of US patients. That is because the company would be incentivised to wait until it could win an approval for a larger group of patients.

Drugmakers have criticised the different (nine and 13-year) timeframes given to small molecule and biologics before Medicare negotiation can begin. This distinction creates a perverse disincentive for companies and investors to invest in drugs that form the backbone of the pharmaceutical industry, they say.

In a survey conducted this year by Phrma, the main industry lobby group, almost two-thirds of members said they expect to shift their R&D away from small molecule medicines. Ninety-five per cent of members said they expected to develop fewer new uses for medicines because of the limited time available before government price setting occurs.

Four of the first 10 drugs targeted for Medicare negotiation are small molecule treatments for type 2 diabetes, a disease which affects about 35mn Americans.

“The negative implications are obvious. If pharmas were disincentivised to develop small molecule treatments for this disease before, they certainly have got the message now,” says Tim
Opler, a banker at Stifel, an investment bank. “And, we can’t remember the last large venture round done for a small molecule [that] targeted type 2 diabetes.”

The IRA’s impact on smaller biotechs and emerging biopharma companies with annual sales below $500mn is particularly important as last year they were responsible for about two-thirds of the industry’s R&D pipeline, according to IQVIA, a multinational company that provides consultancy services to the industry.

“The IRA impacts not just the drugs targeted for negotiation today but the entirety of the biotech ecosystem and funding decisions,” says Rachel King, interim president and CEO of the Biotechnology Innovation Organization.

**A modest start**

But many researchers say the doomsday arguments advanced by the pharma and biotech industries are exaggerated.

Lower prices following Medicare negotiation could spur higher patient demand for selected drugs, with some patients no longer having to ration supply.

The industry is in a strong financial position. Last year it generated almost $1.5tn in revenue, up from just under $1tn a decade ago. An analysis of the finances of the 14 most valuable drug companies published in 2021 by the committee on oversight and reform in Congress found they could afford to maintain or even exceed their R&D spending if they reduced spending on stock buybacks and dividends.

“From 2016 to 2020, the 14 leading drug companies spent $577bn on stock buybacks and dividends — $56bn more than they spent on R&D over the same period,” said the report.

Many experts say the IRA reforms are much weaker than current practices in Europe and other developed countries. For example, European health authorities can negotiate lower prices when drugs are initially launched, not only on those approved 9 or 13 years earlier.

Marc Rodwin, a professor of law at Suffolk University, says the IRA legislation is “very moderate” and does little, given most of the drugs on Medicare’s negotiation list have been on the market for nine or 10 years. “By that point the drug has already more than recouped its investment and done quite well,” he says.

Under the IRA rules, older drugs can also escape Medicare negotiation if they face generic competition. Some of the first 10 drugs listed by US health authorities are nearing their patent expiry, meaning they could face generic competitors before January 2026 when the first negotiated prices are due to take effect.

Some experts argue the reforms could in fact stimulate more innovation as companies are forced to battle harder to achieve growth. The only way to have a “larger share of the pie”, says
Kenneth Kaitin, a professor at the Tufts Center for the Study of Drug Development, “is by having novel drugs that treat diseases where there are few other medications available”.

However, he says it would be worth watching whether venture capitalists are more reluctant to invest in biotechs trying to treat some conditions if they do not think they will get as large a return on investment.

Suerie Moon, co-director of the global health centre at Geneva’s Graduate Institute, says US health officials had chosen the list of 10 drugs for negotiation carefully. At first, some were surprised that many of the drugs were nearing their patent expiry, but Moon said that it shows they are preparing to be challenged.

“By choosing products that are almost off patent, you have companies who will have been able to recoup multiple times over whatever investments they have made in R&D,” she says.

The IRA reforms are starting off slowly, she adds. But they send an important signal to industry that healthcare systems will consider questions like the cost of R&D, the effectiveness of the product, and what the alternatives are. “The signal is important, so there’s a deterrent effect for excessive pricing,” she says.

For patients like Hadfield, who have struggled for years to pay for their drugs, the IRA reforms represent an overdue victory over one of the most powerful lobbies in Washington. But he warns the legal battle is not won yet.

“The pharma companies are trying to get away without having to negotiate,” he says. “They are trying to find a loophole to get out of this and shouldn’t be allowed.”