Medicare’s Historic Prescription Drug Price Negotiations

On August 29, 2023, the Biden administration announced the first 10 drugs whose prices will be negotiated with pharmaceutical companies through the Centers for Medicare & Medicaid Services (CMS).1 CMS’s initial list features drugs that are among the most commonly used and highest in total spending in Medicare Part D, including treatments for blood clots (apixaban [Eliquis] and rivaroxaban [Xarelto]), diabetes (empagliflozin [Jardiance] and sitagliptin [Januvia]), cardiovascular disease, and cancer. Collectively, these 10 drugs cost CMS $50.5 billion between June 1, 2022, and May 31, 2023, and Medicare enrollees paid $3.4 billion in out-of-pocket costs in 2022.2 CMS will negotiate prices for up to 60 Medicare-covered drugs during the next 4 years and up to 20 additional drugs annually in subsequent years. Pharmaceutical companies filed multiple lawsuits challenging the lawfulness of Medicare price negotiations (Table). This Viewpoint evaluates the legal claims and policy implications of historic drug price negotiations.

Drug Price Negotiation Program
The Inflation Reduction Act (IRA) of 20223 authorized CMS for the first time to negotiate the price Medicare pays for pharmaceuticals. Congress did not authorize drug price negotiations in creating Medicare Parts A or B in 1965. When it enacted Medicare Part D drug benefits in 2003, it expressly proscribed price negotiations. After the IRA’s passage, CMS issued guidance detailing how it would negotiate “maximum fair prices.”4 As in other Medicare programs, participation in negotiations is voluntary. Manufacturers who choose not to participate may withdraw from Medicare and Medicaid or pay an excise tax on select drugs sold to Medicare. Medicare price negotiations are projected to save US taxpayers $25 billion by 2031.5

Legal Challenges to Price Negotiations
Pharmaceutical companies have sued in diverse geographic regions, claiming that the IRA and CMS regulations violate free speech, take property without fair compensation, and deprive companies of due process of law. They also claim that excise taxes on companies that refuse to negotiate but still choose to sell drugs to Medicare constitute excessive fines. Additionally, there are arguments based on separation of powers principles.

Compelled Speech. The First Amendment not only protects the freedom of expression but also guards against compelled speech. Drug manufacturers argue that CMS’ drug price negotiations force them to say they agree to maximum “fair” prices even though they do not believe prices are fair. CMS requires companies to reach terms over fair prices contractually but does not compel them to endorse speech with which they disagree. Participation in Medicare is voluntary. Manufacturers can choose whether to negotiate and are free to exercise their free-speech rights to publicly state that negotiated prices are unfair.6

Government Takings. Under the Fifth Amendment, government cannot take private property “for public use, without just compensation.” Takings arise when government physically acquires private property (eg, eminent domain) or limits its use so as to unreasonably devalue it (“regulatory takings”). Manufacturers argue that CMS is “taking” their property by negotiating prices lower than the market rate. Yet manufacturers have no right to charge Medicare prices they set unilaterally; nor is CMS obligated to pay such prices. Just like any market participant, CMS is choosing the amount it is willing to pay—within congressionally set parameters. Other government entities, including the Veterans Administration, US Department of Defense, US Coast Guard, US Public Health Service, and Medicaid, already negotiate drug prices.

Due Process. The Fifth Amendment also prohibits the government from depriving persons of “life, liberty, or property without due process of law.”7 Pharmaceutical companies argue that CMS will arbitrarily deprive them of property by not allowing them to sell patented drugs to Medicare at market prices, and CMS did not afford sufficient notice and the right to be heard. These claims are inaccurate. The IRA methodically details how CMS must negotiate, laying out factors CMS has to consider. Most important, negotiations are a bilateral process, giving companies wide input. IRA procedures safeguard manufacturers’ interests in a fair process. Given a lengthy and structured negotiation process, Congress acted constitutionally.

Excessive Fines. Manufacturers claim that excise taxes violate the Eighth Amendment’s prohibition of excessive fines. The Supreme Court has clarified that the Eighth Amendment prohibits government from imposing excessive fees, typically as punishments for crimes that are “grossly disproportional” to the gravity of the offense.7 Companies argue that levying an excise tax for failing to sell their drugs to Medicare based on maximum fair prices somehow constitutes an unconstitutional punishment. Excise taxes are not punitive,8 but rather remedial in ensuring that the government recoups money for drugs sold to Medicare at exorbitant prices. Manufacturers can avoid the excise tax altogether by refusing to sell their drugs and withdrawing from Medicare and Medicaid.

Separation of Powers. Under constitutional separation of powers principles, Congress alone holds legislative authority, not executive agencies (Article 1, §1). Under the nondelegation doctrine, courts examine whether Congress improperly delegated its legislative functions to agencies. Pharmaceutical companies claim that Congress improperly delegated its legislative powers by giving CMS broad authority to negotiate drug prices without sufficient guidance. Yet the nondelegation doctrine has not been formally applied by the Supreme Court since 1935.

Federal agencies are indispensable in achieving Congress’ legislative goals. The Supreme Court has long held that Congress may delegate broadly to enable
administrative agencies to address complex problems in health, safety, and the environment. Delegation is permissible as long as Congress lays out clear policies with appropriate boundaries, which is what Congress did in the IRA. It tasked CMS with implementing price negotiations, detailing guidance on how to conduct the negotiations. Congress also set guardrails for CMS, including establishing the class of drugs eligible for negotiation, maximum price thresholds, and factors to consider in determining each drug’s fair price.

Recently, the Supreme Court struck down administrative rules on climate change, COVID-19 mitigation, and student loan forgiveness based on the major questions doctrine, an administrative law principle that presumes Congress did not empower executive agencies to issue rules of “vast” political or economic significance without clear statutory language. Although the IRA has major policy significance, Congress explicitly and unambiguously granted CMS power to negotiate drug prices. The Supreme Court would be usurping Congress’ legislative power to solve problems of vital social importance if it strikes down drug price negotiations.

**Litigation Strategies and Pitfalls**

The industry’s litigation strategy hinges on filing myriad cases across the country designed to achieve a predictable split in judicial decisions. Even a single federal judge could temporarily nullify CMS’ drug pricing negotiations until appellate courts intervene. Ultimately, review before the Supreme Court seems inevitable.

Congress broke through decades of drug company control of the Medicare market in recognition of spiraling, uncontrolled costs. The US health care system spends twice as much per capita on prescription drugs as peer nations. In 2019, the US spent $1126 per capita on prescribed medicines, whereas comparable countries spent $552. Per capita prescribed medicine spending in the US increased by 69% from 2004 to 2019 compared with 41% in comparable countries. Peer countries set prices directly or limit how much government will spend on health care, actively negotiating prices. This is what Congress authorized CMS to do. Prescription drug prices are expected to decrease for tens of millions of beneficiaries, just as they did for insulin earlier this year.

Expecting taxpayers and mostly elderly Medicare patients to pay appreciably higher costs for prescription drugs than in other countries is unfair and unsustainable. Lowering prices is widely popular, with 82% of respondents in a recent poll saying drug costs were unreasonable. Among respondents taking 4 or more drugs, 37% reported having difficulty affording their prescriptions. Reducing drug prices should be a policy decision made by Congress, yet the final determination is likely to rest with the Supreme Court.

**Table. Litigation Regarding CMS Drug Pricing Negotiation Authority**

<table>
<thead>
<tr>
<th>Short case name</th>
<th>District court</th>
<th>Date filed in 2023</th>
<th>First Amendment, compelled speech</th>
<th>Fifth Amendment Due process</th>
<th>Takings clause</th>
<th>Separation of powers</th>
<th>Unconstitutional procedure act</th>
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* Source: Hodge et al.  

REFERENCES