Analyzing the impact of the Inflation Reduction Act of 2022 on biosimilars in the United States: a simulation with adalimumab products.

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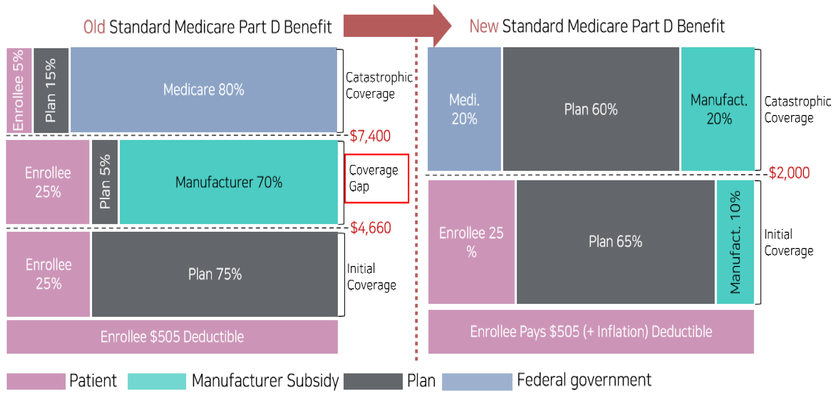
OBJECTIVES

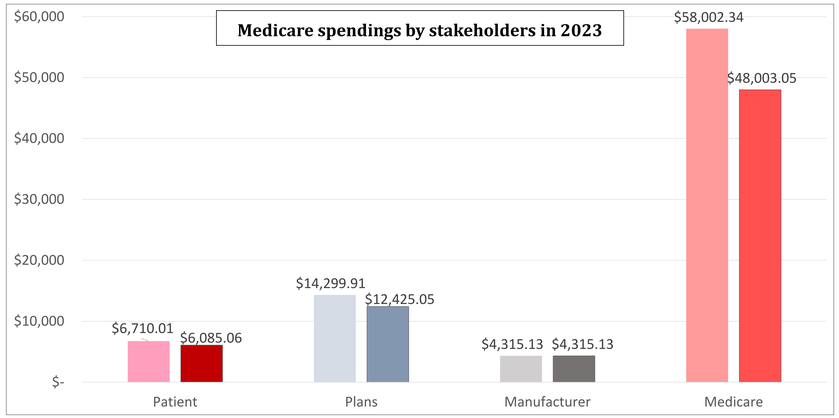
In 2022 the US government announced the Inflation Reduction Act (IRA), which included several provisions to lower Medicare patients' prescription drug costs and reduce medication cost spending by the federal government. Starting in 2024, the IRA caps out-of-pocket (OOP) spending for Medicare Part D enrollees by eliminating the 5% co-pay within the catastrophic threshold. Then, from 2025, the legislation adds a $2,000 hard cap on patient out-of-pocket spending and lowers Medicare's coverage from 80% to 20%, once the patient reaches $2,000 OOP cap. From this point, which is called the 'catastrophic coverage stage', OOP payment will not incur anymore. Instead, managed care plans must take over 60% and manufacturers will pay 20% of the annual medication costs.

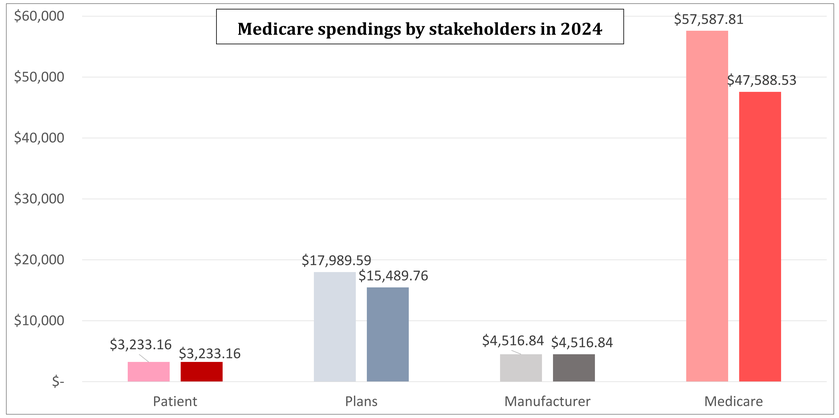
In this study, our aim is to explore the implication of the Inflation Reduction Act to each stakeholder by comparing drug costs for Humira and its biosimilar CT-P17 during 2024 and 2025 versus in 2023.

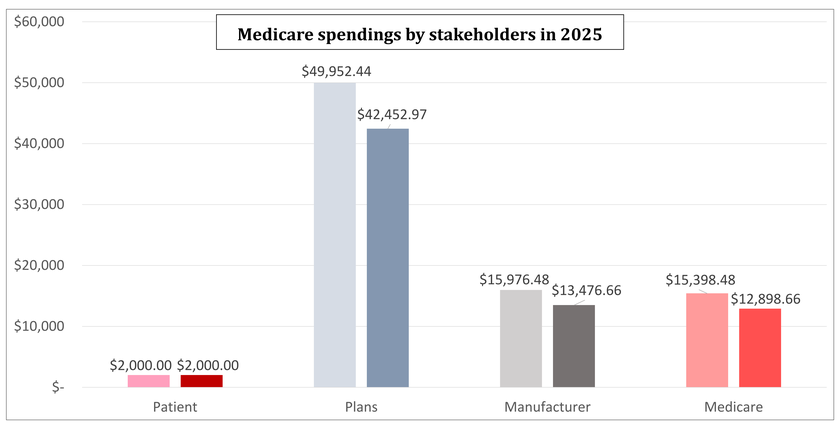


METHODS

This study compares the annual drug acquisition cost and the amount levied to each stakeholder for treating a patient with either Humira or CT-P17. Costs shared by the government (or Medicare), managed care plans, manufacturers, and beneficiaries, were compared under the scheme of Medicare Part D standard eligibility group. Wholesaler acquisition cost (WAC) of CT-P17 was assumed to be 15% lower than the originator's WAC. Price assumption for CT-P17 was drawn through landscape analysis of US biosimilars price at launch.







RESULTS

According to the study results, in 2024 patient out-of-pocket spending for Humira and CT-P17 would decrease 48% and 47% respectively, and even more in 2025 due to the $2,000 cap. Results showed that Medicare spending would slightly decrease in 2024 and would drop sharply by nearly 75% in 2025. Managed care plans and manufacturers would face some growth on their expenses in 2024, and in 2025 that they would face nearly a three-fold increase. However, the introduction of CT-P17 may reduce Medicare's burden by 17.36% in 2024 and 16.23% in 2025. For managed care plans, the expenditure may decrease by 13.90% in 2024 and 15.01% in 2025 as a result of replacing originator with the CT-P17.

	2023		2024		2025	
	Originator	CT-P17	Originator	CT-P17	Originator	CT-P17
Patient	$ 6,710.01	$ 6,085.06	$ 3,233.16	$ 3,233.16	$ 2,000.00	$ 2,000.00
Plans	$ 14,299.91	$ 12,425.05	$ 17,989.59	$ 15,489.76	$ 49,952.44	$ 42,452.97
Manufacturer	$ 4,315.13	$ 4,315.13	$ 4,516.84	$ 4,516.84	$ 15,976.48	$ 13,476.66
Medicare	$ 58,002.34	$ 48,003.05	$ 57,587.81	$ 47,588.53	$ 15,398.48	$ 12,898.66

CONCLUSION

The implementation of the IRA is expected to reduce financial burden for patients and the federal government, while increasing managed care plans and manufacturers' charge. This study showed that raised drug price would aggravate burden for plans and the manufacturers, who are the main price setters in the market. The IRA is expecting such impacts would finally lead the stakeholders to find an appropriate price level in the biopharmaceutical market. Furthermore, the study also suggests that the use of biosimilars would allow Medicare and managed care plans to reduce prescription drug expenditure and expand patient access to biological treatments.