S. 2292, Over-the-Counter Monograph User Fee Amendments
Senator Jim Banks (R-IN) and Senator Tim Kaine (D-VA)

Sec. 1. ***Short Title*** – This Act may be cited as the "Over-the-Counter Monograph Drug User Fee Amendments."

Sec. 2. ***Findings*** – This section provides that Congress finds that fees authorized by this Act will be dedicated to over-the-counter monograph drug activities.

Sec. 3. ***Definitions*** – This section amends the Federal Food, Drug, and Cosmetic Act including by allowing testing procedures applicable to over-the-counter drugs as long as those procedures reflect voluntary consensus standards.

Sec. 4: ***Authority to Assess and Use OTC Monograph Fees*** – This section makes updates to the assessing and collecting of fees for Fiscal Years 2026-2030, including the timeline by which fees shall be collected each fiscal year. This section also allows the Food and Drug Administration to issue a one-time facility fee adjustment for Fiscal Years 2028-2030 if it makes a determination the adjustment is necessary.

Sec. 5. ***Reauthorization; Reporting Requirements*** – This section extends existing reporting requirements on over-the-counter monograph drug activities through Fiscal Year 2023.

Sec. 6. ***Sunset Date*** –This section sunsets the over-the-counter monograph drug user fee program on October 1, 2030.

Sec. 7. ***Effective Date*** – This section provides that the act shall take effect on October 1, 2025 or the date of the enactment with the exception of fees that shall take effect on October 1, 2025, regardless of the date of enactment.

Sec. 8. ***Savings Clause*** – This section states that the Act will not affect the collection of fees for activities prior to Fiscal Year 2026.