Pioneering Antimicrobial Subscriptions To End Upsurging Resistance (PASTEUR) Act of 2026

Section-by-Section Summary

SECTION 1. SHORT TITLE

The title of the bill is the **"Pioneering Antimicrobial Subscriptions To End Upsurging Resistance Act of 2026"** or the **"PASTEUR Act of 2026."**

SECTION 2. PURPOSE

This section describes the purpose of the PASTEUR Act of 2026, emphasizing that the Act is intended to ensure the availability of antimicrobials in order to—

- Stimulate a new era of research, development, and market access for lifesaving medicines;
- Ensure the appropriate use of lifesaving medicines;
- Maintain the highest medical care standards for American patients;
- Promote national health system preparedness; and
- Defend the United States and its military.

SECTION 3. DEVELOPING ANTIMICROBIAL INNOVATIONS

This section amends the Public Health Service Act to add "**Part X-U.S. Novel Antimicrobial Supply Contracts**".

Part X—U.S. Novel Antimicrobial Supply Contracts

Section 399PP. Contract Application, Award, and Implementation

Subsection (a): In General

This subsection authorizes the Secretary of Health and Human Services to enter into contracts with sponsors of eligible antimicrobials for the purpose of ensuring sustained availability of such antimicrobials in the United States.

Subsection (b): Eligible Antimicrobial

This subsection outlines eligibility requirements for an antimicrobial drug or biological product, which must:

- Treat a pathogen identified as an "urgent" or "serious" threat in the most recent **Antibiotic Resistance Threats in the United States** report published by the CDC, or another pathogen the Secretary determines appropriate in consultation with the Advisory Group; and
- Address an unmet medical need.

Subsection (c): Applications

This subsection relays application requirements for eligible sponsors. Sponsors of eligible antimicrobials may apply for a contract not later than two years after FDA approval or licensure of the product. Applications must include information necessary to determine the antimicrobial's score under the valuation methodology established in Subsection (d), but are not required to include information related to pricing or research and development costs.
The Secretary must review each application within 90 days. Applications are denied if the antimicrobial's score falls below the minimum threshold and approved if the score meets or exceeds that threshold. Sponsors may submit revised applications with materially new information beginning one year after denial and no more frequently than every two years thereafter.

Subsection (d): Scoring
Within 270 days of enactment, the Secretary, in consultation with the Advisory Group and relevant HHS agencies, and after consideration of public comments, must promulgate regulations establishing:

1. A transparent, quantitative scoring methodology for eligible antimicrobials; and
2. A minimum score required for contract eligibility.

Eligible antimicrobials are scored across three weighted categories:

- Major contributions to patient care, such as improved outcomes, reduced toxicity, improved dosing, or advantageous routes of administration;
- Innovative characteristics, including novel classes, novel mechanisms of action, or the ability to address serious or life-threatening infections with unmet need; and
- Health system and public health benefits, such as resistance mitigation, U.S. manufacturing capacity, improved stability, and reduced burden of antimicrobial resistance.

Subsection (e): Contract Requirements
As a condition of entering into a contract, a sponsor must:

- Ensure commercial availability of the antimicrobial in the United States within 30 days of first payment, and ensure sufficient supply for susceptibility test device manufacturers;
- Publicly identify, track, and report drug resistance data and trends;
- Develop and implement education and communication strategies for healthcare professionals and patients regarding appropriate use;
- Submit a plan for appropriate use and antimicrobial stewardship, including a general description of marketing practices; This plan also may include a plan to collect data on the impact of diagnostics, antimicrobial stewardship programs, and other appropriate use efforts on patient outcomes and healthcare costs;
- Submit a plan for registration in additional countries with unmet medical need, if requested;

- Maintain a reliable supply chain and submit a shortage mitigation plan within 30 days if the FDA determines a shortage exists;
- Manufacture the antimicrobial at a volume sufficient to meet U.S. patient needs within 30 days of the first payment;
- Adhere to recognized manufacturing and environmental best practices; and
- Comply with any additional terms required by the Secretary.

Subsection (f): Annual Payments
The Secretary must make annual subscription payments to contract sponsors for the duration of the contract, beginning no later than 180 days after contract approval.
Annual payments must:

- Be no less than $75 million and no more than $300 million, adjusted annually for inflation; and
- Be reduced by the sponsor's net U.S. revenue from sales of the antimicrobial during the prior year.

The Secretary may require disclosure of revenue information for payment calculation purposes, subject to strict confidentiality protections. The Secretary may terminate annual payments if the sponsor permanently withdraws from the US market, materially fails a requirement after an opportunity to correct, or does not conduct a postmarket study by the FDA during the contract. This subsection does not authorize the Secretary to disclose any trade secrets or use evidence from comparatively clinical effectiveness research to limit patient access.

Subsection (g): Contract Term
Contracts remain in effect until the earlier of:

- Ten years after contract approval; or
- The approval and market entry of a generic or biosimilar competitor.

Contracts remain in force even if the treated pathogen is later removed from the CDC threat list.

Subsection (h): Other Government Participation
This subsection directs the Secretary to encourage other federal entities to participate in similar antimicrobial incentive programs.

Subsection (i): Authority Vested in the Secretary
This subsection authorizes the Secretary to carry out contracts without regard to otherwise applicable federal procurement laws if necessary to further the purposes of the Act.

Section 399PP-1. Critical Need Antimicrobial Advisory Group
Subsection (a): In General

This subsection requires the Secretary to establish a **Critical Need Antimicrobial Advisory Group** within 60 days of enactment to support implementation of the PASTEUR subscription mechanism.

Subsection (b): Members
The Advisory Group shall consist of 15 members, including:

- At least 4 board-certified infectious disease physicians;
- At least 4 experts in antimicrobial resistance, health economics, or antimicrobial development and commercialization;
- At least 4 patient or caregiver advocates; and
- 3 additional individuals meeting one of the above criteria.

Subsection (c): Chair
The Secretary must appoint a nonvoting Chair who meets the qualifications in Subsection (b).

Subsection (d): Conflicts of Interest
Members are subject to strict conflict of interest restrictions.

Subsection (e): Applicability of FACA
The Federal Advisory Committee Act generally applies, except that the Advisory Group is not subject to termination requirements under Section 1013.

SECTION 399PP-2. ENCOURAGING APPROPRIATE USE OF ANTIMICROBIALS AND COMBATING RESISTANCE
Subsection (a): Health Facility Grant Program
This subsection directs the Secretary, acting through the CDC, to establish a grant program within one year to support antimicrobial stewardship and resistance monitoring efforts in hospitals, nursing facilities, and other healthcare facilities. The grants shall support the judicious use of antimicrobials and participation in the National Healthcare Safety Network Antimicrobial Use and Resistance Module or the Emerging Infections Program Healthcare-Associated Infections Community Interface activity of the CDC. Priority is given to facilities without existing stewardship programs, including rural, critical access, Tribal, and safety net hospitals. All entities receiving grants must adhere to nationally recognized guidelines and best practices.

Subsection (b): Antimicrobial Stewardship Pilot Program for Outpatient Facilities
This subsection requires the Secretary to establish a pilot grant program guided by consultation with expert professional societies within two years to support antimicrobial stewardship in outpatient settings. To qualify, an entity must be a physician, a hospital outpatient department, an urgent care center, or a retail clinic, with priority for the latter two. All entities receiving grants must adhere to nationally recognized guidelines and best practices. The Secretary must report to

Congress on the outcomes of the pilot and recommendations for broader implementation within 5 years of enactment.

Subsection (c): Surveillance and Reporting of Antimicrobial Use and Resistance
This subsection directs the Secretary, in collaboration with external stakeholders, to intensify and expand antimicrobial use and resistance surveillance through the National Healthcare Safety Network and other systems, including collection of consumption, resistance, and diagnostics data. Beginning two years after enactment, the Secretary must make such data publicly available through regularly issued reports and explore opportunities for near real time access.

SECTION 399PP-3. DEFINITIONS
This section defines key terms for purposes of Part X, including "antimicrobial drug," "contract," "contract antimicrobial," and "eligible antimicrobial."

SECTION 399PP-4. APPROPRIATIONS
Subsection (a): In General
This subsection provides **$6 billion in mandatory funding** for fiscal year 2026 to carry out the program, to remain available until expended.

Subsection (b): Allocation
This subsection limits administrative and stewardship grant spending to no more than 6.5 percent of total funds.

Subsection (c): Emergency Designation
This subsection designates the funding as an emergency requirement for budgetary purposes.