KILPATRICK TOWNSEND

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Legislative Update: The PASTEUR ACT – Incentivizing Discovery and Development of Novel Antimicrobial Drugs

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With everything that was happening this past winter, it would have been easy to miss the introduction of S. 4760: The PASTEUR Act. On December 9, U.S. Representatives Mike Doyle (D-PA) and Drew Ferguson (R-GA) introduced the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act to encourage the development of critically needed antimicrobials and antibiotics.[1]

According to the Centers for Disease Control and Prevention (CDC) 2019 report Antibiotic Resistance Threats in the United States ("CDC Report"), "more than 2.8 million antibiotic-resistant infections occur in the United States each year, and more than 35,000 people die as a result."[2] Globally, that number has been put at 700,000 deaths per year, and estimates project that number reaching 10 million a year by 2050.[3]

Concerns about the rise of antibiotic-resistant infections date well back into the 20th Century, yet investigational new drug applications (INDs) for new, systemically acting antibacterial drugs consistently and dramatically declined between the 1980s and 2000s.[4]

In an effort to reverse this trend, in 2012, Congress enacted the Generating Antibiotic Incentives Now (GAIN) Act to promote the development of Qualified Infectious Disease Products (QIDPs).[5] QIDPs target "serious or life-threatening infections" caused by a group of specified pathogens, as determined by the Secretary of HHS. [6] The GAIN Act provided incentives to drug sponsors in the form of 5-year exclusivity extensions for QIDPs on top of all non-patent exclusivities available through the Hatch-Waxman and Orphan Drug Acts. The Act also made QIDPs automatically eligible for priority review (6-month FDA review targets rather than 10-month[7]) and fast-track designation (more frequent communication with FDA, rolling review, eligibility for accelerated approval[8]).

Despite the incentives set up by the GAIN Act, the number of antibacterial INDs initiated with the FDA from 2010-2019 was lower than in any of the preceding three decades.[9] The number has been steadily dropping in recent years, such that as of the end of 2019, the number of active antibacterial INDs had declined to an 11-year low.[10] The PASTEUR Act takes a more direct approach to incentivizing research investment in the antimicrobial space and ensuring drug availability when needed.

At the heart of the PASTEUR Act is a "delinked" subscription program. Moving away from volume driven payments (thus, delinked), the drug sponsor of a "critical need antimicrobial" will instead receive a payment of

"not less than $750,000,000 and not more than $3,000,000,000" in exchange for patient access to the drug through Federal health programs at no cost.[11]

Applications for critical need antimicrobial designations may be filed within 5 years of drug approval and will be reviewed by the Secretary of DHHS and a new Committee on Critical Need Antimicrobials to be made up of federal agency representatives, with input from a new Critical Need Antimicrobials Advisory Group that will include outside experts and patient advocates. Eligibility and contract size will be determined based on whether the antimicrobial drug is likely to provide certain "favored characteristics," [12] including:

- treating a "prioritized infection" as determined by the Secretary, Committee, and Advisory Group, "taking into account infections for which there is an unmet medical need"; [13]
- improving clinical outcomes for patients with multi-drug resistant infections;[14] and
- being a first-approved drug that treats certain multi-drug resistant infections, and, to a lesser extent, second and third drugs that treat such infections.[15]

Contracts will be paid out over a period of "no less than 5 years or greater than the greater of 10 years or the remaining period of time during which the sponsor has patent protections or a remaining exclusivity period with respect to the antimicrobial drug."[16]
Drug sponsors must agree to certain requirements, including:

- ensuring "commercial and Federal availability"; [17]
- producing "the drug at a reasonable volume"; [18]
- ensuring "a reliable drug supply chain"; [19] and
- tracking and reporting drug resistance data.[20]

The Bill also contemplates a transition period while regulations are being finalized, during which the Secretary may enter into "transitional subscription contracts of up to 3 years in length" with drug sponsors. [21]
The bill currently contemplates $11 billion in initial funding to support the program with the Government Accountability Office carrying out a study on the program's effectiveness within 6 years.

We will follow the progression of this Bill and provide updates. For additional details of and thoughts on the PASTEUR Act as well as shortcomings of the GAIN Act, see our expanded discussion in Lexology.

Footnotes

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[1] The PASTEUR Act, S. 4760, 116th Cong. (2020), https://www.congress.gov/bill/116th-congress/senate-

bill/4760/text?r=2&s=1; U.S. Congressman Mike Doyle, *Congressmen Doyle & Ferguson Introduce PASTEUR Act to Promote New Antimicrobial Drugs 3* (Dec. 9, 2020), https://doyle.house.gov/media/press-releases/congressmen-doyle-fergusonintroduce-pasteur-act-promote-new-antimicrobial.

[2] CDC, *Antibiotic Resistance Threats in the United States* (Dec. 2019), https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.

[3] United Nations Interagency Coordination Group on Antimicrobial Resistance, *No Time to Wait: Securing the Future from Drug-Resistant Infections*, Report to the Secretary-General of the United Nations (2019), https://www.who.int/docs/default-source/documents/no-time-to-wait-securing-the-future-from-drug-resistant-infections-en.pdf?sfvrsn=5b424d7_6.

[4] Nidhi Dheman, et al., *An Analysis of Antibacterial Drug Development Trends in the US, 1980 – 2019*, Clinical Infectious Diseases ciaa859 (2020), https://pubmed.ncbi.nlm.nih.gov/32584952/.

[5] 21 U.S.C. § 355f.

[6] *Id.* at § 355f(g); 21 C.F.R. § 317.2.

[7] FDA, *Priority Review* (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review.

[8] FDA, *Fast Track* (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track; FDA, *Accelerated Approval* (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval.

[9] Dheman, *supra*, note 4.

[10] *Id.*; Jonathan Slater, *QIDP: What Have We GAINed*, Pharma Intelligence (2019), https://pharmaintelligence.informa.com/~/media/informa-shop-window/pharma/2019/files/article-packs/qidp---what-have-we-gained-whitepaper.pdf.

[11] S. 4760 §§ 4(b), 4(c)(1).

[12] *Id.* § 2(c)(1).

[13] *Id.* §§ 2(c)(2)(a), 2(c)(1).

[14] *Id.* § 2(c)(2)(B).

[15] *Id.* § 2(c)(2)(C).

[16] *Id.* § 4(c)(2)(A).

[17] *Id.* § 4(b)(1).

[18] *Id.* § 4(b)(8).

[19] *Id.* § 4(b)(6).

[20] *Id.* § 4(b)(2).

[21] *Id.* § 2(f)(1).