Oral Statement

of the

Pharmaceutical Care Management Association (PCMA)

Before the

U.S. Pharmacopeia Roundtable on Biologics Nomenclature:
Request for Stakeholder Feedback

June 23, 2020

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Good morning. I am Claire Wulf Winiarek, vice president of Policy for the Pharmaceutical Care Management Association, or PCMA. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the health insurance exchanges established by the Affordable Care Act (ACA). Our members work closely with employers, health plans, and other issuers to secure lower costs for prescription drugs and promote better individual health outcomes.

PCMA appreciates this opportunity to share our industry's perspective on U.S. Pharmacopeia's proposed revision to Section 2.20 of its *General Notices* relating to biologics nomenclature.

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PCMA supports accelerating the entry and greater availability of low-cost generic drugs and biosimilar and interchangeable products into the market.

As all other public comments this morning have shared, PCMA echoes these sentiments. We continue to recommend alignment in the approach to biosimilar naming and promotional labeling with that for brand and generic small-molecule drugs where no suffix is used. We believe the current convention, which USP's proposed revision would further, confuses patients and clinicians and can promote the mistaken belief that interchangeable products are not truly interchangeable.

Patients and clinicians need express clarity that these therapeutic substitutions are really and truly interchangeable. For many patients and clinicians alike, these therapies are new and there may be a degree of uncertainty around switching and substitution. Anything short of that clarity would reinforce caution from patients and clinicians and thus impede the ability to achieve a truly competitive biosimilar market.

Thank you, again, for the opportunity to provide input. We look forward to hearing from other stakeholders.