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Generics

Access to Affordable Medication Delayed Is Health Care Denied: Senate Judiciary Committee Introduces CREATES Act




By James W. Matthews, David L. Rosen, Katy E. Koski and Jason L. Drori

Following months of public outcry and Congressional probes into significant drug price increases, the Senate Judiciary Committee introduced legislation targeting ''behavior that blocks competition and delays the creation of affordable generic drugs'' and biosimilar products. The bill, entitled the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2016 (the ''Creates Act''), S. 3056, punishes the strategic refusal of ''innovator'' companies to: (1) share drug samples needed for generic and biosimilar regulatory testing and approval; and (2) agree on a shared safety protocol for so-called ''REMS products.'' The bill is the latest in a string of legislative efforts around the country focusing on drug affordability and price transparency.

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Regulatory Background.

To gain FDA approval, a generic drug must be chemically identical or ''bioequivalent'' to its branded counterpart. A generic biological product likewise must be ''highly similar,'' *i.e.*, ''biosimilar,'' to the licensed reference product.

When and how a generic or biosimilar product (or brand drug or biologic) enters the pharmaceutical supply chain varies depending on whether the product is subject to Risk Evaluation and Mitigation Strategies (''REMS'') requirements. REMS originated with the FDA Amendments Act of 2007, which authorizes distribution restrictions and other REMS for medicines with higher toxicity and risk potential. A REMS may include Elements to Assure Safe Use (''ETASU''), such as restricted distribution, physician and patient education, and/or evidence of safe-use conditions. By law, REMS requirements cannot be used to ''block or delay'' generic approval. 21 U.S.C. § 355-1(f)(8).

Nevertheless, FDA has publicly stated ''we have found cases in which sponsors have tried to use the REMS to block generics.'' Such efforts have been challenged in private antitrust litigation and generated more than 100 inquiries to FDA. The Federal Trade Commission has told Congress it ''continue[s] to be concerned about potential [REMS] abuses . . . to impede generic competition,'' which ''may violate the antitrust laws.'' Enter the CREATES Act.

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The CREATES Act.

Section 3 of the CREATES Act establishes causes of action for ''delays of generic drugs and biosimilar biological products.'' An ''eligible product developer,'' *i.e.*, an ANDA applicant or 351(k) applicant, could bring a federal civil action against the license holder for a ''covered product''—defined as an approved drug or biological ***other than*** one for which there is a short-term shortage—alleging the license holder: (1) ''has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms;'' or (2) for products subject to a REMS with ETASU, (i) ''failed to reach agreement with respect to a single, shared system of elements to assure safe use with respect to the covered product[] or . . . at least 120 days have elapsed since the developer first initiated an attempt to reach an agreement''; or (ii) ''refused to allow the eligible product developer to join a previously approved system of elements to assure safe use with respect to that product.'' The bill authorizes judges to award injunctive relief and damages ''sufficient to deter'' similar delaying conduct. Damages cannot exceed the revenue earned from sale of the drug during the refusal period, however.

The CREATES Act exempts innovators from liability from ''the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities.'' Additionally, innovators are not liable if, in fact, they ''had [no] access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms'' or if ''the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder.''

Reactions and Implications.

The CREATES Act enjoys broad support from the generic industry, physicians, pharmacists, hospitals, consumer advocacy groups, antitrust experts, and insurers. During a recent (June 21) Congressional hearing, the CREATES Act was praised for confronting anticompetitive regulatory manipulation by promoting competition and, in turn, improving consumer choice and welfare. The hearing's lone dissenter, the Pharmaceutical Research and Manufacturers of America (''PhRMA''), claimed the bill ''uses a blunt instrument to address a narrow issue.'' Among other things, PhRMA objected to litigation as the mechanism for resolving product safety concerns and breakdowns in complex, multiparty REMS negotiations.

These criticisms raise legitimate issues. Reliance on litigation to remedy delays in generic entry risks a slow, expensive, and unpredictable enforcement process. Determining if a ''term'' is ''commercially reasonable,'' for example, presents fact-bound, context-specific questions typically reserved for a finder of fact. What legal consequence, if any, flows from a generic's failure to engage in good faith negotiations to join the brand's shared REMS?

The law also could leave innovators facing conflicting statutory obligations. It would allow ''[a]n eligible product developer [to] submit . . . a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU,'' in which case ''provision of the covered product by the license holder under the terms of [an] authorization will not be a violation of the REMS for the covered product.'' Yet, it (currently) does not amend the statutory provisions governing the enforcement of REMS programs. 21 U.S.C. § 355(p)(1)(B); 21 U.S.C. § 333(f)(4)(A). Without a legislative fix, sharing samples of a drug with REMS with ETASU could expose a brand company to civil and criminal penalties.

Some or all of these matters may be mooted by amendments to the CREATES Act. Time will tell.

Conclusion.

The CREATES Act seeks to maintain the elusive balance between encouraging development and continued research for new drugs and biologics while ensuring timely availability of lower-cost generic and biosimilar drugs. While the fate of the CREATES Act remains uncertain, its impact on the American healthcare system would be significant for stakeholders on all sides of the public debate over drug affordability.

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