

Industry Voices: Navigating Uncharted Territory- Understanding Product Liability Risks in Biosimilars

DECEMBER 10, 2015

DANIEL S. BRETTLER | LIFE SCIENCE PRACTICE LEADER AT CONNER STRONG & BUCKELEW
KENNETH PIÑA | MANAGING PRINCIPAL AT CORE RISK LTD.

The launch of the first biosimilar in the U.S., Sandoz's Zarxio, has stimulated tremendous market opportunities, with sales predictions for biosimilars pointing to \$25 billion by 2020, according to a 2014 Thomson Reuters report.

But even after this first product has hit the market, industry stakeholders remain in a regulatory holding pattern waiting for the FDA's pending guidance on biosimilar nomenclature. It's not yet clear whether the FDA issuance of its biosimilar labeling draft guidance will differentiate biosimilars from their brand-name reference biologics or adopt requirements similar to the "sameness" regimen in the labeling of generics.

To complicate matters, the Centers for Medicare and Medicaid Services (CMS) recently finalized a payment rule categorizing all physician-administered biosimilar drugs that mimic the brand-referenced original into an equal calculation category, a decision that has the potential to compromise patient care, patient safety tracking, and reduce market spending and competitiveness in the biopharmaceutical sector.

Regardless of FDA guidance and further legislative directives, companies launching biosimilar products will likely continue to grapple with critical issues in an evolving and uncertain regulatory and legal landscape. In view of this, it's critical for drug companies entering this market to adopt a balanced perspective of their opportunities, while proactively assessing potential risk exposures. Most likely, this will include two key areas with regard to product liability: 1) failure to warn and labeling issues; and 2) manufacturing and design defects.

POTENTIAL FAILURE TO WARN/LABELING ISSUES

The generic drug market provides the closest legal parallel to biosimilar warning and labeling rules. While biosimilars are meant to produce the same effects and outcomes as their biologic counterparts, by definition they are not identical. Because of this, there is lack of clarity as to whether or not companies need to warn patients about the differences in biological make-up.

For example, the label for the U.S.'s first biosimilar, Zarxio, has caused controversy because it's almost identical to that of the original biological, Amgen's Neupogen. The label does not state that the product was approved as a biosimilar to its brand original, Neupogen. Also, it has not been determined to be interchangeable (i.e., substitutable for Neupogen). Thus, unlike a generic drug, which can be "substituted" by the pharmacist for the brand name product, Zarxio cannot be used interchangeably with Neupogen at this time absent the express direction of the treating physician.



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In general, drug companies can be held responsible for inadequate labels in product liability suits. Given the unique nature of biologics and biosimilars, each product category may ultimately be liable and responsible for its own labeling procedures and treated as separate products instead of following the model of generics.

POTENTIAL MANUFACTURING AND DESIGN DEFECTS

The complex nature of biological manufacturing and the production variations that can modify the activity, stability and immunogenicity of the final biological product open the door for potential allegations of defective manufacturing. In addition, drug companies can be held accountable for potential issues inherent to the production of biologics. Because of their unique source material and the multifaceted manufacturing processes, biosimilars' efficacy and safety profile may be different from the original biologic and sometimes, even vary from batch to batch. As small-scale studies are required for approval of a biosimilar, it might be argued that the biosimilars' safety profile is not fully understood because fewer patients were exposed to them during clinical development.

INSURANCE IMPLICATIONS

Drug manufacturing companies entering this sector must proactively address their potential risks, including possible personal injury litigation, and plan to protect biosimilar producers by use of risk transfer mechanisms, such as insurance. However, as this is a new area for insurance companies, specialized attention must be given to insurance policy language to ensure that the policy will provide the intended and desired coverage and fill any coverage "gaps."

Leading carriers are writing policies addressing particular exposures related to biosimilars; however, with each biosimilar being different, custom language might need to be included in the insurance program to provide adequate cover. Although many carriers are holding out for more clarity before determining their coverage positions, insurance could ultimately prove to be a differentiator for drug manufacturing companies entering the marketplace.

SAFEGUARDING THE FUTURE: CHARTING A RISK MANAGEMENT PLAN

As companies consider product liability and insurance implications, it's in their best interest to develop the risk management infrastructure, including a proactive plan to educate insurers about their biosimilar(s) that will allow them to move forward with commercialization. By proactively identifying, addressing and safeguarding against safety issues, companies can significantly increase the likelihood that they can secure insurance coverage that is relevant and responsive.

Regardless of how regulatory decisions shape the future of biosimilars, drug companies must closely monitor the potential risk exposures that these products introduce to their organizations. By learning from best practices in the generics markets and understanding the differences that relate to the marketing of biologics, companies can take effective steps in anticipation of FDA guidance, allowing them to take advantage of new opportunities while the inevitable precedent-setting legal rulings play out.