

## Axinn Successful in Protecting FDA Approval of Generic Versions of Otsuka's Abilify

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### ATTORNEYS

Landmon, Chad

A team of attorneys from Axinn successfully intervened on behalf of Zydus Pharmaceuticals on the side of the U.S. Food and Drug Administration in the U.S. District Court in Maryland to oppose Otsuka Pharmaceuticals' motion for a temporary restraining order. Otsuka sought the order to prohibit FDA from granting approvals for any generic versions of Otsuka's \$4 billion prescription brand drug aripiprazole, which Otsuka markets under the name Abilify®.

Otsuka claimed a seven-year market exclusivity for Abilify under the orphan drug designation, as the FDA approved Abilify for the use in the treatment of Tourette's disorder in pediatric patients. Otsuka also alleged that generic competition is likely to cause the drug maker irreparable harm. Today, U.S. District Judge George Hazel denied Otsuka's motion for a temporary restraining order, allowing generic versions of Abilify to enter the market. The court's ruling will provide significant cost savings for consumers as generic competition will cause drug prices to decrease. The ruling also reaffirms FDA's discretion in allowing generics to carve out indications from their labels that are protected by marketing exclusivity.

Partner Chad Landmon led the Axinn team.