News Release

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WLF URGES FDA FREEZE ON APPLICATIONS FOR BIOSIMILAR LICENSING BASED ON PRE-2010 REFERENCE PRODUCTS

The Washington Legal Foundation (WLF) today urged the Food and Drug Administration (FDA) to defer all work on any applications for approval of "biosimilar" products, where the application is based on a reference product for which the biologics license application (BLA) was filed before March 23, 2010 (the date that Congress adopted legislation permitting approval of biosimilars). WLF argued that approval of such applications would require use of trade secret information that was submitted to FDA based on assurances that the trade secrets would be maintained. WLF asserted that use of such information to approve biosimilars would expose the federal government to massive liability under the Fifth Amendment's Takings Clause.

WLF filed its comments with FDA in support of a Citizen Petition filed in 2012 by Abbott Laboratories. Abbott is licensed to market several biological products, including Humira®, a TNF inhibitor widely prescribed to treat rheumatoid arthritis and other conditions. Abbott's petition argued that FDA use of its trade secrets (or the trade secrets of any other BLA sponsor that submitted its BLA before March 2010) to approve a biosimilar would destroy the value of the trade secrets and would trigger a federal obligation to provide "just compensation" under the Fifth Amendment based on the value of the lost trade secrets. FDA has not taken any action on Abbott's petition.

"WLF is concerned that approving biosimilars without first giving serious consideration to Fifth Amendment compensation claims that would arise therefrom would seriously erode both property rights and public confidence in the reliability of government promises," said WLF Chief Counsel Richard Samp after filing WLF's comments. "If FDA determines that it is free to ignore its past promises of confidentiality to BLA applicants, businesses subject to government regulation will be less willing in the future to spend the massive sums necessary to develop innovative and life-saving products," Samp said.

The federal government has regulated the marketing of biological products since 1902. Before issuing a license to market such products, FDA requires the BLA applicant to demonstrate that its products meet standards designed to ensure "safety, purity, and potency." Several studies have concluded that research and development costs for a new biological product range from $1.24 billion to $1.33 billion.

Scientists recognize that, due to the chemical complexity of a biological product, it is nearly impossible for potential competitors to replicate the product precisely. Accordingly, until recently there was little discussion in Washington regarding authorization of low-cost generic versions of biological products. Congress eventually determined, however, that competitors were capable of making "biosimilars" (a product with many similar attributes to the reference product). Accordingly, in March 2010 it adopted the Biologics Price Competition and Innovation Act (BPCIA) to create a pathway for the licensing of biosimilars that could compete with existing products. The law provides that the biosimilar applicant need not demonstrate that its product is safe and effective. Rather, it need only demonstrate that the product is biosimilar to the reference product; FDA is to rely on the safety and effectiveness data previously submitted to the agency by the sponsor of the reference product.

But as Abbott points out in its petition, such data have long been deemed to be trade secrets, and FDA officials repeatedly assured BLA applicants that it would neither release the data nor use the data for the benefit of potential competitors. WLF's comments assert that under well-established trade secret law, FDA "use" of the data to approve the products of competitors constitutes an infringement of the property rights of the firm that submitted the data.

WLF stated that firms that submitted their BLAs prior to adoption of the BPCIA had a "reasonable investment-back expectation" that the federal government would not take actions to destroy the value of their trade secrets. Use of the trade secrets to approve a competitor's product would destroy their value. WLF argued, therefore, that sponsors of pre-March 2010 BLAs are entitled to "just compensation" under the Fifth Amendment's Takings Clause for the loss in value of their trade secrets. WLF noted that Congress did not make allowance for payment of Takings Clause compensation to the sponsors of approved BLA, suggesting that Congress did not authorize FDA to approve biosimilars based on any reference product whose sponsor was given assurances that its trade secrets would not be used to benefit others. Virtually all pre-March 2010 reference products fit into that category, WLF asserted.

WLF is a public interest law and policy center with supporters in all 50 states. WLF regularly litigates in support of private property rights, including the rights of owners of intellectual property.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF's comments is posted on its web site, www.wlf.org.