No. _____

In the Supreme Court of the United States

HI-TECH PHARMACEUTICALS, INC. AND JARED WHEAT,
Petitioners,
v.
FOOD & DRUG ADMINISTRATION, ET AL.,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

To increase the dietary supplements available to the public, the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), 21 U.S.C. §321(ff), amended the Federal Food, Drug, and Cosmetic Act. DSHEA's amendments allow manufacturers to sell supplements, without first obtaining FDA approval, if their ingredients are, among other things, "constituent[s]" of "herb[s] or other botanical[s]." 21 U.S.C. §321(ff)(1)(C) & (F). The dietary supplements at issue in this case contain an ingredient known as DMAA, which studies have shown occurs in geranium plants. The courts below held that, even if these studies are accurate, DMAA is not, as a matter of law, a "constituent" of a "botanical"—and thus is not presumptively marketable as an ingredient in dietary supplements under DSHEA—because these studies show that DMAA appears in geraniums only in trace quantities, and DMAA has no prior history of being directly extracted from the plant for medicinal, cosmetic, or dietary use. The question presented is as follows:

> Did the Eleventh Circuit err in holding that a substance that naturally occurs in a plant is not a "constituent" of an "herb or other botanical"—and therefore cannot be included in presumptively marketable dietary supplements under the Dietary Supplement Health and Education Act—if the substance naturally occurs in the plant only in trace quantities and has no prior history of being extracted from the plant for medicinal, cosmetic, or dietary use?

PARTIES TO THE PROCEEDINGS

Petitioners Hi-Tech Pharmaceuticals, Inc. and Jared Wheat were appellants below. Respondents United States Food and Drug Administration, United States Department of Health and Human Services, and United States of America were appellees below. Respondent Alex Azar, in his official capacity as Secretary of the Department of Health and Human Services, succeeded to that office on January 29, 2018, at which time Secretary Azar was automatically substituted as a party under Federal Rule of Appellate Procedure 43(c)(2). Upon assuming office, Secretary Azar was an appellee below. Respondent Stephen M. Hahn, in his official capacity as Commissioner of the United States Food and Drug Administration, succeeded to that office on December 17, 2019, after the entry of judgment below, at which time Commissioner Hahn was automatically substituted as a party under Federal Rule of Appellate Procedure 43(c)(2).

CORPORATE DISCLOSURE STATEMENT

Hi-Tech Pharmaceuticals, Inc. is not a publicly traded company. It has no parent company, and no company owns 10% or more of its stock.

RELATED PROCEEDINGS

This case arises from the following proceedings in the United States District Court for the District of Columbia, the United States District Court for the Northern District of Georgia, and the United States Court of Appeals for the Eleventh Circuit, listed here in chronological order:

Hi-Tech Pharmaceuticals, Inc. v. Hamburg, No. 1:13-CV-01747 (D.D.C.) (transferred to N.D. Ga. Aug. 1, 2014).

Hi-Tech Pharmaceuticals, Inc. v. Hamburg, No. 1:14-CV-24790-WBH (N.D. Ga.) (merged into No. 1:13-CV-0675-WBH Aug. 1, 2014).

United States of America v. Undetermined Quantities of All Articles of Finished and In-Process Foods, No. 1:13-CV-03675-WBH (N.D. Ga. Apr. 3, 2017), *available at* 2017 WL 4456903.

United States of America v. Undetermined Quantities of All Articles of Finished and In-Process Foods, No. 17-13376 (11th Cir. Aug. 20, 2019), *reported at* 936 F.3d 1341.

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