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By ACMS

May 29, 2025

Catherine O'Hagan Wolfe
Clerk of Court
U.S. Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007

Re: *Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Dep't of Health & Human Servs.*, No. 24-2092 (2d Cir.)

Dear Ms. Wolfe,

Boehringer responds to the Government's letter regarding *AstraZeneca Pharms. v. U.S. Dep't of Health & Human Servs.*, 2025 WL 1338088 (3d Cir. May 8, 2025).

AstraZeneca has—at most—marginal relevance to this appeal. *Boehringer* contends that the Medicare Drug Pricing Program is unconstitutional on takings, due process, and First Amendment grounds, and that CMS issued the Manufacturer Agreement in violation of the Administrative Procedure Act's notice-and-comment requirement. *AstraZeneca* addresses just one of those four distinct theories (due process), and on that issue, its analysis is both distinguishable and incorrect.

As the Government acknowledges, the due process claim in *AstraZeneca* concerned “different property interests than *Boehringer* asserts here.” Dkt. 237.1 at 2. *Boehringer* has asserted interests in “physical doses of Jardiance®” and “confidential data regarding Jardiance®,” Opening Br. 26-27; Reply Br. 9-12, which *AstraZeneca* did not address.

AstraZeneca incorrectly determined (at *6) that a manufacturer has no property interest in the “ability to sell its drugs at a market rate.” That conclusion conflicts with the Fifth Circuit's *NICA* decision and breaks with precedent holding that price controls trigger due process safeguards. Opening Br. 26-27; Reply Br. 9-11. *AstraZeneca* concluded that one of these authorities—*Bowles v. Willingham*, 321 U.S. 503 (1944)—is inapplicable because the Program does not regulate “private market transactions.” *AstraZeneca*, at *7. That reasoning is flawed in two main respects.

First, neither *Bowles* nor any like case has limited due process protection to regulation of private markets. Indeed, this Court has recognized that Medicare participants have a property interest where precedent and “statutory provisions” “mandat[e]” a “defined administrative outcome.” *Barrows v. Becerra*, 24 F.4th 116, 139 (2d Cir. 2022). Precedent and the statute

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support such an interest here by requiring CMS to adopt a non-confiscatory “maximum fair price” for Jardiance®. 42 U.S.C. § 1320f-2(a)(1). The Program exposes Boehringer to arbitrary deprivation of that interest—to a risk of receiving *less* than a fair price—by omitting bedrock procedural safeguards. Reply Br. 10-11.

Second, the public/private distinction is artificial where, as here, the government constitutes half the relevant market and regulates transactions between private entities. Opening Br. 7.

Sincerely,

/s/ Kevin F. King

Kevin F. King

*Counsel for Appellant Boehringer
Ingelheim Pharmaceuticals, Inc.*

cc: Counsel of record (via ACMS)