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Kevin King

Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 5488
kking@cov.com

By CM/ECF

August 14, 2025

Patricia S. Dodszuweit
Clerk of Court
U.S. Court of Appeals for the Third Circuit
James A. Byrne U.S. Courthouse
601 Market Street
Philadelphia, PA 19106

Re: *Janssen Pharmaceuticals, Inc. v. Secretary, U.S. Department of Health & Human Services*, No. 24-1821 (argued Oct. 30, 2024) — Response to Government's Letter Regarding *Boehringer Ingelheim Pharmaceuticals, Inc. v. HHS*, No. 24-2092 (2d Cir. Aug. 7, 2025)

Dear Ms. Dodszuweit:

The Government overlooks serious shortcomings in *Boehringer*'s analysis.

On compelled speech, *Boehringer* cites this Court's "actual compulsion" test, but then applies the stricter "legal compulsion" requirement from *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993). Op. 39-41. Conflating these tests led the court to miss important distinctions between them and disregard the regulatory consequences for refusing to sign the Manufacturer Agreement, which demonstrate actual compulsion. Janssen Reply 15-16; Oral Arg. 58:47-59:20 ("softer standard" under First Amendment). Even under a legal-compulsion framework, *Boehringer* errs by adopting CMS's atextual "good cause" approach to expedited Medicare and Medicaid withdrawal. Janssen Reply 16.

Boehringer's unconstitutional-conditions analysis is equally flawed. According to *Boehringer*, the Program does not impose unconstitutional conditions because the compelled statements are "related to the government's legitimate goal of controlling Medicare costs." Op. 46. Yet Congress can set prices without coercing manufacturers to call them "fair" and has done so in countless programs. Appellees *still* have not identified a single statute that compels the sort of value-laden statements at issue here. Oral Arg. 1:07:00-1:08:41. *Boehringer* ignores these points entirely.

Moreover, *USAID* rejected *Boehringer*'s toothless relevant-to-the-objectives test. Janssen Reply 26. *Boehringer* concludes that the Program does not "regulate speech outside the contours of the program" because "it does not regulate … private market" sales. Op. 46. But *USAID* clarified that requiring a party to adopt the Government's views "by its very nature" regulates outside a program's scope, and that allowing Congress to "manipulat[e]" a program's scope "to subsume the challenged condition" would reduce the First Amendment "to a simple semantic

exercise." Janssen Reply 25-26. *Boehringer* does not confront those crucial parts of *USAID*, or the compelled statements' distortion of private-market pricing and the broader public debate.

Finally, *Boehringer* incorrectly concludes that CMS is "a market participant, not a regulator." Op. 33-34 n.11. CMS's regulatory powers are not "separat[e] from" the "negotiation," *id.*; they permeate it. CMS does not "participat[e] in the marketplace as any other economic actor would," *id.*; it mandates sales at below-market prices, can unilaterally amend the Manufacturer Agreement, and imposes penalties if manufacturers do not acquiesce, Janssen Reply 13-14.

Respectfully submitted,

/s/ Kevin F. King
Kevin F. King

Counsel for Plaintiff-Appellant
Janssen Pharmaceuticals, Inc.

cc: counsel of record (via CM/ECF)