IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCIATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members, Plaintiffs, vs. XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services, *et al.*, Defendants.	Civil Action No. 1:23-cv-00707-DAE

PLAINTIFFS' MOTION FOR LEAVE TO FILE THEIR RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

Pursuant to Rule CV-7(B) and (E)(1) of the Local Rules of the Western District of Texas, Plaintiffs National Infusion Center Association, Global Colon Cancer Association, and Pharmaceutical Research and Manufacturers of America, each on behalf of itself and its members, (together, "Plaintiffs") file this motion for leave to file the attached Plaintiffs' response to Defendants' Notice of Supplemental Authority.

On November 2, 2023, Defendants filed a Notice of Supplemental Authority, ECF No. 50, in support of their Motion to Dismiss, ECF No. 39. Among other issues, the Notice of Supplemental Authority ignores Plaintiffs' primary standing argument and inaccurately describes the relevant inquiry with respect to standing. Given that the parties have already filed the

documents contemplated by Rule CV-7, Plaintiffs respectfully request leave to file a very brief response, attached hereto as Exhibit A, to Defendants' Notice of Supplemental Authority.

Dated: November 7, 2023

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
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NATIONAL INFUSION CENTER ASSOCIATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members, Plaintiffs, vs. XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services, *et al.*, Defendants.	Civil Action No. 1:23-cv-00707-DAE

PLAINTIFFS' RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY IN SUPPORT OF MOTION TO DISMISS

The Government's notice of supplemental authority, ECF No. 50, exaggerates the significance of a *single example* of financial injury while continuing to ignore the procedural injuries that constitute the Complaint's gravamen. For two reasons, the "supplemental authority" has no effect on the standing analysis.

First, the Government's argument inverts the standing inquiry. Plaintiffs have shown that, as things currently stand, the IRA will cause NICA's members harm beginning in 2026 because there will be an MFP on Stelara that will reduce Medicare Part D reimbursements. Pls. Opp. 14. The Government falsely suggests that harm will occur only in 2028 when *Part B* reimbursements are affected. Defts' Notice of Supp. Auth 2. Because HHS in fact listed Stelara for Government-

imposed price caps, and that listing injures NICA starting in 2026, Plaintiffs are under no burden to *disprove* the Government's assertion that the drug *might* later be deselected (an assertion that is entirely conjectural). Rather, it is *the Government* that must support its assertions that harm will be averted. Even if the Government might later introduce evidence to support this "possib[ility]," "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

Second, financial harm from lower future drug reimbursements is not Plaintiffs' principal claimed harm supporting standing. Though the Government tries to wish these allegations away, NICA alleges that "the IRA inflicts [harm] *now* by depriving NICA's members of constitutionally required due process, impermissibly delegating legislative power to the agency, and coercing compliance via excessive fines." Pls. Opp. to Mot. to Dismiss 6, ECF No. 47. Those are "here-and-now injur[ies]," *Axon Enter. v. FTC*, 598 U.S. 175, 192 (2023), that NICA is *already suffering* regardless of the details of any specific drug's future reimbursements. The Government also ignores unrefuted allegations that the IRA is "already impacting the ability of NICA's members to raise debt and equity funding for their operations," Supp. Nyquist Decl. ¶ 20, ECF No. 47-2, another independently cognizable injury.

Plaintiffs respectfully submit that the Government's motion to dismiss should be denied.

Dated: November 7, 2023

Respectfully submitted,

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