United States Department of Justice
Civil Division, Federal Programs Branch
1100 L St. NW
Washington, DC 20005

May 27, 2022

By ECF
The Honorable Paul W. Grimm
United States District Judge
District of Maryland
6500 Cherrywood Lane
Greenbelt, MD 20770

Re: *Pharmaceutical Research and Manufacturers of America v. Becerra, et al.*, No. 8:21-cv-00198-PWG (D. Md.)

Dear Judge Grimm:

Six months after the U.S. District Court for the District of New Jersey issued a lengthy opinion rejecting two of the same claims at issue in this litigation, *see Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-00634-FLW, 2021 WL 5150464 (D.N.J. Nov. 5, 2021), Plaintiff PhRMA filed a letter brief apprising this Court of that supplemental authority and contesting certain of that court's findings. Proposed Letter Br. ("Letter"), ECF No. 34-2 (May 2, 2022). Defendants respectfully write to respond to PhRMA's letter brief, as this Court permitted on May 9, 2022, *see* ECF No. 35.

As PhRMA admits, Letter at 2, the *Sanofi* court rejected the same Appointments Clause challenge to the ADR Rule raised in this litigation, and, although Sanofi has appealed its loss on other issues, it has abandoned its Appointments Clause challenge, *id.* at 5 n.5. PhRMA nonetheless quibbles with aspects of the court's reasoning and urges this Court to "decline to follow the foregoing rulings by the *Sanofi* [c]ourt." *Id.* at 5. But Defendants already have explained why *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021), demonstrates that ADR Board members are lawfully appointed inferior officers, *see* Defs.' Reply in Supp. of Summ. J. ("Reply") at 15-19, ECF No. 31, and PhRMA's disagreements with the *Sanofi* ruling provide no reason for this Court to hold otherwise.

PhRMA first contests the *Sanofi* court's determination that the Secretary exercises sufficient control over panel members' decisions. Letter at 3. True, the court based that finding on the fact that ADR panel decisions are not self-effectuating, 2021 WL 5150464, at *25-26, not—as Defendants argued—on the fact that neither the 340B statute nor the ADR Rule contain any restriction on the Secretary's inherent authority to reverse panel decisions. But contrary to PhRMA's portrayal, the court did not "reject[] several of the theories … advanced" by Defendants to demonstrate this fact. Letter at 2. Instead the *Sanofi* court merely presumed that the Secretary cannot reverse panel decisions because the ADR Rule sets forth no express internal appeals mechanism, and seems to have misapprehended Defendants' arguments on the point. 2021 WL 5150464 at *24-25 ("HHS responds that the ADR Board poses no constitutional infirmity *because the Secretary can supervise members in other ways besides direct review* ….") (emphasis added). As Defendants explained in briefing to this Court, however, *Arthrex* confirms that the absence of a formal appeal mechanism does not bind a principal officer from countermanding the decisions of subordinates because a principal officer enjoys inherent

authority to do so absent an *express* restriction on that power. Reply at 16-18 (citing *Arthrex* and earlier authorities for the proposition that, absent an express restriction on power to review, principal officer "freely may exercise discretionary review"). And PhRMA still has failed to point to any express restriction on the Secretary's power to review and countermand panel decisions with which he disagrees—because no such express restriction exists. *Cf.* Reply at 17-18 (explaining why finality provision in ADR Rule merely confirms that a panel decision is final agency action reviewable in district court but does not bind Secretary from taking discretionary action). The *Sanofi* court's alternate rationale (that the Secretary exercises sufficient control by determining whether to effectuate panel decisions) does nothing to upset these well-grounded principles; indeed, the *Sanofi* court did not address Defendants' arguments regarding the Secretary's inherent authority.[1]

PhRMA next challenges the *Sanofi* court's determination that the Secretary enjoys at-will removal power over Board members, regardless whether civil-service protections may apply to those individuals' other (pre-existing) government employment. Letter at 4. Here PhRMA confuses individuals' status as inferior officers—which has constitutional significance—with their employment as civil servants—which does not. As Defendants have explained, "a federal employee becomes an officer when s/he receives an *appointment* by the Secretary to the ADR Board … and it is removal from one's office—not reassignment from the task at hand—that has constitutional significance." Reply at 19. ADR Board members differ from the APJs in *Arthrex* in that they have pre-existing federal employment to which they could return after having their inferior-officer appointments to the Board revoked—but that government employment has no relevance to the Article II question whether an inferior officer properly is appointed. Moreover, PhRMA ignores another key distinction: *Arthrex* concerned a scheme wherein Congress explicitly had incorporated the competitive-service statute's for-cause removal protection *to apply to the APJs in that capacity*, *see id.* at n.9 (citing 35 U.S.C. § 3(c)), whereas here there is no statute incorporating civil-service protections to Board members in their capacity as federal officers. On remand in *Arthrex*, the Federal Circuit adopted this reasoning in rejecting a separation-of-powers challenge to the Acting Director of the Patent Office—although that individual had for-cause removal protection in his role as Commissioner of Patents, he was removable by the President at-will from his role as Acting Director. *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 18-2140, Slip Op. 18 (Fed. Cir. May 27, 2022). Likewise, under 340B, the Secretary enjoys unfettered discretion to fire Board members from their status as federal officers for any reason or no reason whatsoever, which is the only inquiry with which Article II is concerned (after all, there is no constitutional infirmity in general for-cause protection for regular federal employees). And even if this Court disagreed on the removal point, the Secretary's ability to reverse ADR panel decisions renders the scheme constitutional even if for-cause removal applied.

[1] The *Sanofi* court correctly noted that, even if the finality language were dispositive in insulating Board decisions from sufficient control by the Secretary, *Arthrex* teaches that the proper fix would be severing any restraint on the Secretary's power of control, not setting aside the Rule in its entirety. 2021 WL 5150464, at *24 n.40. *See* Reply at 16 (demonstrating that "the absence of any statutory constraint on discretionary review by the Secretary of final decisions of his subordinates makes the ADR Rule analogous to the *Arthrex* Court's statutory *fix*—not the initial constitutional *violation*"). PhRMA attempts to avoid that result by arguing that "it is the rule, not the statute, that empowers the Board to issue final decisions without review by a superior officer," Letter at 4 n.4. But this ignores that the finality language on which PhRMA grounds its argument derives from the statute, 42 U.S.C. § 256b(d)(3)(C), not only from the Rule, and thus they must rise or fall together.

Finally, PhRMA contests the *Sanofi* court's determination that HRSA adequately addressed comments concerning updated audit guidelines. Letter at 4-5. Defendants already have explained why that argument is meritless, and PhRMA's letter adds nothing new. *See* Mem. in Supp. of Mot. to Dismiss or for Summ. J. at 17-20, ECF No. 26-1.

Dated: May 27, 2022

Respectfully submitted,

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